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Evaluation of surgical outcomes using administrative hospital data

By

Yesar El-DHUWAIB

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Read in the name of your Lord who created. He created human beings from a clot. Read and your Lord is the most Honourable. He who taught (human beings the use of) the pen. Taught human beings what they knew not.

To my wife Susan and my sons Aban and Dan, for their love and support

Acknowledgement

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Abstract

Hospital Episode Statistics (HES) is the main hospital administrative dataset in England. Since the early 1990s HES has been used for research. The aim of the thesis is to evaluate the use of HES data to measure surgical outcomes.

Objectives:

1. Can HES data be used to measure rare surgical complications when there is a code?
2. Can HES data be used to measure rare surgical complications when there is no code?
3. Can HES data be used to compare different types of surgery for the same condition?
4. Can HES data be used to measure changing trends in surgical practice?
5. Can HES data be used as a national audit tool?
6.

Methods: Hospital Episode Statistics from @1, @2, @3. @4 and @5 were used to address each individual objective. HES data were obtained from the National Health Service (NHS) Information Centre and stored into Microsoft SQL server for analysis. HES data were cleaned and converted into clinical database. Patients' data were identified using operative and diagnostic codes. All duplicates were removed and patients were followed across time and place to identify complication. For each study a different Statistical approach was planned to answer each question.

Results:

Objective 1: Venous Thromboembolism (VTE) following colorectal resection was used to answer this objective. A total of 35,997 underwent colorectal resection during the period of study. The VTE rate was 2.3%. Two hundred and one (0.56%) patients developed VTE during the index admission and 571 (1.72%) were readmitted with VTE. Following discharge from the index admission, the risk of VTE in patients with cancer remained elevated for six months compared with two months in patients with benign disease. Age, postoperative stay, cancer, emergency admission, and emergency surgery for patients with inflammatory bowel disease (IBD) were all independent risk factors associated with an increased risk of VTE. Patients with ischaemic heart disease and those having elective Minimal Access Surgery (MAS) appear to have lower levels of VTE.

Objective 2: Bile duct reconstruction following Laparoscopic Cholecystectomy (LC) in England was used for this objective. Five hundred seventy-two thousand two hundred and twenty-three LC and attempted LC were performed in England between April 2001 and March 2013. Five hundred (0.09%) of these patients underwent Bile Duct Reconstruction (BDR). The risk of BDR for Admission with other causes is significantly lower than acute cholecystitis (Odds ratio OR0.48 (95%CI 0.30—0.76). The regular use of On Table Cholangiogram (OTC) (OR 0.69 (0.54—0.88) and high consultant caseload >80 LC/year (OR 0.56 (0.39—0.54) reduced the risk of BDR. Patients who underwent BDR were 10 times more likely to die within a year than those who did not require further surgery (6% vs. 0.6%).

Objective 3: Laparoscopic versus open repair of inguinal hernia: a longitudinal cohort study was used for this objective. Between April 2002 and April 2004 125,342 patients who underwent inguinal hernia repair were included in the analysis and they were followed until April 2009. There were no differences in postoperative stay between the laparoscopic and open groups except for the laparoscopic bilateral hernia repair patients who had a shorter stay than the open group. Infection and bleeding were more common following open repair, whilst urinary retention and injury to an organ were more frequent after laparoscopic repair. Reoperation for another inguinal hernia was more common after laparoscopic (4.0%) than after open repair of primary inguinal hernia (2.1%). There was no difference in reoperation rate following repair of a recurrent inguinal hernia. Consultant caseload was strongly inversely correlated with reoperation following laparoscopic but not open repair of primary inguinal hernia.

Objective 4: Epidemiological trends in surgery for rectal prolapse in England was used for this objective. During the study period, a total of 25,238 adults underwent a total of 29,379 operations for rectal prolapse [median age 73 years (IQR 58-83) years; female to male ratio: 7:1]. Median LOS was 3 days (IQR 1-7) with an overall in-hospital mortality rate of 0.9%. Numbers of total admissions (2001: 4,950 vs. 2012: 8,927) and of patients undergoing prolapse surgery (2001: 2,230 vs. 2012: 2,808) significantly increased ($P < 0.001$ for trends) throughout the study period. The overall increase in surgery (up about 1/3rd overall and 44% for elective) was dwarfed by an increase in popularity of laparoscopic surgery (increased 15-fold during the period). Overall prolapse reoperation rate (as a surrogate of recurrence) was 12.7%. The lowest recurrence rate was observed for elective open resection (9.1%) but this had the highest mortality (1.9%) Laparoscopic and perineal fixations were also associated with low reoperation rates (<11%) but lower mortality rates of approx. 0.3% for elective surgery. The data refute a trend toward subspecialisation (by surgeon or hospital) during the study period.

Objective 5: Definitive management of Gallstone pancreatitis in England was used for this objective. A total of 5,454 patients were admitted with GSP between April 2007 and April 2008, of whom 1,866 (34.2%) underwent definitive treatment according to BSG guidelines, 1,471 on the index admission. Patients who underwent a cholecystectomy during the index admission were less likely to be readmitted with a further bout of GSP (1.7%) than those who underwent endoscopic sphincterotomy alone (5.3%) or those who did not undergo any form of definitive treatment (13.2%). Of those patients who did not undergo definitive treatment before discharge, 2,239 received definitive treatment following discharge but only 395 (17.6%) of these had this within 2 weeks. Of the 505 patients who did not undergo definitive treatment on the index admission and who were readmitted as an emergency with GSP, 154 (30.5%) were admitted during the 2 weeks immediately following discharge.

Conclusion

Hospital Episode Statistics can be used to measure surgical outcome in a number of useful and reproducible ways. HES can be used to measure mortality, complications, compare different surgical approaches, assess the effect of changes in practice, and assess caseload outcome association. Those metrics can be used to inform health care planners, develop guidelines, inform patients, and reward hospitals for improved outcome. The use of HES, however, has weaknesses which to a certain extent could be overcome easily with minor alteration in the way that diagnostic, consultant/operator and procedure fields are recorded.

Published papers

1. Venous Thromboembolism following colorectal resection

Yesar El-Dhuwaib, C. Selvasekar, D. Corless, M. Deakin, J. SLavin

Colorectal Disease Journal 2017 Apr;19(4):385-394. doi: 10.1111/codi.13529

Presented at

- the European Association for Endoscopic Surgeon (EAES) in Brussels 2012

2. Bile duct reconstruction following laparoscopic cholecystectomy in England

Yesar El-Dhuwaib, J. Slavin, D. Corless, I. Begaj, D. Durkin, M. Deakin

Surgical Endoscopy August 2016, Volume 30, Issue 8, pp 3516–3525

Presented at

- The European Association for Endoscopic Surgeon in Brussels 2013 and it was nominated for Karl Storz Award at EAES in Brussels 2013.

3. Laparoscopic versus open repair of inguinal hernia: a longitudinal cohort study.

Yesar El-Dhuwaib, D. Corless, C. Emmett, M. Deakin, J. Slavin

Surgical Endoscopy March 2013, Volume 27, Issue 3, pp 936–945

Presented at

- The British Hernia Society, Glasgow 2008 and was awarded Brenden Devlin Prize
- The Association of Laparoscopic surgeon of Great Britain and Ireland (ALSGBI), Colchester 2009 and it was awarded top 4 abstracts.
- Association of Surgeon of Great Britain and Ireland annual meeting, Bournemouth 2010.

4. Epidemiological trends in surgery for rectal prolapse in England 2001-2012; an adult hospital population-based study

   Yesar El-Dhuwaib, A. Pandyan, C. Knowles

   Colorectal Dis. 2020 Oct;22(10):1359-1366.

Presented at

- The Association of Coloproctology of Great Britain and Ireland, Edinburgh, 2016.

5. Definitive management of Gallstone pancreatitis in England

   Yesar El-Dhuwaib, M. Deakin, G. David, D. Durkin, D. Corless, J. Slavin

   Annals of Royal College of Surgeon of England: 94 Issue: 6, May 2012, pp. 402-406

Presented at

- The Annual Pancreatic Society of Great Britain and Ireland (PSGBI), Birmingham 2010.

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1 Introduction

One of the aims of all doctors is to inform patients about the nature of their disease and the best modality of treatment. Doctors should explain all treatment options and present an unbiased summary of the pros and cons of each option. They should also inform patients about the risk of harm associated with each option, in particular, the one selected. Such discussions normally occur during the consultation between the doctor and patient[1]. Doctors are required, where possible, to support their advice with appropriate evidence and data. This thesis discussion is limited to general surgery only.

1.1 Evidence based medicine

The concept of Evidence Based Medicine was first introduced in mid-19th Century[2]. But it was not practiced in the way it is known today until 1990 where Gordon Guyatt from McMasters University Internal Medicine, introduced a new concept in medicine he called "Scientific Medicine"[3]. The term described a novel method of teaching medicine at the bedside. It was built on groundwork laid by his mentor David Sackett drawing on a combination of best experience and best evidence. Although the term was received well, some of his colleagues made some suggestions that made Guyatt returned with a new title that described the core curriculum of the residency program: "Evidence-Based Medicine" (EBM)[4].

The current definition of EBM is *the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient and, in practice, it requires the explicit integration of an individual's clinical expertise with the best available external clinical evidence from systematic research*. An individual's clinical knowledge is derived from formal learning, experiential learning (some of which will be under supervision), continuing professional development, and scholarly activity (i.e. reading research). This is consistent with the traditional models of EBM.

It is often perceived that EBM is based on knowledge from traditional research. However, this does not imply that the knowledge gained from other sources of information such as audits, registry and other types of administrative/process control data. Traditional research is a slow process that takes a long time to generate important new knowledge. The results may not be published or it could take years to be published and it out of date at the time of publication. A survey of non-published and delayed publication of vaccine were published in the BMJ in 2014 analysed 384 trials (85% sponsored by industry)[5]. Of 355 trials (404,758 participants) that were completed, 176 (n=151,379) had been published in peer reviewed journals. Another 42 trials (total sample 62,765) remained unpublished but reported results in ClinicalTrials.gov. The proportion of trials published 12, 24, 36, and 48 months after completion was 12%, 29%, 53%, and 73%, respectively. Including results posted in ClinicalTrials.gov, 48 months after study completion results were available for 82% of the trials and 90% of the participants. This shows the difficulty in conducting trials and publishing them. In addition to the trouble of conducting a trial and publishing it, it often takes few years to convert an idea into a trial. There is huge effort needed to design a trial and obtain ethical approval. Such delays are barriers to effective implementation of EBM.

Research from other source of information may be as good as traditional research to obtain the relevant information and inform the medical community with current relevant information. For example, in 1995 there was a national outcry due to high mortality following paediatric cardiac surgery in Bristol. Researchers at Imperial

College drew upon HES data to assess whether the mortality in Bristol had a high mortality when compared to other centres in UK and identified that this was the case. The lessons learnt from this use of HES data changed practice nationally.

EBM has become well established and consistently embedded in the medical practice since the 2000s. Clinicians are no longer allowed to practice without their practice being routinely scrutinised [6]. Health Care Authorities tend to provide national guidelines based on the best evidence available to the medical and surgical communities. For example, National Institute of Clinical Excellence (NICE) oversees all service provision and new technology in the country and regularly reviews the best available evidence to support, or not, a new method of treatment [7]. Other relevant professional specific societies are also responsible for certain aspects of surgical practice, for example in general surgery other such responsible bodies are The Association of Coloproctology of Great Britain and Ireland (ACPGBI)[8], The Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS)[9], and British Society of Gastroenterology (BSG)[10].

In surgery, the main aspects of research are almost always focused on improving surgical outcomes. Randomised control trials or comparative studies to find the best method of practice are necessary to inform clinicians about the best types of practice or surgery. Guidelines are later developed based on these studies. However, such primary studies that inform these guidelines are difficult and expensive to conduct.

1.2 Traditional research and data

Conventional datasets are the traditional method of collecting data. These are normally collected by medical staff for research and audit purposes. These data are often analysed by the same team collecting them and the results will be published thereafter. Prospective data are often collected as part of randomised control trials or other types of studies such as cohort studies. The data are often complete and rigorously collected. There is a lot of effort made to design the study and what types of information are needed. They are collected for certain periods of time for a specific reason. Therefore, these datasets, although robust, are limited in breadth.

Sometimes researchers decide to review the clinical data retrospectively to perform retrospective studies. They review patient case notes and review what happened to those patients. These studies, whilst useful, are likely to be broad but limited in robustness.

1.2.1 Meta-analysis and Systematic Review

Meta-analysis is regarded as the most powerful tool to inform practitioner about certain level of evidence. A good meta-analysis is always considered as level one in the evidence of Medicine tool kit. Some databases such as Cochrane, is regarded as the ultimate evidence-based medicine for any particular research[11].

A good systematic review can be given a similar level of evidence to meta-analysis. According to the centre for Evidence-Based Medicine, Systematic review of randomised control trials with good homogeneity is given level 1A. where is systematic review of cohort studies with good homogeneity is given level 2A, and systematic review of case control studies with good homogeneity is given level 3A[12].

Although Cochrane reviews regarded as the ultimate level of evidence, it is not uncommon to find a Cochrane review that fails to provide conclusions due to insufficient data. For example, Wake et al in 2005 attempted to assess Transabdominal Pre-Peritoneal (TAPP) vs Totally Extraperitoneal (TEP) laparoscopic techniques for inguinal hernia repair. They found there are 8 studies but no randomised control trials. They concluded that there was insufficient data to allow conclusions to be drawn about the relative effectiveness of TEP compared with TAPP. Efforts should be made to start and complete adequately powered RCTs, which compare the different methods of laparoscopic repair[13]. However, such a study is yet to be conducted (last checked in Jan 2020).

Meta-analyses are not without their weaknesses. Selection bias is one of the quoted weaknesses of them. It has been suggested by Dickersin et al in 1994 that a small modification in search criteria, may results in a significant effect on the number of studies selected[14]. Another weakness is publication bias. Positive results are more likely to be published than negative ones. Turner et al in 2008 showed 97% of studies with positive results are published compared to only 12% where the results were negative when they analysed antidepressant[15]. This will lead to biased results when conducting meta-analysis. Heterogeneity of data is another weakness of meta-analysis. Despite best effort of researchers to produce well designed meta-analysis, there are factors that they found very difficult to adjust for such as heterogeneity of the data and availability of the data[16, 17]. Finally, if the methodology used for meta-analysis is not robust enough, it can produce confounded results that can be detrimental to patient care [18].

1.2.2 Randomised Control Trial

Randomised Control Trials (RCTs) are the second most important level of evidence. A good multicentre randomised control trial can be classified as level one evidence[12]. It is a study in which people are allocated at random to receive one of several clinical interventions. One of these interventions is the standard of care. The control may be a standard practice, a placebo, or no intervention at all. It measures and compares the outcomes after the participants receive the interventions.

RCTs are difficult to conduct and requires a lot of collaborations, funding, and commitments from many centres for a long period of time. For example, ROSSINI 2 trial is currently recruiting patients[19]. The trial aim is to recruit 6610 patients from 64 centres over a 2-year period. Although the trial is up to date with the recruitment process (Jan 2020), the commitment from these centres are crucial to complete the trials. Sometimes trial fails to recruit and has to be closed in the middle due to difficulty in recruiting patients such as PROSPER trial[20].

Solheim in 2019 wrote an invited article about RCT in surgery. He stated "*surgical RCTs are usually not done in stages and choosing the most appropriate endpoints and estimations about effect sizes and statistical power can therefore be difficult. As a result, most surgical RCTs are comparable with phase II drug trials and are therefore small and sometimes more explorative in nature. Second, recruitment may be problematic. Patients are often more reluctant towards invasive, risky, and non-reversible interventions if the treating physician has no clear treatment recommendation. Also, operative treatments are usually not as common as drug treatments, and this affects recruitment. Third, pre-inclusion bias may be problematic, not at least in studies comparing surgery with non-operative treatment. Often, patients referred to surgery have already tried several non-operative treatments. This may* *introduce expectation bias and reduce the likelihood of demonstrating an effect of further non-operative management*”[21].

Although the above may be true for some surgical trials, there are a number of very good well-designed trials such as controlled trial of arthroscopic surgery for osteoarthritis. The researchers designed phase 2 trial and analysed the results to calculate the number of participants and then conducted phase three trial[22].

Practice in the real world is different from trials. The outcome in the real world may not reflect the results from RCT or be similar. Often these trials performed in certain centres which have better resources and different level of skills. These are often not available to the rest of the healthcare providers and therefore, transferring the experience may not be possible. In fact, even a surgeon who participates in RCT may not follow the results later, once the trials are finished[23].

Finally, RCTs are based on randomising patients but not surgeon. Surgical outcome varies considerably among healthcare providers and surgeons. Therefore, performing multicentre RCT to compare surgical outcome may end up with biased results. For example, looking at the NBOCA[24] the 90 days mortality varies between zero and 6%.. In pancreatic surgery the quoted mortality figure is between 1 and 3 % in tertiary centres of excellence. However, in non-academic centres the mortality figures could be as high as 11.4%[25]. This variability may skew the end results of any RCT.

With the development of National Institute for Health Research (NIHR) and its huge budget of £1 billion. Research, patients, and randomised control trials have benefitted significantly. It produced a framework for all patient and clinicians in the NHS to participate in multicentre trials. All clinicians have the ability to join national trials by registering their centre and themselves as principle investigator for their centre. This has resulted in many well-designed multicentre trials[26].

1.2.3 Cohort Study

Cohort Study is conducted by following one or more samples (cohorts) prospectively to determine and evaluate the outcome of a specific intervention or disease and to identify what are the risk factors associated with it. As the study is conducted, outcomes from participants in each cohort are measured and relationships with specific characteristics determined. These studies are cheaper and easier to conduct than randomised control trials. Cohort study can also be standardized and matched to a control group[27].

1.2.4 Cross-sectional Study

Cross-sectional Study is performed by collecting data on the whole population at a single point in time to examine the relationship between a health-related disease or intervention and other variables of interest[28].

Cross-sectional studies therefore provide a snapshot of the frequency of a disease or other health related characteristics in a population at a given point in time. This methodology can be used to assess the burden of disease or health needs of a population and is therefore useful in informing the planning and allocation of health resources

1.2.5 Case Control Studies

Case Control Studies compare patients who have a disease with patients who do not have the disease (controls) and look back retrospectively to compare how frequently the exposure to a risk factor is present in each group to determine the relationship between the risk factor and the disease[27].

Case control studies are observational because no intervention is attempted and no attempt is made to alter the course of the disease. The goal is to retrospectively determine the exposure to the risk factor of interest from each of the two groups of individuals: cases and controls.

1.3 Non-conventional large datasets

These data are collected for a number of reasons. They are divided into three main categories. Cancer Registry Data which are collected by cancer network for auditing purposes. National Audits which are collected to audit national data and Administrative Data which are collected for non-clinical purposes.

1.3.1 Cancer Registry Data

In the UK, National Cancer Intelligence Network collects data on all cancer patients on a national level. The network is divided on a geographical basis and all hospitals within the area should follow that network. The data collected are mainly about cancer staging and other patient demography. While the aim is to have 100% accurate and complete data, the cancer network set a goal of 70% complete cancer staging record by 2013. They managed to achieve 76% but they admitted there are huge variations in data entry among health care providers and clinical commissioning groups[29].

1.3.2 National Dataset

These are either national audits or national registry. They are often collected for certain periods of time and they require a great deal of collaboration and dedication on a national level. They can be performed on the good will of people such as Chole S study which is evaluation of cholecystectomy surgery over a two month period in over a 100 hospitals[30]. Or they can be mandatory such as The National Emergency Laparotomy Audit NELA[31]. In order to perform such a massive audit, the group has to secure multimillion-pound funding to fund the audit. The group managed to make participation on the audit mandatory through the Healthcare Quality Improvement Partner (HQIP). Hospitals record their data regularly but the case assignment remains a problem to the auditor. Case assignment varies between 50 and 95%[31]. Similar problems occur in other national databases, such as National Bowel Cancer Audit Programme NBOCAP. Despite the fact they are mandatory and published per hospital and surgeon, they are incomplete. A simple look at the data will show the case ascertainment varies between different hospitals somewhere between 70 and 110%[24] .

Another national Audit was established in the last couple of years called "Perioperative Quality Improvement Programme (PQIP)". Although, it is not mandatory, many hospitals are signing up to it. It is also organised and funded by The Royal College of Anaesthetists[32]. At the moment, the data are produced for audit purposes but they started working on research outcomes as well. In all these audits, one can expect the data to be accurate and complete but they are not validated by external audit.

1.3.3 Administrative Data

Health care administrative data are generated at every encounter with the health care system, whether through a visit to a physician's office, a diagnostic procedure, an admission to hospital, or receipt of a prescription at a community pharmacy. The terms "Health Care Utilization Data"[33], "Administrative Health Care Billing Records"[34], "Administrative Claims Data"[35], or simply "Claims Data" are synonymous with "health care administrative data". These data are collected for administrative or billing purposes, yet may be leveraged to study health care delivery, benefits, harms, and costs[35]. They are often collected for administrative purposes by non-clinical staff such as clinical coders. There are many data available in the UK and internationally. These are some examples of available data

1.3.3.1 International Dataset

Most developed countries have some sort of administrative data that has the potential to inform research.

1.3.3.2 American Dataset

The National (Nationwide) Inpatient Sample (NIS)[36] is the largest publicly available all-payer inpatient care database in the United States. It contains data from approximately 8 million hospital's admissions each year. Restricted access data files are available with data use agreement and brief online security training. The 2012 NIS was redesigned. The new NIS is a sample of discharges from all hospitals participating in Healthcare Cost and Utilization Project (HCUP). For prior years, the NIS was a sample of hospitals. The NIS allows for weighted national estimates to identify, track, and analyse national trends in health care utilization, access, charges, quality, and outcomes. The NIS is drawn from States participating in HCUP. NIS data are available since 1988, allowing analysis of trends over time. The NIS includes charge information for all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured.

1.3.3.3 Danish Dataset

There have been several studies from Denmark using the national administrative database or a combination of both administrative and clinical databases by linking both datasets. There are four different nationwide registers: The Danish National Patient Register, The Danish Civil Registration System, The Danish Register of Medicinal Product Statistics, and The Danish National Health Service Register for Primary Care. Each dataset has different criteria, which can be used for certain types of research. Researchers may use all datasets to come up with a specific conclusion such as comparing different Danish Regions Regarding Demographic Characteristics, Healthcare Utilization, and Medication Use-A Descriptive Cross-Sectional Study[37].

1.3.3.4Swedish Dataset

The Swedish National Inpatient Register (IPR), also called the Hospital Discharge Register, is a principal source of data for numerous research projects. The IPR is part of the National Patient Register. The Swedish IPR was launched in 1964 (psychiatric diagnoses from 1973) but complete coverage did not begin until 1987. Currently, more than 99% of all patients including surgery and psychiatric hospital discharges are registered in the IPR. A previous validation of the IPR by the National Board of Health and Welfare showed that 85-95% of all diagnoses in the IPR are valid[38].

1.3.3.5UK Dataset

There are three main datasets. Hospital data, General practice data and the Office of National Statistics mortality data.

1.3.3.5.1 Hospital Dataset (Hospital Episode Statistics)

In England, all healthcare providers should convert their patient's journey in the hospital into clinical codes. They use international classification of disease (ICD 10)[39] codes for the diagnosis and Classification of Interventions and Procedures version 4 (OPCS 4) for the operative and intervention codes[40]. They have strict rules they should follow and all patients case notes should be translated into clinical codes within 30 days of discharge. Once this is completed, another code (Health Resource Group Codes (HRG)) is given to each patient that represents the tariff for that procedure and admission[41].

The data is then submitted to the NHS digital by each health care provider to get paid for the work they carried out in their hospital. This is called Payment by Results. The data is then collected by the NHS Information Centre and Hospital Episode Statistics (HES data) created.

1.3.3.5.2 Office of National Statistics Mortality Dataset

The Office of National Statistics (ONS) collects and keeps all records of death that occur in the UK[42]. ONS produce data on a monthly basis about all deaths, cause of death, place and date of death. These data are linked to HES data so researchers can access them to produce a better understanding of mortality in hospital and following discharge.

1.3.3.5.3 GP Dataset

There are 3 main types of data.

1.3.3.5.3.1 The General Practice Research Database (GPRD)

GPRD is the world's largest database of anonymised longitudinal medical records from primary care[43]. It contains comprehensive observational data from clinical practice; it is a valuable tool for academic research in a broad range of areas including clinical epidemiology, disease patterns, disease management, outcomes research, and drug utilisation. GPRD is a highly valued resource by Pharma and Biotech Companies because of its high-quality longitudinal person specific records that enable drug safety, outcomes and economic research. The ability to link data from hospital or disease registers adds to this capability. The data available are between 1987 and 2010. The data covers over 10 million patient records and can be accessed for research purposes.

1.3.3.5.3.2 Clinical Practice Research Datalink (CPRD)

CPRD is primary care and linked data that offers a high-quality source of complete and representative healthcare information for investigating the nature and cause of disease[44]. CPRD collects fully-coded patient electronic health records from GP practices across the UK. Primary care data held by CPRD includes over 20 million patient lives, with over 5 million currently registered and active patients, representative of the UK population with respect to age, gender and ethnicity. All data are anonymised to protect the identity and confidentiality of patients. Access to CPRD is subject to protocol approval by and Independent Scientific Advisory Committee.

1.3.3.5.3.3 The Health Improvement Network database (THIN)

The Health Improvement Network (THIN) represents collaboration between two companies; In Practice Systems (INPS) - who developed Vision software used by General Practitioners (GPs) in the UK to manage patient data, and IMS Health who then provide access to the data for use in medical research[45]. THIN data are collected during routine practice and regularly delivered to THIN. Since THIN data collection began in 2003, over 500 Vision Practices have joined the scheme.

Research studies for publication conducted using THIN data are approved by a nationally accredited ethics committee which has also approved the data collection scheme. The UCL Research Departments Primary Care & Population Health (PCPH) and Infection & Public Health (IPH) have acquired a full license to THIN for the purposes of conducting large-scale epidemiological, clinical and health care utilisation studies.

THIN data currently contains the electronic medical records of 11.1 million patients (3.7 million active patients) equivalent to 75.6 million patient years of data collected from 562 general practices in the UK, covering 6.2% of the UK population. All data are fully anonymised, processed and validated by CSD Medical Research UK.

1.4 Benefit and drawback of non-conventional data

A meta-epidemiological survey of 337 Studies that use routinely collected health data shows that the most common reason why researchers use routine data are limited generalizability of trial results to the "real world" (37.6%), evaluation of specific outcomes (31.9%) or specific populations (23.5%), and inconclusive or inconsistent evidence from randomized trials (25.8%)[38].

Routine data are freely available and cheap. As the data is routinely collected by hospitals for administrative purposes, they do not cost a lot of money to use. In fact, in most cases they are available by non-profit government organisation for research purposes. They often charge administrative fees for data handling. Data analysis requires training and experience but it is not impossible or out of proportion. Routine administrative data can be used to assess all centres in the country and all patients. Therefore, it can give a true reflection on the current practice and can identify problems in the current practice among healthcare providers.

It is very good at giving a broad view about the practice and changing practice for the coded procedures. By analysing several years, researchers can understand the shift in changing practice and can also predict what will happen in the future.

Large datasets are very good at investigating hospital volume and consultant caseload in association with surgical outcome[46, 47]. Such analysis is unique to those large datasets because of the size of the data and number of operations provided by each surgeon/ healthcare providers. Because large administrative data reflect the whole practice across the nation, these studies are population based and therefore do not require sampling power. Some of these studies assess hundreds of thousands of patients[48].

The drawbacks of these large routinely collected data are the following. There is a problem with large data sets that are collected due to the potential sources of error at the point of data entry. Miscoding is another weakness of these data. Data error could be produced because of typing error, poor documentation in the original patient notes, misinterpretation of the patients' notes and when there is no specific code that describes the diagnosis or procedure.

Research from large datasets give a very good global picture of the current problem such as recurrence of a hernia and the outcome can be assessed immediately. Whereas large multicentre trials can give a similar result but require years to design, develop and publish.

Large data sets lack a lot of information such as the significance of comorbidity (e.g. grade of heart failure or COPD), significance of ischaemic heart disease. The sequence of comorbidity. For example, if a patient developed angina and he was treated by cardiac stent and now the patient is asymptomatic is completely different from a patient who had cardiac stent and continues to develop symptoms of angina.

Research from large data sets is very good to give a global picture but struggle with details and therefore, it should act as complementary to traditional research and not as a replacement.

1.5 Hospital Episode Statistic (HES)

The history of HES dates back to 1982 when the government in the white paper "liberating the NHS" has established a system to collect and use hospital activity data to secure good quality outcome and inform patient's choice. A steering group chaired by Dame Edith Körner published a report on the collection and use of hospital activity information in 1982[49]. A 10% sample collected nationally of patients admitted to the National Health Service (NHS) in England was established and it was mainly to give a rough idea about hospital activities. Later Körner report has resulted in the formation of Hospital Episode Statistics Data (HES) that was established during 1987. HES were published for the first time during the financial year 1989-90 and continued since then. Initially, the data collection was made by regional health authorities, and as a result of the changes in the NHS, these bodies were abolished and the NHS-Wide Clearing Service (NWCS) was established to collect and store HES data. In 2006 the National Programme for IT (NPfIT's) and Secondary Uses Service (SUS) took over this job.

HES have evolved dramatically in the last 2 decades to reflect the changes in the NHS and the new requirement of the hospital policy changes. In addition, several systems of classifications were introduced. The data depends on 3 systems: The International Classification of Diseases (ICD) that represents diagnosis; the Office of Population, Censuses and Survey (OPCS) that represents operations and procedures; and Health resource Group (HRG) that is used for payment. In 1995, the ICD changed from 9th revision to 10th revision, and the OPCS 4.4 version was introduced during 2007/2008 as an upgrade from the previous version of OPCS 4.3. Augmented data i.e. critical care data, was introduced during 1997.

The data in its current form contain details about every single patient treated by the NHS Trusts in England, including acute hospitals, primary care trusts, mental health trusts, and the independent sector, such as treatment centres and care given to private patients in NHS hospitals.

From 1989 HES contain all information about inpatients, whereas out-patients data were added from 2003 and Accident and Emergency data were added in 2008. During 2007 over 16 million records of inpatients data were collected nationally. The data is collected by each NHS Trust, PCT, and Independent Treatment Centre and sent to the NHS Information Centre (NHSIC) each month. The data is managed by a private company "Northgate" that stores and cleans the data according to defined protocols. The data is then anonymised and provided to end users by "Northgate" under the supervision of the NHSIC. The NHSIC was recently demolished and NHS digital has taken over its role as well as many other activities.

1.6 Measurement of Surgical Outcomes using HES Data

Before embarking on the research, a question was raised question whether HES data can be used to measure surgical outcomes and what are the evidence for that. In 1995, there was a significant incidence at Bristol with high mortality of paediatric cardiac surgery. This led to a national public inquiry. The report of Bristol inquiry chaired by Ian Kennedy showed a need for changes to the NHS culture and management[50]. The inquiry was set up in 1998 to investigate the deaths of 29 babies undergoing heart surgery at the Bristol in the late 1980s and early 1990s, the 529-page report effectively provided a blueprint for wider reform of the NHS[51]". The government published a new policy of first-class service for all NHS patients and quality in the new NHS in 1998[52]. A definition of clinical governance was introduced and The clinical governance became a fundamental part of the NHS and it is directly report to the Trust board[6]. The NHS Plan: a plan for investment, a plan for reform (2000) pledged a significant increase in the NHS budget and significant cultural changes to the NHS[53].

A group from Imperial College investigated the mortality of paediatric cardiac surgery from HES and from Cardiac Surgical Registry (CSR). Their aim was to investigate whether Bristol mortality results can be identified from administrative data. Data from the CSR (January, 1984, to March, 1996) and HES (April, 1991, to December, 1995) were obtained for all 12 major centres in England in which paediatric cardiac surgery is done. Two age-groups were defined: children younger than 1 year and children aged between 1 and 15 years. Two different classifications of operative procedures were used: the first comprised broad classes of either open (requiring cardiopulmonary bypass) or closed operations, and the second consisted of 13 procedure groupings (11 open, two closed). For the HES data, mortality rate was based on admissions for whom discharge status was known (discharge home, transfer to another hospital, or death in hospital). Admissions with unknown discharge status were excluded.

Three stages of analysis were undertaken. First, overall mortality within each epoch was estimated with 95% CIs. Second, expected mortality in Bristol was estimated, allowing for between-centre variability. Specifically, within each procedure group they modelled between-centre variability using a variance-components (random-effect) model for the 11 centres (excluding Bristol). The expected number of deaths in a hypothetical centre with Bristol level of activity was then predicted, and excess deaths in Bristol were estimated by subtracting these expected numbers from the observed numbers of deaths. The entire analysis was then repeated in turn for each of the remaining centres. And finally, traditional analysis to assess statistical significance and robustness.

They showed for children younger than 1 year, in open operations, the mortality rate in Bristol was around double that of the other centres during 1991–95: within the CSR, there were 19.0 excess deaths (95% Confidence interval 2–32) among 43 deaths; and in HES, there were 24.1 excess deaths (12–34) among 41 deaths recorded. There was no strong evidence for excess mortality in Bristol for closed operations or for open operations in children older than 1 year[54]. This shows HES can be used to measure outliers in surgical mortality and it can be used to assess healthcare providers with a very good degree of confidence.

The same group looked at HES data again and published their results in the British Medical Journal in 2004[55]. They investigated the trends in mortality of open cardiac surgery in children in Bristol and England between 1991 and 2002. They used similar methodology and selection criteria as previous mentioned. Their main outcome was Mortality in hospital within 30 days of a cardiac procedure.

They identified 5221 open operations between April 1996 and March 2002 in children under 1 year and 6385 in children aged 1-15 years. Mortality for all centres combined fell from 12% in epoch 3 to 4% in epoch 6. Mortality in children under 1 year at Bristol fell from 29% (95% confidence interval 21% to 37%) in epoch 3 to 3% (1% to 6%) in epoch 6, below the national average. The reduction in mortality did not seem to be due to fewer high-risk procedures or an increase in the numbers of low risk cases (figure 1). Their work was a landmark in the use of HES data to measure mortality. The original work showed HES can be used to identify the problem and it can also be used to measure the effect of an intervention on patient outcome as in the second paper.

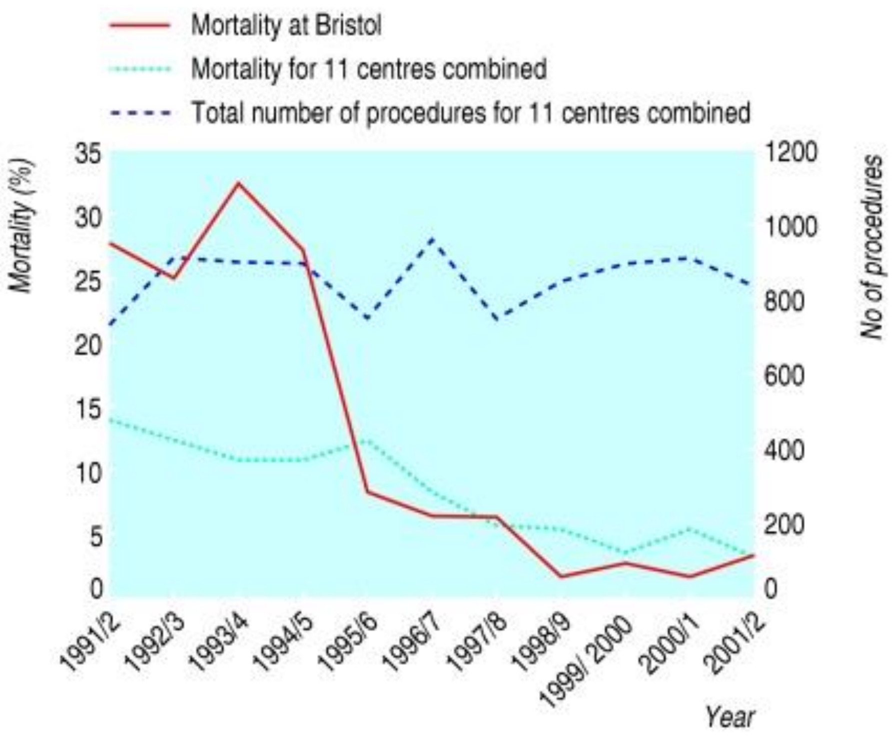

Figure 1: Mortality (based on admissions with known outcome) for and number of open operations on children aged under 1 year from April 1991 to April 2002 in 11 English centres; data derived from hospital episode statistics[55].

From this example, we can conclude with good confidence that HES can be used to measure mortality and the impact of any intervention. This raised the question whether we can use HES data to measure surgical outcomes in general surgery other than mortality?

1.7 HES reliability

We have shown earlier HES can be used to measure mortality and the impact of intervention in the mortality. However, one cannot be sure how reliable administrative data.

There are 2 systematic reviews of clinical coding accuracy in the literature. The first was published in 2001 by Campbell et al[56]. The systematic review search found 30 papers. Only 21 papers were from the UK and were reviewed (12 from England and Wales and 9 from Scotland). Accuracy of coding varied between 53% and 100% over the 39 datasets, with a median of 90%. Procedures and operations were generally coded more accurately than diagnoses.

In the 14 datasets concerned with OPCS codes (operative codes), accuracy ranged from 53% to 100%, with a median of 97%. The 25 ICD (diagnostic codes) datasets varied in accuracy from 53% to 98%, with a median of 84%. Overall accuracy rates were similar in Scotland to those in England and Wales. The median accuracy rates were 89 per cent (range 53–100 per cent) for the 22 Scottish datasets and 90% (range 53–100%) for those in England and Wales. Strong trends suggesting differences emerge when diagnostic and procedural codes are considered separately. The median accuracy rate for diagnostic codes in Scotland is 82% (range 53–98%; 14 datasets) compared with 91% (range 74%–98%; 11 datasets) in England, Wales and Northern Ireland. For procedural codes, accuracy rates are higher in Scotland (median 98%, range 85–100%; eight datasets) than in England, Wales and Northern Ireland (median 69.5% (range 53-100%): six datasets).

The study concluded "*Coding accuracy on average is high in the United Kingdom, especially for operations and procedures. However, policy-makers, planners and researchers need to recognize and account for the degree of inaccuracy in routine hospital information statistics. Further research is needed into methods of improving and maintaining coding accuracy*".

Another systematic review was published in 2011 by Burns et al[57]. The authors concluded "*Accuracy rates are improving. Current levels of reported accuracy suggest that routinely collected data are sufficiently robust to support their use for research and managerial decision-making*". The authors reviewed 32 articles which investigated the accuracy of clinical coding. 25 of them compared routinely collected data directly with patients' case notes or operation notes. Only 14 studies were from England and the rest were from either Wales or Scotland. The authors also reviewed 7 other studies which compared routinely collected data with clinical registries. 5 of them were from England and 2 from Scotland. The overall median accuracy was 83.2% (IQR: 67.3–92.1%). The median diagnostic accuracy was 80.3% (IQR: 63.3–94.1%) with a median procedure accuracy of 84.2% (IQR: 68.7–88.7%).

When the author compared those studies that included data prior to the introduction of Payment by Results (PBR) in 2004 and those afterwards, the accuracy improved from [pre-PbR 77.0% (IQR: 66.2–89.0%) to post-PbR 86.1% (IQR: 73.1–96.1%)]. The accuracy of the primary diagnosis also improved from [73.8% (IQR: 59.3–92.1%) to 96.0% (IQR: 89.3–96.2%). There was no difference in overall accuracy between multiple hospital and single site data sets. When Scottish studies were compared with those assessing English data, there were no differences in overall, procedure or diagnosis accuracy. Those studies that used random sampling for case selection had lower median accuracy [random accuracy 83.1% (IQR: 68.0–88.2%) versus non-random 93.7% (IQR: 90.3–95.0%).

The author (Burns) also looked at studies that compare HES data to another database such as registry data. They found 7 studies (5 from England and 2 from Scotland). One of the studies is using data from the eighties, leaving only 4 from England. One study examined Clostridium difficile rates reported on HES database against those reported to the Health Protection Agency (HPA). This showed recording of C. difficile infection to be higher from HPA data than from HES data. In contrast, compared with HPA data for orthopaedic SSIs, there were many more SSIs and numbers of procedures recorded from HES data for all four orthopaedic procedures, although the infection rates themselves were broadly similar. These findings reflect the limitations of both methods used and the author suggested that there is a case for using both sources of information[58].

The second paper is to compare patient volume and outcomes in vascular surgery between an administrative data set (Hospital Episode Statistics) and a clinical database (National Vascular Database). HES data recorded twice as many procedures as the National Vascular Disease (NVD) registry (HES n= 16 923 and NVD n= 8462) with slightly higher death rates recorded on HES (HES, 18% and NVD, 15%). The study concluded that there are significant differences in total numbers between HES and the NVD. If the National Vascular Database is to become a credible source of information on activity and outcomes for vascular surgery, there is a clear need to increase the number of contributing surgeons and to increase the completeness of data submitted[59].

A similar study compared HES and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) colorectal cancer database. The study found a higher number of colorectal procedures reported on HES (HES n= 7516 and ACPGBI n= 6617) with comparable overall mortality at a national level [HES 418 (5.6%) versus ACPGBI 383 (5.8%), P= 0.416][60]. This paper again showed HES data is superior to specialist data registry.

The last paper compared HES data and Central Cardiac Audit Database (CCAD). The study found a higher number of reported infant cardiothoracic procedures on the CCAD than on the HES (HES, n= 1745 and CCAD, n= 2182). The reported mortality was lower on HES than on CCAD [HES n= 74 (4.2%) versus CCAD n= 139 (6.4%)]. However, the two datasets differed in the types of procedures included in the analysis with all procedures included in the CCAD and a limited number included in the HES data analysis. The definition of 30-day mortality differed between data sets, with HES recording only those deaths in hospital and the CCAD including all deaths in and out of hospital. Thus, the comparison was inhibited by different coding systems and difficulty in defining the same procedures and outcomes[61].

Elaine Burns et al (2011) suggested clinical registries are purpose-built databases for prospective data collection. In contrast to the inclusive mandatory administrative data sets, clinical registries are mostly voluntary. They will not include all patients with a given condition nor will data entry be complete.

The second systematic review has shown good data accuracy and it provides good evidence to accept research performed from HES. The authors in their discussion acknowledged the limitations of their findings and the heterogeneity of the data that prevented them from performing meta-analysis. They discussed what constitutes a reliable data with data accuracy aims for 100% accurate or more realistic 95%. However, their findings of median 86.1% (IQR: 73.1–96.1%) for procedure codes and 96.0% (IQR: 89.3–96.2%) for diagnostic are acceptable for research. They concluded Accuracy rates are improving. Current levels of reported accuracy suggest that routinely collected data are sufficiently robust to support their use for research and managerial decision-making[57].

1.8 General Surgery

As discussed, earlier HES data can be used to measure outcome (mortality) and discussed the systematic review of administrative data reliabilities. One can say that HES is a good data for measuring outcomes. An evaluation of surgical outcomes in general surgery is discussed in the thesis.

Surgery as a branch is very wide, it covers, General Surgery, Orthopaedic Surgery, Urology, Otolaryngology, Ophthalmology, Neurosurgery, Cardiac Surgery, Thoracic Surgery, Paediatric Surgery and Transplant Surgery. General Surgery used to cover many of these specialities until it was decided to make them a speciality by itself such as urology and paediatric surgery. General surgery at the moment covers a number of sub-specialities like colorectal surgery, upper GI surgery, Hepatopancreatobiliary surgery, vascular surgery, and breast and endocrine surgery. All general surgeons are able to perform emergency surgery such as appendicectomy and elective surgery such as hernia repair and gallbladder surgery.

This thesis is aimed at developing an approach to evaluate surgical outcomes of general surgery using HES data. Because the field of general surgery is very wide, the research will be limited to common surgical pathologies, i.e. it should be a pathology treated by all general surgeons, and the patient with these diseases should present to the general surgeon and not to the specialist surgeon such as stomach cancer.

A decision was made to choose common surgery from general surgery, lower GI surgery and upper GI surgery.

- General surgery (inguinal hernia repair). Inguinal hernia is very common. Each year, over 62,000 patients undergo surgery in England as discussed later in the thesis.
- Upper GI surgery (Gallstone and gallbladder). Gallstone and cholecystectomy is very common problem in surgery. Each year there are over 45,000 patients undergo surgery in England as discussed later in the thesis.
- Lower GI surgery (large bowel resection and surgery for rectal prolapse). Elective and emergency large bowel resection comprise the majority of lower GI surgery and each year there are over 35,000 operation performed in England as discussed later in the thesis.

From the general surgery inguinal hernia was selected for the research. Inguinal hernia is the most common surgical operation that all surgeons are able to treat. Inguinal hernia can be treated by open surgery or laparoscopic surgery. The outcomes of inguinal hernia were defined and a comparison between open and laparoscopic approaches was performed.

The most common upper GI surgery condition is Gallstone disease. The gallstone can cause symptoms from the gallbladder such as biliary colic and cholecystitis or it can cause symptoms from passing into the bile duct and cause obstructive jaundice and gallstone pancreatitis. Patients with gallstone disease offered cholecystectomy (gallbladder removal). Patients undergoing cholecystectomy can develop a number of complications. Bile duct injury is the most important complication and the research will aim at investigating bile duct injury rate and factors that may contribute to it.

The gallstone may not cause symptoms in the gallbladder and they may pass into the bile duct and cause either obstructive jaundice or gallstone pancreatitis. Gallstone is the most important cause of pancreatitis and they account around 50% of all cases of pancreatitis. Patients should undergo cholecystectomy during index admission or within 2 weeks of discharge from index admission[62]. The research will investigate compliance with this guideline and the outcome if the patients do not receive the treatment within this time.

From lower GI surgery, bowel resection surgery was selected. Bowel resection is very common and they could be performed as an emergency or elective. Although almost all elective surgery is performed by the colorectal surgeons, emergency surgery is performed by all General Surgeons. Patients undergoing bowel resection may develop a number of complications such anastomosis leak, bleeding, infection etc… one of the important complications that is not very well studied is Venous Thromboembolism (VTE) following surgery. The research will investigate the rate of VTE following bowel resection, timing of the VTE and factors associated with VTE.

The last topic selected for the research is surgery for rectal prolapse. Although this is more of colorectal speciality, it is very important. Surgery for rectal prolapse is changing. The incidence of rectal prolapse is unknown and the Pelvic floor society is keen to restrict surgery for those patients to only surgeon with special interest in pelvic floor surgery. The research will investigate the changing trends in surgery for rectal prolapse and look at different types of surgery. The study will also explore the number of surgeons performing surgery and whether surgery for rectal prolapse should be offered by a specialist surgeon.

1.9 Surgical outcomes

Recently the government encouraged the relative royal colleges to publish surgeon outcomes. The Royal College of Surgeons of England for example is working toward improved methods of ensuring high standards in surgical practice through public reporting of operation outcomes. A reliable system of measuring outcomes will have many benefits[63]:

Greater public transparency and accountability.

Enable surgeons a better basis for judging and improving their practice.

Offer patients the basis to make informed choices about their care.

Evidence for service improvement and quality assurance of operations.

Better data for health service commissioners when making funding decisions.

Surgical outcomes are very broad terms that include many outcomes and these are the main ones.

1.9.1 Mortality

Perioperative mortality is the most important outcome of surgery. It can be either observed (crude) mortality rate or Standardised Mortality Rate (SMR). Crude mortality rate where the results represent the true figure without any adjustment whereas SMR is defined as the ratio of observed deaths in a study group to expected deaths in the general population. The expected death is traditionally calculated using the age to adjust for it (sometimes it is called age specific mortality rate). However, in the last 15 years, a number of other factors were used to adjust for standardised mortality ratio such as age, gender, comorbidity, and social class, and other factors[64].

Mortality is often reported over a specific period of time. In-hospital mortality is defined as death during index admission regardless of the time period. Other method of reporting perioperative mortality rate is to specify a specific time period following the index surgery. This could be reported after 30 or 90 days postoperatively and called 30-day postoperative mortality and 90-days postoperative mortality rate.

The benefit of in-hospital mortality it covers the whole patient admission until discharge and it often occurs when the patient is well and fully recovered from surgery regardless of the time; i.e. patient could remain in hospital for 4 months and die and this patient will be missed if we use 30- or 90-days mortality. However, the drawback of such measurement it excludes all deaths occur following discharge. 30 days postoperative mortality is the preferred method in most literature, however the preferred method of describing perioperative mortality following surgery in the UK in colorectal cancer surgery is 90 days from date of operation[24].

The reported 90 days postoperative mortality includes all deaths that occur within this time period, even if the death occurs due to natural causes and not related to the actual surgery. The argument of the government is this rule applies to every surgeon and therefore, it shouldn’t discriminate between surgeons or hospitals[65]. There are some evidence that support the government point of view of recording 90 days postoperative mortality[66].

1.9.2 Morbidity and Complications

Morbidity and complications are the second most measured outcomes in surgical practice after mortality. In any research that involves surgery morbidity is always measured and the figures are very important to inform the readers and patients about the complication rate and what they may experience in the perioperative period. Morbidity varies from simple surgical site infection or urinary tract infection to multiorgan failure. In general, the complications can be divided into surgical complications such as those directly related to surgery such as bleeding, collection, anastomotic leak, and injury to other organs during surgery; and systematic complications such as chest infection, Venous thromboembolism, myocardial infarction, and renal failure. Another classification of morbidity is early and late complications. Early complications are the ones that occur in the immediate postoperative period. Late complications, on the other hand, are the ones that occur many months following surgery such as recurrence of hernia operation or venous thromboembolism.

The Royal College of Surgeon of England has issued guideline that all hospitals should run a monthly meeting of morbidity and mortality (M&M) so hospitals monitor their practice and constantly improve the quality of care delivered to their patients[67].

1.9.3 Length of stay

Length of hospital stay is often considered a marker for efficiency. The average cost per bed day varies between £222 (2015/16 Enhanced Tariff Option)[68] to £400[69]. Therefore, hospitals that discharge patients a day earlier than their counterpart will save a considerable amount of money by freeing hospital beds. Hospital stay of patients is often determined by many factors such as patients' premorbid conditions, operative technique (minimal invasive therapy), hospital culture, complications, and social care[70].

1.9.4 Readmission rate

Another parameter that can be used to measure surgical outcome is readmission rate[71]. This is often measured over a certain period of time (normally 30 days) and it indicates failed discharge. Hospitals in the NHS at the moment are penalised for any readmission and they are not paid for the readmission[72]. Recently, some hospitals started auditing this practice and all cases discussed in their weekly M&M meetings and they discuss whether the readmission was related to surgery or not. If not, they amend their results of readmissions[73].

Readmission rate should always be measured in addition to the length of stay. This is because both parameters are related to each other. Early discharge is often associated with higher readmission rate and longer hospital stay is associated with lower readmission rate. Hospitals who keep their patients longer in the hospital will allow for all complications to occur while patients are still hospitalised. Therefore, their readmission rates are often low. On the other hand, hospitals that discharge their patients early often have a higher readmission rate in general as some patients will develop certain complications a few days later and require readmission[74].

1.9.5 Patient satisfaction, reported outcome, and quality of life

One of the important aspects of measuring surgical outcome is to measure patient satisfaction with their treatment; patient reported outcome survey of operations and their quality of life. While patients may survive an operation, they may not be happy with the outcome of surgery. Their unhappiness may be related to the hospital journey or because they had a bad experience with a particular person. These are often measured by hospitals locally. Hospitals often record patient feedback (complaints and compliments). Hospitals also measure their patients' satisfaction by sending surveys to patients and relatives, such as Friend and Family Test (FFT)[75]. NHS England publishes these data on a monthly basis and each NHS Trust publishes their results on a monthly basis for each speciality. These types of patient satisfaction surveys are more directed at patient and family experience from the service they received.

Patient Reported Outcome Measures (PROMs) are collected nationally by all NHS Trusts[76]. It is designed to assess the quality of care delivered to NHS patients from patient perspective. Currently covering four clinical procedures, PROMs calculate the health gains after surgical treatment using pre- and post-operative surveys. It is delivered for four procedures: hip replacements, knee replacements, groin hernia, and varicose veins surgeries.

PROMs have been collected by all providers of NHS-funded care since April 2009. PROMs measure a patient's health status or health-related quality of life at a single point in time, and are collected through short, self-completed questionnaires. This health status information is collected before and after a procedure and provides an indication of the outcomes or quality of care delivered to NHS patients.

Quality of life of patients after certain surgical intervention has been developed for years and they represent a significant part of patient's outcome. There are general quality of life survey and disease specific quality of life. General quality of life index is a survey sent to patients with a number of qualities of life aspect. There are a number of these survey such as 36-item short form survey[77] and the Rand -36[78] where 36 different aspects of life are measured. They measure quality of life in general and can be used following every operation. Another method to measure quality of life following surgery is by using disease specific quality of life measures. These are very popular in pelvic floor surgery. For example, constipation related quality of life[79] and the Faecal Incontinence Quality of Life scale (FIQL)[80].

1.10 Aim and Objectives

Most of surgical researches are based on surgical outcomes. The research that can inform the risk analysis is normally derived from published prospective clinical trials or retrospective analyses of existing datasets. However, restricting the information to only the traditional research sources has limitations, however, there are other valuable sources of information a surgeon can draw upon. The aim of this thesis is therefore, to explore one such source of information. The Hospital Episode Statistics (HES) is a national data warehouse of all National Health Service (NHS) patients treated in NHS hospitals or private hospitals. The process of extracting data from the HES is not a trivial task and within this thesis there is an added aim of developing a methodology to convert HES (administrative data) into useful clinical data that can be used to study surgical outcome. To develop an algorithm to cover all surgical outcomes will be beyond the scope of a PhD and therefore for the purposes of this thesis, the aim is to develop and validate a protocol for the following five objectives:

1. Can HES data be used to identify rare complications when the code is available?
2. Can HES data be used to identify rare complications when the code is not available?
3. Can HES data be used to compare different types of surgery for the same condition?
4. Can HES data be used to measure changing trends in surgical practice?
5. Can HES data be used as a national audit tool?

For each of these objectives, A different surgical pathology will be used. This research will be limited to common pathologies that are seen by all general surgeons on a regular basis. One or two examples from each subspecialty of general surgery is chosen as follows.

- General surgery (inguinal hernia repair)
- Upper GI surgery (gallstone and gallbladder)
- Lower GI surgery (Bowel resection and surgery for rectal prolapse)

2 Literature review

As discussed in the previous chapter the aim of thesis is to evaluate surgical outcomes using hospital administrative data and 5 objectives were set to deliver the aim: an example was selected for each objective as follow.

1. Can HES data be used to identify rare complications when the code of this complication is available?
    - Example used: Venous Thromboembolism following Bowel resection.
2. Can HES data be used to identify rare complications when the code is not available?
    - Example used: Bile duct injury following laparoscopic cholecystectomy.
3. Can HES data be used to compare different types of surgery for the same condition?
    - Example used: Compare laparoscopic and open inguinal hernia.
4. Can HES data be used to measure changing trends in surgical practice?
    - Example used: Surgery for rectal prolapse.
5. Can HES data be used a national audit tool?
    - Example used: Definitive management of gallstone pancreatitis.

2.1 Literature review

The aim of the literature review is:

- Identify if any of the objectives has been investigated in the past from HES data. An example from general surgery was chosen for each objective.

- Is there historical data from other source of data that answer these objectives (this will be discussed in the introduction of each study in the relevant chapter).

A literature review is performed to identify if any research from HES data was studied in the past to answer any of these objectives. The literature review is focused on inguinal hernia, gall stone and bowel pathology as per objectives. The literature search is limited to years between 1990 (The start of HES data in 1989) and 2011 (The start of the part time PhD), adult patients, English language, and for studies that used HES data only. For each category, the search is divided into anatomy, disease or pathology, types of surgery or surgical procedures, and HES data. A thesaurus assessment of all terms used is performed and explode term is used if available. For HES data search, Some published studies do not use the term HES data or Hospital Episode Statistics in their abstracts. Terms such as in England or English database is used instead. Therefore, a searched for all studies with the term England was performed to capture all studies and then only papers that are relevant was selected.

Healthcare Databases Advanced Search (HDAS) Engine is used for the literature search. HDAS is provided in partnership between National Institute of Clinical Excellence (NICE) and Health Education England (HEE). The search is limited to Medline database only. The search was performed in July 2019. Due to technical reason with the HDAS (limit can only be applied to the last search), the limit "Date of publication between 1990 and 2011, English language, and adult age group" was applied to the last search.

2.1.1 Inguinal hernia

The aim of the literature review is to examine if any study from HES data that was performed in the past to investigate inguinal hernia repair. The aim of the objective in this example is to compare laparoscopic and open inguinal hernia repair. A literature search of all studies that used HES data to study outcome of inguinal hernia surgery was performed. All terms related to inguinal hernia anatomy was searched and only inguinal hernia was found. The second stage is to assess the terms for pathology which is inguinal hernia. There are a number of procedures used to repair inguinal hernia which are listed in the table below. The search term used for the dataset were HES data, England, and Hospital Episode Statistics. A thesaurus term is used if available.

Anatomy	Number	Pathology	Number
Exp "Inguinal hernia"	11231		
Total	11231		
Surgical techniques		HES data	
Open inguinal hernia repair	1484	HES data	1037
Laparoscopic inguinal hernia repair	2035	Hospital Episode data	1216
Total extraperitoneal hernia repair	407	Exp "England"	103666
Transabdominal preperitoneal hernia repair	406		
Lichtenstein inguinal hernia repair	613		
Mesh inguinal hernia repair	1869		
Suture inguinal hernia repair	317		
Shouldice inguinal hernia repair	203		
Total	3787	Total	105055

Table 1: terms used for inguinal hernia literature review

As of July 2019, a total of 11,231 papers were published in the literature with the term inguinal hernia (explode). A total of 3,787 papers were published in the literature studying inguinal hernia repair. And finally, for the terms HES, "Hospital Episode Statistics" and for England (explode), the literature was searched and a total of 105055 papers were published during the same period of time as shown in table 1.

Anatomy, pathology and surgical technique results were combined using the term "OR". The results were then combined with HES data results using the term "and". A total of 69 articles were identified. The limits were then applied and only 9 papers were found. All abstracts were reviewed and all of them were selected because they mention the term England or a place in England rather than because they were derived from HES data. Therefore, as of 2011, there was not a single study published in the literature from HES data assessing inguinal hernia as shown in figure 1.

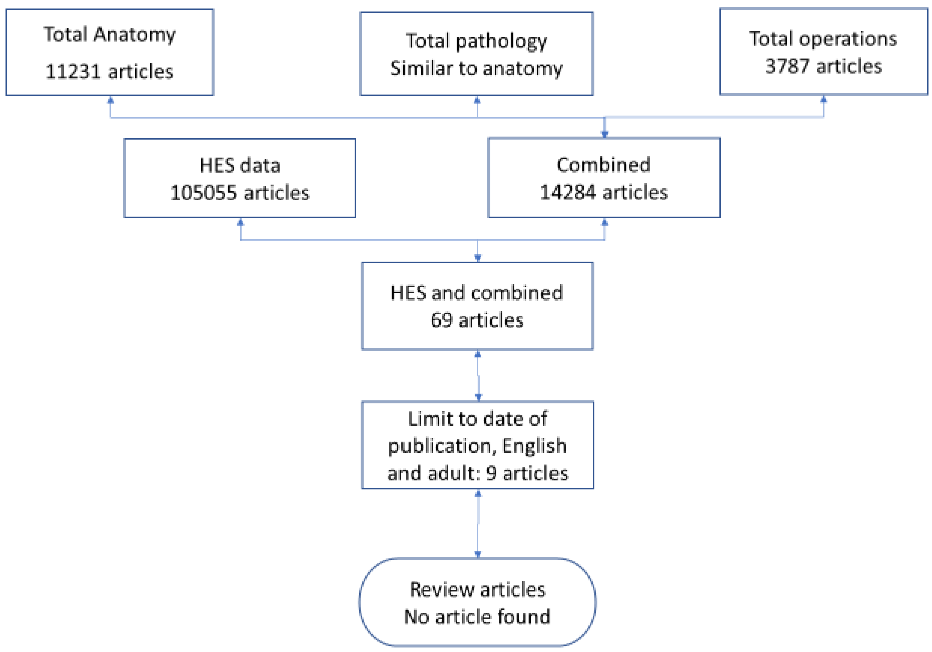

Figure 1: Flowchart of inguinal hernia literature review

As indicated in the objectives, a comparison of different types of inguinal hernia repair is to be performed as an example of the objective. The study will identify all inguinal hernia which was performed in England. Laparoscopic inguinal hernia can be performed using TAPP or TEP. HES data don't have the codes required to differentiate between both types. Therefore, Laparoscopic repair is going to be used for the research. Open inguinal hernia repair can be performed by all other types mentioned in table 1. HES data again can't differentiate between these types and therefore, Open inguinal hernia repair will be used for the research. The research compares laparoscopic and open inguinal hernia as an example of the use of HES data to compare different surgical treatment. The comparison of these operation is based on short term outcome (early complications such as bleeding, infection, and urinary retention). and long-term complications in terms of reoperation which is a surrogate for recurrence.

2.1.2 Gallbladder

The aim of the literature review is to identify any study published in the literature from HES data investigating gallbladder diseases. Two examples are identified from gallbladder disease to represents two objectives of the research. The first objective is can HES data be used to identify rare complications when there are no codes for the complication. Bile duct injury following laparoscopic cholecystectomy is the example used for this objective.

The second objective is can HES data be used as a national audit tool. Definitive management of gallstone pancreatitis is the example for this objective. Before these examples are performed, A literature review of all studies used HES data to study outcome of gallbladder was performed to make sure none of these studies has been published before.

Anatomy		Disease	
Exp. Gallbladder	14,807	Exp “Gallstone”/ or exp “cholelithiasis”/ or exp “cholecystolithiasis”	38,803
		Exp “jaundice Obstructive”/ or “exp “cholestasis, extrahepatic”/ or exp “mirizzi syndrome”	6,639
		Gallstone pancreatitis	1,279
		Biliary colic	962
		Exp “Gallbladder neoplasms”/ or exp “gallbladder diseases”	35,433
		Exp “ acalculous Cholecystitis”/ or exp “cholecystitis”/ or exp “gallbladder diseases”/ or exp cholecystitis, acute”/ or “cholangitis”	47,320
		Gallbladder empyema	268
		Gallbladder mucocele	74
		Gallbladder perforation	1,001
Total studies	14,807	Total studies	72,850
Surgical techniques		Dataset	
Exp “cholecystectomy”/ or 2xp “cholecystectomy, laparoscopic”/ or exp “biliary tract surgical procedures”	37,044	Hospital Episode data	1,216
Exp “Cholecystostomy”	726	Exp “England”	103,666
Subtotal cholecystectomy	239	HES data	1,037
Removal of gallbladder	909		
Total studies	37,581	Total studies	105,055

Table 2: terms used for gallbladder literature search

The terms used for search strategy is illustrated in table2. Terms related to gallbladder anatomy is gallbladder. The second stage was to assess the terms for pathology which is gallstone and by using thesaurus terms, explode gallstone, cholelithiasis and cholecystolithiasis were found. Other pathology terms were used in the same way as illustrated in table 2. The procedures used to remove gallbladder are cholecystectomy and subtotal cholecystectomy. Other terms used for procedure is cholecystostomy which is used to describe radiological drainage of gallbladder. Finally, a search for dataset that includes HES data, England, and Hospital Episode Statistics was performed. A thesaurus term was used if available. Table 2 shows all terms used and the number of studies as of July 2019. If there were thesaurus terms available then explode term was used and this is written exp. If there were no thesaurus terms then a searched for the term was used.

A total of 14,807 papers were identified with the term Gallbladder (explode) for anatomy. 37,581 papers were identified in the surgical technique as of July 2019. A search for all the terms used for any disease or pathology related to gallstone such as gallstone pancreatitis or biliary colic was performed. All terms are listed in table 2. A total 72,850 articles were found for the same period. Finally, for HES data the number was 105,055.

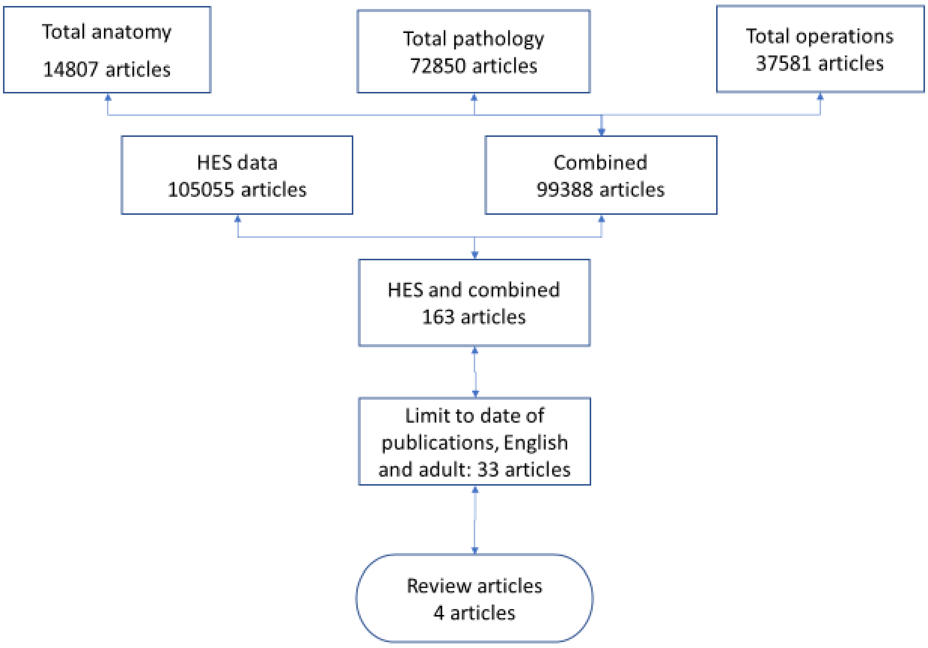

Figure 2: flowchart of gallbladder literature review

A combined search for anatomy, surgical techniques and pathology or disease was performed using the term “OR” a total of 99,388 articles were identified. The results were combined with HES data and 163 articles were identified. A limit of published year 1990 to 2011, adult patient and English literature were applied to the results. The number was reduced to 33 study as shown in figure 2. All abstracts were reviewed and the majority of articles were related to the England term used and not applicable to HES. Only 4 articles were identified.

2.1.2.1Review of papers

The first paper published in the literature from HES data studying gallbladder disease was in 2003 and reported on gallstone admission and surgery between 1989 and 2000[81]. The study investigated admission with gallstone diseases by gender over time, the results were adjusted for age and presented per 100,000 population. The study also investigated the admission for surgery over time adjusted for age and presented for male and female. And finally, the study investigated endoscopic surgery for gallstone disease over the same period of time.

The study found Between 1989/1990 and 1999/2000, the age-standardized hospital admission rates for cholelithiasis increased by 30% for males and 64% for females. Admission rates for cholelithiasis increased progressively with age from 1.1 per 100,000 in the 0–14-year age group to 277.1 per 100,000 in the ≥85-year age group in 1999/2000. The age-standardized percentage of hospital admissions for cholelithiasis with an operation fell significantly by 16.9% from 1989/1990 to 1999/2000. The male operation rate decreased from 54.2% to 44.0% and the female rate from 61.2% to 50.9%. Females had a higher percentage of admissions for cholelithiasis with an operation than males in each year of the study. The frequency of operation was approximately 50–60% for most age groups, but decreased progressively with advancing age at ≥65 years. The proportions of admissions undergoing therapeutic endoscopy increased several-fold, especially amongst older individuals. Case fatality rates declined. The male rate fell by 32% from 0.6% to 0.4% and the female rate by 42% from 0.5% to 0.3%. In general, there was a downward trend in case fatality rates for cholelithiasis throughout the study period. Case fatality rates following admission for cholelithiasis were highest in the 75–84 year and for patients over 85 year.

The second paper investigated emergency admission with gallbladder pathology and investigated the emergency surgery rate and readmission[82]. The study showed there were 25,743 patients admitted as an emergency with acute gallbladder disease in England between April 2003 and March 2004. Of these, 3,770 patients (14·6%) were readmitted as an emergency with acute gallbladder disease during the period April 2003 to March 2005. The number of readmissions ranged from one to ten. The total number of readmissions was 4,770, accounting for 15·65 of all 30,513 admissions. The male: female ratio of the 21,973 patients admitted once was 33: 67 and was similar to the ratio of 31: 69 in those admitted more than once. The mean (SD) age of those admitted once was 57.9 (19.1) years and of those admitted more than once was 54·0 (19.8) years ($P < 0·001$). The study showed emergency surgery for acute gallbladder disease was very low (14.7%), the attempted laparoscopic approach for those who underwent surgery was 70.3% with the national conversion rate for emergency laparoscopic cholecystectomy was 10.7%. The study also investigated the length of stay of each cohort (no surgery, open surgery, laparoscopic surgery and converted cases). The postoperative hospital stay after a successful laparoscopic cholecystectomy was significantly lower than that after an open cholecystectomy or a conversion to an open cholecystectomy (median (IQR) 2 (1–4) versus 6 (3–10) days; $P < 0·001$). The remaining 21,952 patients who did not have an emergency cholecystectomy had a median hospital stay of 5 (IQR 2–8) days. The study investigated emergency readmission with gallstone diseases for cohort who did not undergo surgery and they found a significant number of patients were readmitted with the same pathology (15.6%). The study was a milestone in gallstone disease and showed emergency surgery for acute admission with gallstone disease is low in England.

The same group published later another study about conversion rate of (elective and emergency) laparoscopic cholecystectomy[83]. The study investigated conversion rate of laparoscopic cholecystectomy and its association with patient related factors and non-patients related factors. The study showed the conversion rate was 5.2% for the study period (elective and emergency). The conversion rate for elective surgery were 4.6% and for the emergency surgery were 9.6% (a drop from previous study 10.7%).

The mortality rate was low at 0.24% for the intervention/whole population. However, the mortality rate for open surgery is much higher (1.7%) than conversion cases (0.5%) and for laparoscopic surgery (0.06%) (P<0.01).

The study investigated factors associated with conversion and found patients related factors such as age, gender mode of admission, and diagnosis are significantly associated with higher conversion rare. Age < 40 conversion rate was 2.1% compared to10.9% for age >70 (P<0.01). Male conversion rate was 9.8% compared to female 3.7% (P <0.01). patients with biliary colic are less likely to have conversion 3.6% compared to patients with cholecystitis 6.1% (P<0.01).

The study also investigated the non-patients related factors such as consultant caseload and hospital volume of surgery. The study showed consultant caseload is inversely associated with higher conversion rate (P<0.01). the study showed consultant with caseload of less than 10 have a conversion rate of 8.7% compared to 3% for consultant who perform over 70 case a year.

The authors calculated the previous year consultant case load and used it for the studied year. This provides standardisation across all surgeon. The study showed the conversion rate for emergency cholecystectomy decreased from the previous year published in the previous article by them. This suggests surgeons' skills and possibly patient's selection are getting better. The study also suggests surgeon who perform surgery regularly for benign disease (gall bladder) have a better outcome than those who offer surgery occasionally.

The fourth paper identified in the literature search was about acute pancreatitis rather than gallstone. Because gallstone is one of the causes of pancreatitis, the study will be included in the literature review. The study investigated the incidence of acute pancreatitis and its mortality and geographical variations and its associated with alcohol intake[84]. The study found between1998 and 2003 there were 55,960 cases of acute pancreatitis. The calculated incidence was 22.4 per 100,000. The incidence increased from 20.9 per 100,000 (95% CI 20.6–21.4) in 1998/99 to 23.5 (95% CI 23.1–23.9) in 2002/03. The incidence varied between 10.0 per 100,000 in Cambridge and 46.1 in Gateshead. At the regional level, the highest rates were in the North East (28.3 per 100,000 per year) and the North West (27.3 per 100,000) and the lowest rates were in the East of England (18.1) and the South East (18.3). They found the majority of mortality occurs in the first week of admission and the mortality is significantly associated with increasing age P<0.01). Gallstone as a cause is responsible for 27% of acute pancreatitis patients.

The literature has investigated mortality rates and rates of conversion in patients admitted for gallbladder surgery. However, postsurgical complications of cholecystectomy have not been investigated. While the literature has investigated the trends of admissions of gallstone to hospitals, it did not study other gallstone diseases such as bile duct injury following laparoscopic cholecystectomy, gallstone ileus, management of gallstone pancreatitis, management of cholangitis have not been investigated.

Bile duct injury is the most important complication of cholecystectomy, bile duct injury is associated with significant mortality and morbidity to patients[85]. Therefore, there is a need to investigate this complication from HES and investigate all factors that may increase the incidence of bile duct injury. There are no codes for bile duct injury in the HES data. Therefore, bile duct reconstruction will be investigated as a surrogate for bile duct injury and this will be the example of measuring complication following surgery when there is no code for that complications.

Another complication of gallstone disease is gallstone pancreatitis. The last study reviewed showed the incidence of pancreatitis and it showed gallstone account for only 27% of the total cases. Patients admitted with gallstone pancreatitis should undergo definitive management of gallstone pancreatitis during index admission or within 2 weeks of discharge[62]. An assessment of all hospital compliance with this guideline is required as well as an assessment of what happens to the patients if they didn't receive the definitive treatment in time. This study will be used as an example of using HES data as a national audit tool.

Each study is published in a chapter later in the thesis. The need for each study is discussed in details in the introduction of each chapter.

2.1.3 Bowel pathology

The last two objectives of the research are from bowel pathology. The first is can HES data be used to identify rare complication when there is a code? An example of this objective is development of Venous Thromboembolism following bowel resection. The other objective is can HES data be used to identify changing trends in surgery for rectal prolapse? Prior to the studies being performed, literature review of all studies that used HES data to investigate outcome for bowel surgery was performed to make sure none of these studies has been published in the past.

Anatomy	Number	Disease	Number
Colon	157,485	Rectal prolapse	2,878
Exp “Rectum”	38,703	Obstructive defecation	179
Exp “lower gastrointestinal tract” or exp Intestine, Large	187,427	Faecal incontinence	2,092
Exp “anal canal”	17,672	Exp “Rectal diseases”	224,658
Bowel	140,390	Exp “Diverticulitis/ or exp “Diverticular disease”/ or “Diverticulum”	22,401
		Exp “Inflammatory bowel disease”/ or exp Colitis. Ulcerative”/ or Crohn Disease”	76,823
		Exp “Colitis. Ischemic”/ or exp Colitis, microscopic”/ or exp “proctocolitis”	2,384
		Larger Bowel Obstruction	151
		Exp “colonic disease, Functional”	11,071
		Exp “Colonic psudo-obstruction”	680
		Exp “colorectal neoplasm”/ or exp “Colonic neoplasm”/ or “sigmoid neoplasm”	191,513
		Exp “anus neoplasm”/ or exp “rectal neoplasm”	45,584
		Exp “Colonic Polyps”	8,068
Total	414,451	Total	313,269

Table 3A: literature review of all studies for bowel in HES dataset

Surgical techniques	Number of papers	Dataset	Number of papers
Exp “colectomy”/ or exp “colon”/ or exp proctocolectomy, restorative”	83,460	Hospital Episode data	1,216
Bowel resection	13,671	Exp “England”	103,666
Anterior resection	14,762	HES data	1,037
Ileocolic resection	600		
Panproctocolectomy	93		
Exp “colectomy”	19,776		
Hemicolectomy	3,719		
Sigmoid colectomy	997		
Exp “proctectomy”	3,344		
Exp “surgical stomas”/ or exp “colostomy”	10,119		
Bowel anastomosis	34		
Rectopexy	802		
Delormes procedure	225		
Altemeier's procedure	37		
Sacral nerve stimulation	1,315		
Total	123,005	Total	105,055

Table 3B: literature review of all studies for bowel in HES dataset

The terms used for search strategy is illustrated in table 3. Terms used for anatomy are bowel, colon, rectum and lower gastrointestinal tract. The second stage in the literature search was to assess the terms for pathology. This was divided into functional bowel problem such as rectal prolapse and faecal incontinence. Colonic neoplasm such as cancer and polyp. Inflammatory bowel disease such as colitis, and benign bowel pathology such as diverticulosis. Prior to search any term, Thesaurus search for all terms was performed to find any MESH term available for each of the term used. If thesaurus term was identified, then a term explode was selected and this is highlighted as exp prior to the term. There are a number of surgical procedures for bowel surgery and these terms are list in table 3. Finally, a search for HES data, England, and Hospital Episode Statistics was performed as explained previously.

A total of 414,451 paper were identified for the anatomy of bowel as of July 2019. 123,005 studies were identified for surgical techniques for bowel surgery and 313,269 papers were identified in pathology or diseases section as shown in table 3 (A & B).

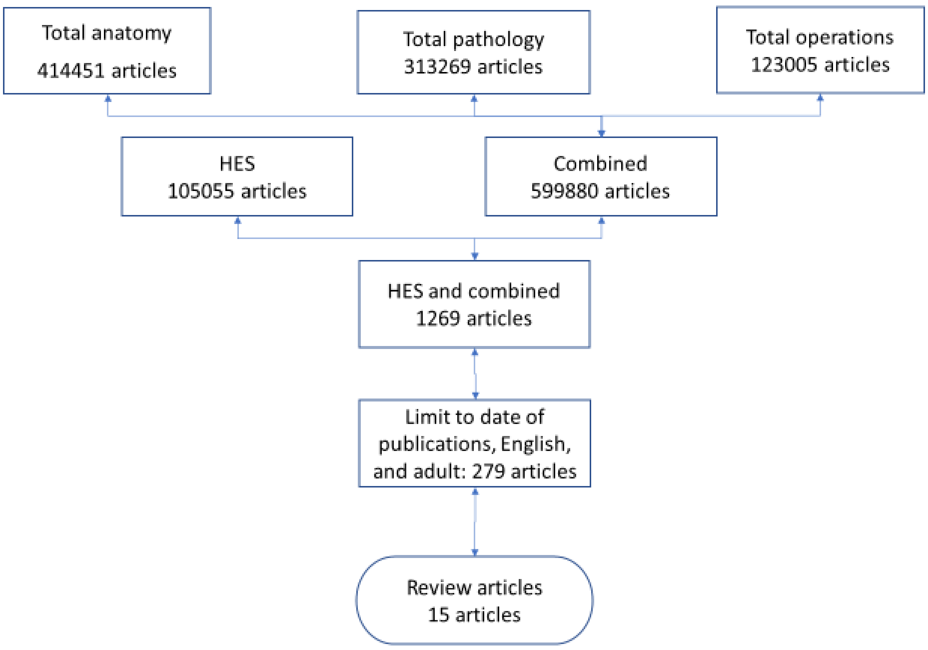

Figure 3: Flowchart for literature review of studies from HES data on bowel pathology

A combining search for anatomy, pathology, and operations was performed using term "OR". A total of 599,880 articles was identified in the literature up to July 2019. The results were combined with HES data results using the term "and". A total of 1,269 articles were identified. The limit was applied as described previously to the results and

279 articles were identified. All abstracts were reviewed and the majority of them were selected due to the presence of England term in the searching strategy. Only 15 papers from HES data studying bowel disease published in the literature up to 2011.

2.1.3.1Review of papers

There are 15 papers published in the literature that covers bowel surgery, pathology and anatomy for HES data. The majority of them were published in 2010 and 2011. None of the studies were used to assess venous thromboembolism following bowel resection. The review also didn’t identify any paper that investigated surgery for rectal prolapse or indeed examined changing practice to inform planners. The need for this study is discussed in details in the relevant chapter. A review of all published papers is listed below.

The first two paper from HES data investigating bowel pathology were published in 1995 and 1998. Both researches were from the early days of HES data and the methodology used were limited to the aim. The aim of the first paper was to investigate the incidence of Crohn’s disease in Oxford and England. the study linked Oxford data to the National data[86]. Age-standardized admission rates were calculated from the Hospital In-patient Enquiry and the Oxford Record Linkage Study. In addition, annual hospitalized prevalence, first hospital admission rates (as a proxy for incidence) and readmission rates were calculated for the Oxford population. The study showed neither episode-based (hospital admission) nor person-based (oxford data) rates increased for ulcerative colitis. Relapses resulting in hospital admission were more common for Crohn's disease than for ulcerative colitis.

The aim of the second paper was to investigate trends in hospital activity, hospital admissions, and treatments for colorectal cancer on residents of the South Thames regions (population 8 million)[87]. A total of 18,542 patients were admitted between 1989 and 1993 with colorectal cancer. The number of admissions was doubled (98% increase $p < 0.0001$) in the period studied. The proportion of patients having a day case admission rose from 9% in 1989 to 18% in 1993 ($p < 0.0001$). Overall, 2,894 (16%) patients had a day case admission; 1,894 of these (65%) were also admitted as ordinary (overnight) admissions. The number of Finished consultant episode (FCEs) and admissions per patient rose from 1.37 and 1.28 respectively in 1989 to 2.09 and 1.99 respectively in 1993. FCEs were between 5% and 8% higher than admissions over the five years. Chemotherapy accounted for 50% of the rise in day case admissions; colonoscopy and sigmoidoscopy were associated with a further 18%. Fourteen per cent of the increase in ordinary admissions was also because of chemotherapy. The study describe admission for colorectal cancer in a single area in England. The study is designed to give a descriptive statistic for admission whether day case or overnight stay. The study also investigated the cause of admission such as Chemotherapy.

Both papers were designed to answer a specific aim and it was conducted in simple methodology and the results congruent with the aim. The conclusion of both papers is consistent with their results.

In 2007, a study from Imperial College analysing the use of administrative data or clinical databases as a predictor of risk of death was published[88]. The study aim was to compare risk prediction models for death in hospital based on an administrative database with published results based on data derived from three national clinical databases: the national cardiac surgical database, the national vascular database and the colorectal cancer study. The study created three models from HES data to predict death and compared the results to the best published predictive risk model based on data from the clinical databases. For CABG and abdominal aortic aneurysms, they used the most recent society reports available. For colorectal resection they used the published model in the report on risk adjusted outcomes from the Association of Coloproctology of Great Britain and Ireland. they compared models using receiver operating characteristic (ROC) curve scores (c statistics). The study found the power of the complex predictive model was comparable with that of models based on clinical datasets with ROC curve scores of 0.77 (v 0.78 from clinical database) for isolated CABG, 0.66 (v 0.65) and 0.74 (v 0.70) for repairs of ruptured and unruptured abdominal aortic aneurysm, respectively, and 0.80 (v 0.78) for colorectal excision for cancer.

The study showed risk prediction of mortality from HES data is comparable to data from national registry in prediction of mortality. They study however, is not designed to investigate colorectal cancer, but it is designed to assess reliability of HES data in mortality predictions.

HES were used to investigate season of birth and ulcerative colitis (UC) development as well as to assess temporal changes in the age distribution in inflammatory bowel disease. Each of these aims were published in a separate article by the authors. The former paper was published in 2008[89]. The background to the study is the suggestions that seasonal variations of individual birth time may increase the risk of UC. Infection in the perinatal period was thought to be the cause. The study investigated all admissions with a clinical diagnosis of UC and correlated the diagnosis with the month of birth. The study found there is no correlation between month of birth and UC development later in life.

The latter study investigated temporal changes in the age distribution of IBD[90]. This study used separate hospital statistics from England and Scotland to follow the changes in the age distribution. A cross-sectional study assessed hospitalizations (with Crohn's disease or ulcerative colitis listed as primary or primary plus secondary discharge diagnosis). The admissions were expressed as age-specific and sex-specific rates per 10,000 living population. The separate age-specific rates of Crohn's disease and ulcerative colitis of consecutive 6-year or 7-year time intervals were plotted against their respective age group. The study showed a bimodal age distribution of Inflammatory bowel disease. with a prominent first peak occurring in younger patients with Crohn's disease and a prominent second peak occurring in older patients with ulcerative colitis.

Both studies used the same methodology to study age and inflammatory bowel disease and it was consistent with the aim. The conclusions reaffirmed the results and both studies confirmed the ability of HES data to investigate age related admission of inflammatory bowel disease.

Comorbidity of patients is very well linked to higher mortality rate. Shack et al in 2010 investigated whether the time of onset of comorbidity is associated with survival of colorectal cancer using HES data[91]. HES data were linked to North West cancer registry. Charlson comorbidity score were calculated from HES data and linked to cancer survival from cancer registry. The time between the recording of comorbidity in

HES data and diagnosis of cancer was calculated. The impact of Charlson comorbidity score on one-year survival was investigated as well as the effect of different time frame from the onset of comorbidity and diagnosis on the survival. The study found comorbidity recorded 6 to 18 months prior to the diagnosis is associated with lower survival than those who has their comorbidity recorded after the diagnosis. The study concluded Administrative data provide a good estimate of the prevalence of most comorbid conditions but may be biased for patients with severe comorbidity who are not fit for surgery. The authors concluded that the time window in which a comorbid condition occurs in relation to the cancer diagnosis should be taken into account based on their findings. However, recording comorbidity in HES data doesn't necessarily represent the true onset of the disease, but it represents the timing of recording of the comorbidity in HES. This confounding factor was not discussed by the author and It was not incorporated in their conclusion.

A group from imperial College published 7 studies from HES data on bowel surgery. They compared laparoscopic and open surgery for bowel cancer surgery and rectal surgery for cancer[92]. Their main end point is a 30 day and 1-year mortality. The secondary end point is 28 day readmission and length of stay. Between the study dates 3,709 of 192,620 (1.9%) elective colonic and rectal resections were classified as laparoscopically assisted procedures. After correction for age, gender, diagnosis, operation type, comorbidity, and social deprivation, laparoscopic surgery was a strong determinant of reduced 30 day mortality (odds ratio, 0.57; 95% confidence interval, 0.44-0.74; $P < 0.001$) and one-year mortality (odds ratio, 0.53; 95% confidence interval, 0.42-0.67; $P < 0.001$).

The same group repeated their research but for nonelective Excisional Colorectal Surgery in English National Health Service Trusts: A Study of Outcomes from HES Data between 1996 and 2007[93]. The study investigated the cause for bowel resection and types of surgery. The study also investigated the trend over time of right hemicolectomy and panprocotcoloectomy and terminal ileostomy. The results were calculated per 100,000 population and showed little variations over time. The study investigated the mortality rate for different pathology such as diverticular disease, colitis, cancer, and polyps. the study showed only 0.6% of total cases were performed laparoscopically. The study used binary logistic regression to assess factor associated with 30 days and 365 days mortality rate. The study showed the odds ratio for mortality in advanced age >80 is 12.31 (95%CI 11.27-13.45) when compared to those less than 55 years. Patients with Charlson comorbidity score of >6 is more likely to die compared to those that have no comorbidity OR 5.93 (95%CI 5.33-6.60). Patients with diagnosis of peritonitis were more likely to die compare to other types of diagnosis OR 9.24 (8.15-10.47). The study concluded that mortality rate of non-elective colorectal surgery was high and they recommend a validation study to compare the mortality rate between different healthcare providers.

Another study from the same group demonstrated a new use of HES data to measure quality of service by measuring reoperation rate following colorectal surgery[12]. The primary end point is Reoperation after colorectal resection, defined as any reoperation for an intra-abdominal procedure or wound complication within 28 days of surgery on the index or subsequent admission to hospital. The study showed the overall postoperative reoperation rate for all patients undergoing colorectal resection irrespective of admission status was 6.5% (15,986/246,469). Of these, 13,227 (82.7%)

required a reoperation on their primary admission. The remaining 2,759 patients underwent a subsequent admission that included a reoperation. Emergency patients experienced slightly higher rates of reoperation than elective patients (7.0% v 6.2% with OR = 1.149 95% CI 1.118 to 1.112, P<0.001). A total of 11,536 (4.7%) underwent re-laparotomy after colorectal resection, 1,560 (0.6%) experienced a subsequent stoma related complication requiring surgery, and 3,861 (1.6%) had a wound complication requiring reoperation. The study showed elective and emergency patients who experienced a complication requiring reoperation during their initial admission had a prolonged median length of stay (for elective patients, length of stay 27 (IQR 17–43) days with reoperation (n=7,873) v 11 (9–16) days with no reoperation (n=150,974), P<0.001; for emergency patients, length of stay was 34 (21–55) days with reoperation (n=5,401) v 17 (11–28) days with no reoperation (n=82,071), P<0.001). They also had a higher rate of postoperative mortality (elective patients, 938/7,873 (11.9%) with reoperation v 4,399/150,974 (2.9%) with no reoperation, P<0.001; emergency patients, 1,251/5,346 (23.4%) with reoperation v 12,511/82,126 (15.2%) with no reoperation, P<0.001).

The study showed there is significant variations of reoperation rates among consultant and trusts. The variation varied between none and 50% for the former and none and 17% for the latter. The study used funnel plot to compare Trusts and surgeons. To avoid errors, the study excluded low volume surgeons and Trusts. They defined low volume surgeon as any who performed less than 5 procedures and low volume trusts as any who performed less than 10 procedures over the study period 2000 to 2008.

The Study aim was well thought and the methodology was designed to answer such a question. However, there is a major confounding factor in the study design. The study excluded consultant and Trust with small number, but they didn't explain where did they come up with those definition of small number. Trusts who performed more than 10 procedures over the study period 2000-2008 means the Trust has performed one or two procedure a year. This is a major confounding factor and probably this is the reason behind this huge variation among the healthcare providers.

The same group also published a paper about Volume analysis of outcome following restorative proctocolectomy[94]. The study aimed to determine national provision and outcome following pouch surgery (restorative proctocolectomy, RPC) and to examine the effect of institutional and surgeon caseload on outcome. The study identified all RPC surgery between 1996 and 2008 performed in England. They assessed the association between hospital volume and surgeon caseload over the study period. The authors showed the majority of operations are performed by a low volume hospitals and surgeons. The study grouped surgeon and hospitals into 3 groups. Low volume, intermediate volume and high volume. They study failed to show any difference between these groups of surgeons or hospitals for mortality, length of stay, and readmission rate. The study, however, showed high volume surgeon have a lower failure rate of pouches. The study suggested the number of operations carried out by surgeons and hospitals are very low. The study showed the number of operations was low for all centres. This methodology and results are valid and the conclusion is consistent with the results. This type of studies is important to inform service provision and strategic planner about the importance of centralisation of the service. The author later created a national registry[95] trying to increase the focus on these patients and up to now no definitive decision has been made to centralize the service.

The same group also published a study in 2011 assessing a colorectal perspective on voluntary submission of outcome data to clinical registries[96]. The aim of the study was to identify outcome differences amongst patients undergoing resection of colorectal cancer at English National Health Service trusts using Hospital Episode Statistics (HES). A comparison was undertaken of trusts that submitted and those that did not submit, or submitted only poorly, voluntarily to a colorectal clinical registry, the National Bowel Cancer Audit Programme (NBOCAP). The study showed Unadjusted 30 day in-hospital mortality rates were higher in non-submitting than in submitting trusts (5·2 versus 4·0 per cent; P = 0·005). Submitter status was independently associated with reduced 30-day mortality (OR 0·76, 95%CI (0·61 to 0·96); P = 0·021) in regression analysis. The main end point of the study is mortality, length of stay and readmission within 28 days were analysed using HES data to compare outcomes between submitters and non-submitters to the NBOCAP data set. The comorbidity score of both groups and the social deprivation is significantly different in favour of the submitting group. Most healthcare providers (HCP) were submitting data (132) and only 20 centres didn’t submit data, the study concluded A higher postoperative mortality rate following resection of colorectal cancer was found in trusts that do not voluntarily report data to NBOCAP. Implications regarding the voluntary nature of submission to such registries should be reviewed if they are to be used for outcome benchmarking.

The study is well designed and conducted. The study compared only HCP that submit data and the one who don't submit or submit less than 10% of their data. One of the confounding factors that may be the cause of the higher mortality, is the fact that HCP who submit partial data may not be enthusiastic to submit their poor data. The developed system is a good well-designed system, but probably, the authors should have compared complete submission and incomplete to give a clearer picture.

The last paper published by this group is failure to rescue value as a marker of the standard of care following reoperation for complications after colorectal resection[97]. The study used a system described by Silber and colleagues[98] coined the phrase 'failure to rescue' (FTR) to describe patients who died from an acquired complication following surgery. The metric they described represents the proportion of deaths among patients who experience complications. In a study investigating patients undergoing cardiac surgery they ranked hospitals according to their case-relevant mortality, and observed significant differences in FTR rates between the best and worst ranked units despite equivalent complication rates[99]. Risk adjusting model was developed using comorbidity and social deprivation model. Reoperation rate were calculated within 28 days of surgery. They assessed hospital structure in terms of CT scan HDU bed, ICU bed etc… the study then compared low mortality quintile and failure to rescue with other quintiles and they found there is significant difference between low mortality quintile and high quintile. The study concluded FTR-S rates differed significantly between English colorectal units, highlighting variability in ability to prevent death in this high-risk group. This variability may represent differences in serious surgical complication management. FTR-S represents a readily collectable marker of surgical complication management that is likely to be applicable to other surgical specialties.

The study is well designed and conducted based on published work from the 1990s. the study however, grouped HCP on their mortality figures in low mortality quintile, second, third, fourth, and highest. Then they discovered the failure to rescue is higher in the higher mortality. This raise the question whether these data are interfering with each other.

Another study assessed the association between Clostridium difficile (C diff) diarrhoea in patients with inflammatory bowel disease (IBD) and mortality and length of stay[100]. The study identified all patient underwent surgery for IBD. Then they identified both patients who developed C diff and compared both groups. They study showed patients who developed C diff are more likely to die and have a longer hospital stay in the hospital. they concluded patients with inflammatory bowel disease admitted to NHS hospitals in England with co-existent C. difficile infection are at greater risk of in-hospital mortality and morbidity than patients admitted for inflammatory bowel disease alone.

The last study in this literature review investigated thirty-day postoperative mortality after colorectal cancer surgery in England[101]. The study assessed variations between HCP 30 days mortality rate. The study also assessed factors that increase the risk of mortality. The study adjusted for these factors. The risk adjusted 30 days mortality were plotted in funnel plot to assess variations among HCP. The study showed there is significant variation in 30 day postoperative mortality following major colorectal cancer surgery existed between NHS hospitals in England throughout the period 1998 & 2006. Understanding the underlying causes of this variation between surgical providers will make it possible to identify and spread best practice, improve outcomes and, ultimately, reduce 30 day postoperative mortality following colorectal cancer surgery.

To summarise. HES data in bowel surgery were used in three different approaches in bowel

- To assess the incidence of inflammatory bowel disease and seasonal variation and the association of C diff and IBD.

- To assess mortality. This was demonstrated in calculating mortality rate for elective and nonelective bowel resection. HES was also used to assess whether HES can be used to predict mortality and failure to rescue as well as the cause of death and comorbidity impact on death., HES was used to assess mortality rate in bowel surgery as the end point for volume outcome association in pouch surgery. HES was used to compare between two surgical approaches in bowel resection with mortality as the main end point.

- To assess the reoperation rate following bowel resection as a marker for good practice.

The literature review for bowel showed HES was not used to identify rare complications such as VTE following bowel resection. HES was used to identify IBD cases and pouch surgery, but HES was not used to assess surgery for rectal prolapse. Therefore, it is safe to study these two objectives from HES.

3 Data and Methodology

HES data is an administrative data. In order to perform any clinical research, the data has to be converted into clinical data. The literature review confirmed that all data are converted into clinical data but the studies didn't discuss in their methodology how this process was completed. In this chapter, a description of how HES data can be converted into clinically usable data and ideally with no errors. This step should be performed before any other method of analysis is performed.

Each objective in the thesis is different and the aim of the studies is different too. Each study aim requires different methodology and statistical analysis. Each study methodology is discussed in each chapter but all of the studies share the first step which will be discussed in this chapter.

In this section, HES data is described. The level of ethical approval needed to access the data is discussed. A methodology of how to handle the data and store is discussed. And finally, a discussion of how HES data can be converted onto clinical data and how to analyse it.

3.1 Hospital Episode Statistics

HES data is the national data warehouse for all patients treated by the NHS. The data is collected by each NHS Trust, PCT, and Independent Treatment Centre and sent to the NHS Information Centre (NHSIC) each month. The data is managed by a private company called "Northgate" that stores and cleans the data according to defined protocols. The data is then anonymised and provided to end users by Northgate under the supervision of the NHSIC.

3.1.1 Types of available HES data

Before 2010, the NHSIC classified HES data into 4 categories based on their sensitivity and security. Each category was called Bespoke 1, 2, 3, or 4. Bespoke 1, is freely available online and can be accessed by any individual. Bespoke 2 is any extract that contains particular information about certain groups often requested by a researcher. Bespoke 3 contains all information hosted by the NHS IC about each single admission in England and is supplied as episodes, it does not contain any sensitive data. Bespoke 4 contains sensitive data.

During 2010 the NHSIC made several changes to the classification of data, and as a result the application process has been modified. The term Bespoke was abandoned and the application process was simplified. A data request is divided into: A) Tabulated data that is available free online and can be accessed by any person. B) Tailored summary table that does not require any governance approval. C) Tailored summary table including sensitive data: Requires governance approval. D) Episode records: Requires governance approval. E) Episode records including sensitive data: Requires governance and DSMG (Data Base Monitoring Subgroup) approval. F) Episode records contain patient identifiable information: Requires ECC (Ethical and Confidentiality Committee) approvals. G) Mortality data: Requires ONS (Office of National Statistics) approval.

Sensitive data is defined as any information that cannot identify a patient but is specific to a particular individual - examples include; Hospital Number, Critical Care Number, Accident and Emergency Number, and Consultant Code. Patient identifiable data is defined as any data that can identify a particular patient - examples include; date of birth, post code, and NHS insurance number.

3.1.2 Level of approval

Using patient data for the purpose of research has been controlled by section 60 of the Health and Social Care Act 2001. This act regulates those wishing to obtain identifiable patient information and Data Controllers who are asked to supply identifiable patient information. Section 251 of the NHS Act 2006 allows the common law duty of confidentiality to be set aside in specific circumstances where anonymised information is not sufficient and where patient consent is not practicable. These requests were handed to the newly established ECC (Ethical and Confidentiality Committee) as part of the bigger National Information Governance Board for Health and Social Care (NIGB).

3.2 Apply, store and install HES data into a computer

An application was submitted to the NHSIC and access to the data was granted. There are several steps needed to access and store the data to satisfy the NHSIC governance body. There are also several technical aspects needed to be met before the data can be installed on a computer and make it ready for analysis.

3.2.1 Applying for HES data

The research seeks to develop techniques that use HES data set to measure meaningful surgical outcomes that will allow the characterisation or assessment of surgical care. Therefore, applying for the raw data (episode records) was thought to be the most appropriate option. No attempt was made to obtain sensitive or patient identifiable data, as it was deemed not necessary for this research. An application for Episodes Records without patient identifiable data does not require ethical committee approval, but it does require NHSIC governance approval.

The application was submitted by Mid Cheshire Hospitals NHS Foundation Trust (MCHFT) to the NHSIC. A request of all inpatient hospital data (365 fields) for the financial year 2000/2001 till 2008/2009 was submitted in 2009 and later another request for the data up to April2012 was submitted in 2012. The NHSIC was satisfied with the application and as a result the data was supplied as a delimited text file.

3.2.2 Data security

HES data were transferred by Royal Mail special delivery in the form of text files stored on 8 DVDs. The file containing each year's data set was about 4 Gigabyte in size. The DVDs are stored in a locked locker in the Research and Development Department at MCHFT as required by the NHSIC.

3.2.3 Accessing the data

The data were supplied in the form of a delimited text file, which was compressed as a zip file. Each record (episode) has 365 fields, and each year has at least 13 million individual episodes. WinRAR® was used to unzip the files. Each field was separated from next one by a delimiter. In this case it was vertical bar or pipe (|) rather than the usual comma (,).

Microsoft Office Access is user friendly and easy to understand. A user does not need to learn a programming language such as Structured Query Language (SQL) and most data handling is by windows style queries using a graphical user interface. Nevertheless, it has some disadvantages, the maximum size of the database is 2 GB and the maximum number of fields is only 255 as of Access 2003. Therefore, a different relational database management system (RDBMS) was needed to store and interrogate the base data set. Microsoft SQL server 2005 is used by the Information Technology Department at the MCHFT for managing the hospital data; therefore, it was chosen to store and handle the data because of its availability and support from the Hospital Computer Services Department. Once the data is installed on SQL server. A simple query to identify the patient needed is performed and the data then transferred to ACCESS for further analysis.

3.3 validation of Clinical codes.

3.3.1 Pilot audit of general surgery clinical codes.

The audit was designed to assess the accuracy of diagnostic and operative codes. Due to the fact that I haven’t had any formal training in clinical coding, I shadowed a clinical coding administrator for three days to understand and learn the normal practice of clinical coding.

The study was classified as an audit by the hospital. The audit was divided into three parts: Data collection, clinical coding analysis of the data, and converting the audit results into clinical information.

3.3.2 Participant:

The audit was conducted by 3 individuals: the clinical coding manager, the clinical coding supervisor, and an experienced research fellow in surgery (registrar level) myself.

The sample

A sample of 108 patients was selected randomly by the information department at the hospital using a computer program from all surgical admissions admitted between 1st of January and 1st of July 2010 to Mid Cheshire Hospitals NHS Foundation Trust. These patients could be admitted as an emergency or elective. They could also be admitted as inpatients, day case or they may even be admitted for an endoscopy under a General Surgeon.

3.3.3 Methods

Patients' case notes were retrieved from the medical record. Each patient admission was recoded and inserted into the computer. The codes involve the diagnosis and operation. The diagnoses contain the primary diagnosis (the reason patients admitted to the hospital) and secondary diagnosis (these includes other diagnosis, comorbidity, and complications or misadventures). Whereas operations codes include the primary operation (the main operation the patients had) and secondary operation where all other procedures and operations such endoscopy, urinary catheter, and other operations are coded.

The audit will not only focus on the coding accuracy, but also on the sequence of coding. For example, if the primary diagnosis was coded in the secondary diagnosis then the code is considered inaccurate.

3.3.4 Data analysis

The coding department will calculate their results by percentage of accuracy. For each category: primary diagnosis, secondary diagnosis, primary procedure, secondary procedure.

The second part of data analysis was made by converting the result into more clinically oriented data. The diagnosis is divided into 4 parts: The primary diagnosis, other diagnosis, comorbidity, and complications. If the diagnosis recorded in the audit is different from the original one but clinically similar then the data is considered accurate even if it is considered inaccurate in the initial analysis.

3.3.5 Results

The audit which was performed by the clinical coding manager and her staff showed an accuracy of 80% for Operative codes and 85% for the diagnostic codes. Further analysis of the codes, the majority of the errors was because of the inaccuracy was not in the actual codes but in the sequence of the codes. Many of the codes were recorded as primary diagnosis or operation and the auditor changed it to be the secondary diagnosis or operation. For example, the accuracy of clinical codes increased to 95% for the diagnosis and 90% for operation if the search for the codes in the first three fields was performed rather than the first field only. Therefore, to identify patients, it is important to search for the first three fields.

There is however, some pitfall when using the above methods which should be considered. For simple procedures such as inguinal hernia, performing such analyses can lead to certain problems. A patient can be admitted for major surgery and at the same time, the surgeon decided to repair the hernia. Therefore, searching for inguinal hernia repair in the second or third operative fields will select those patients as well. Adding those patients to the analysis will skew the results of length of stay, mortality, infections etc. To overcome such a problem, the researchers should look for those cases manually. All patients who were recorded to have an inguinal hernia repair in the second and third operative fields should be inspected individually to decide whether to include them or exclude them.

3.4 How to convert HES data into clinical data (inguinal hernia)

This chapter describes how to convert administrative data into a clinical data. Inguinal hernia will be used as an example.

3.4.1 Background for inguinal hernia

A hernia is a protrusion of an organ through the wall of the cavity that normally contains it. While there are many types of hernia, a groin hernia is the most common. This is characterized by a swelling in the groin area that normally disappears when a patient lies flat. It is often diagnosed by a history of a swelling that started after an abdominal strain or following lifting of a heavy object. Clinical examination of a patient will confirm a hernia. Groin hernia can be either inguinal, which is the most common type, or femoral. This study will concentrate on inguinal hernia only.

Inguinal hernias are divided into primary where the hernia has not been repaired before and recurrent where the hernia has been repaired previously. These two types are both of importance and since they are different the outcomes of surgery should be reported separately.

Also, of relevance is the type of repair. Although there are many types of repair, they are divided into 2 main categories: Laparoscopic and open inguinal hernia repair. Laparoscopic repair can be done by TEP (Total ExtraPeritoneal) repair or TAPP (TransAbdominal PrePeritoneal hernia) repair. The open surgery can be repaired by suture such as Bassini or Shouldice or mesh repair. In the current practice the majority of surgeon use mesh for open inguinal hernia unless there is contraindication for mesh such as presence of infection or dead bowel. HES data does not have codes to differentiate between different categories of repair other than open (suture or mesh) and laparoscopic repair.

The site of a hernia poses another variable, as a hernia could be right sided, left sided, or present on both sides. Each group of patients has to be identified separately to facilitate the correct follow up of these patients. This step is crucial to identify recurrence. As patient may have right inguinal hernia repair then 2 years later, he develops a left side and therefore, further repair on the left doesn’t represent a recurrence whereas a second repair on the right side indicate a recurrence.

Patients undergo inguinal hernia can develop several complications. These complications can be divided into early and late. Early complications which occur during hospital admission or the patient readmitted to a hospital within 30 days of discharge. Infection, bleeding, injury to an organ (bowel or bladder), and urinary retention are the most common types of early complications. Late complications are often referred to either recurrence of the hernia or chronic pain.

3.4.2 Aims of this study

The aim of this study is therefore to investigate early and late complications of inguinal hernia repair using HES data.

3.4.3 Method

All patients with primary and recurrent inguinal hernia between April 2002 and April 2009 were identified using SQL server and the results were imported into an ACCESS database for analysis. All inguinal hernia repairs performed in England between April 2002 and April 2009 were identified by searching the first three operative fields of the HES dataset using the Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures (4th revision) codes (OPCS-4) for T20* (primary inguinal hernia) and T21* (recurrent inguinal hernia). Only patients with a matching diagnostic code, International Classification Disease 10th Edition (ICD-10) K40* (inguinal hernia), in the first three diagnostic fields of the HES dataset were included in the final analysis.

Patients were then selected in the operative and diagnostic codes match inguinal hernia. Matching the 2 system (diagnostic and operative) will eliminate all possible coding error. In order to assess the number of cases removed by adopting the method of matching the diagnostic codes and operative codes. A trial of matching on all patients underwent repair in 2002 was performed. This trial showed the number of cases which was not selected was less than 1.2% of all episodes during that year. Patients undergoing laparoscopic repair were identified with the operative code Y50.8 before 2006 and after 2006 with Y50.8 or Y75.*. Any patients didn't have these codes were considered open repair.

Patients who underwent an inguinal hernia repair between April 2002 and April 2004 were used as the initial study cohort. Each patient spell (admission) may contain one or more episodes. These episodes are patient being transferred from one care to another care. These episodes are seen as duplicate in HES data. Duplicate episodes were removed, for example in 2002 the total number of episodes identified was 71357 and after exclusion of duplicates with the same admission date and HESID, 70293 were included in the analysis. The data were divided into primary and recurrent and then into unilateral and bilateral. Each of these subgroups were divided into laparoscopic repair and open repair. If the side of the original operation was not recorded, or the patient was under 18, or was admitted as an emergency, then patients were excluded from further analysis.

Following the initial analysis, a further cohort of patients operated on in the year April 2006 until April 2007 were analysed in a similar manner to confirm the results and see if they had changed following publication of the NICE guidance.

3.4.3.1Early outcome criteria

Early outcome criteria studied were, in-hospital mortality, length of hospital stay, complications and readmission. Complications were identified using ICD-10 codes by searching the secondary diagnostic fields for infection (T814, T857, and T813), bleeding (T810), injury to an organ (T812), and urinary retention (R33). A readmission was defined as any patient readmitted to a general surgeon with a speciality code 100, as an emergency within 30 days of discharge with bleeding or infection, or if a patient was readmitted with urinary retention within two days of discharge.

3.4.3.2Late outcome criteria

Patients were followed using HESID, until April 2009, to identify those requiring a further inguinal hernia repair on the same side. For example, if a patient had an inguinal hernia repair on the left side during 2002, then the dataset was searched to identify the need for a subsequent inguinal hernia repair on the left side or a further bilateral repair.

3.4.4 Technical Points

Type 1 HES data which we used is anonymised; however, HESID is a unique ID generated from a mixture of individual characteristics can be used to link episode records across time and place.

3.4.4.1Dealing with episodes and spells

HES data contains information about episodes rather than spells. A patient spell represents the time from the date of admission until date of discharge. A spell may contain several episodes. This occurs for example when a patient is transferred to another department for an investigation under another consultant e.g. for an endoscopy or where part of the spell is on an intensive care unit when the episode might be generated under an ITU consultant. When we identified patients undergoing inguinal hernia repair therefore, the number of episodes was higher than the number of patients. Some patients also have more than one admission (spell) in a single year, e.g, a patient underwent a right sided hernia repair and was then readmitted with a complication or for a left hernia repair few months later or in another example was readmitted for a recurrent hernia repair on the right side.

When duplicates exist, this can lead to confusion and complicate matters and under some circumstances leads to incorrect results as data interrogation and table linking can lead to an apparent increase in patient numbers.

Removal of the duplicate episodes was a challenge. Manual removal of the data is time consuming and impractical due to the size of the data set. After several attempts, I found the best and most accurate method to remove the duplicate data was to use the query wizard in ACCESS. This is a specific Query designed to find duplicates (Find Duplicate Query Wizard). Using HESID as a patient identifier I ran the Query with HESID alone and in a particular data set could identify all patients with a duplicate ID. This will be a mix of duplicate episodes in the same admission as well as patient who have been admitted more than once. I need another field to identify admissions and I chose the date of admission.

3.4.4.1.1 Method for the removal of duplicate episodes in one spell

In Access

- Click Create and chose Query Wizard. Select Find Duplicate Query Wizard.
- Click the Table you want to remove duplicates from and click next.
- In the available fields chose HESID and date of admission and move them to the duplicate-value field.
- Click next and then move all fields into additional query fields and then click next. The Query Wizard will eventually identify the duplicated data but will not remove them. The Query contains all original and duplicated data e.g. it may contain 50 records with 20 being original and the rest duplicate.

- To remove the duplicates, sort the table by HESID and for each patient record manually delete the duplicated one and leave the original one. This will remove this data from the base table.

3.4.4.1.2 Method for identify the first operation in a single year

In order to create a cohort for this study, the first admission for an inguinal hernia repair must be identified.

In Access

- Click Create then click Query Design and choose the Table you want.
- Select HESID and move to the Table below.
- Repeat the same method for HESID again and for date of admission.
- Click Sigma symbol (total). In the table below, in the total row.
- Click on the group by and changed to count for the second HESID and for the date of admission with criterion first admission and run the query. It will show a table with three fields. The first will give HESID, the second will give the number of counts of HESID, and the third will show the first date of admission.

3.4.4.2Identify complications, surgical approach, age and mode of admission

Following several attempts at dividing the tables into single categories and linking them again, I found this confusing and liable to produce erroneous results. I found the easiest way to identify any of the above was by using an Update Query.

3.4.4.2.1 Mode of Admission

In Access

- For the mode of admission patient will be classified into elective and emergency.
- A new field is created in the original table with name MOA (Mode of Admission). Then an updated query is designed by selecting both the Admission Method and the MOA.
- Insert 11, 12, and 13 in the criteria field for the admission method and insert 1 in the update to field for the MOA and run the query. This will update the MOA and insert 1 for each elective.
- Repeat the method and insert 21, 22, 23, 24, and 28 in the criteria field for admission method and insert 2 in the update to field for MOA and run the criteria.

3.4.4.2.2 Surgical approach

In Access

Create a new field and call it SA.

Using the update query, all operative fields and the SA are selected and moved to the table.

In the criteria for all operative fields search for Y508* or Y75* and insert 1 in the update to field for the SA and run the query. This will enable you to identify all patients who underwent laparoscopic repair.

All patients with blank means they have been operated by open surgery. This can be updated in the same method but select only the SA. Insert "is null" in the criteria field and insert 2 in the update to field and run the query.

Now you can identify the surgical approach in every patient with 1 for laparoscopic and 2 for open repair.

3.4.4.2.3 Complication

Complications could be identified by creating new fields for infection, bleeding, and urinary retention. Then select all diagnostic fields and repeat the method described above using the codes as follows: infection (T814, T857, and T813), bleeding (T810), injury to an organ (T812), and urinary retention (R33). Because patients undergoing repair of an inguinal hernia are almost always a day case or they are discharged the next day most complications will not be recorded in the same admission. Patients were therefore followed to identify any who were re-admitted with complications over the next 30 days of index operations. All patients who were admitted as an emergency under a general surgeon (100) who had or were re-admitted with complication that suggest infection (T814, T857, and T813), bleeding (T810), injury to an organ (T812), and urinary retention (R33) were identified using the original database in SQL server. Using HESID both tables are linked together to identify those who were readmitted with one of these complications. New tables were then created that contained the information with regards to re-admissions under a general surgeon with infection, bleeding, injury to an organ and urinary retention.

In Access

- Using the query design, select both tables. Drag HESID from table 1 (hernia) into HESID table 2 (any of the complications table).
- Double click the joint line and select number 2 use all data from table 1 and only data from table 2 where the joint fields are equal.
- Select and click on HESID from table 2 so that it appears in the table below.

- To identify the time from index admission till readmission, select an empty field and then click on expression builder.
- Select date of admission for table 2 and double click, it will appear at the top box and then insert "-". Select and double click on the date of admission of table 1 and run.
- The new table contains all table one data in addition to the selected fields from table 2 as well as the time from index admission till readmission.
- For this study only readmission within 30 days are important. Therefore, sort the table by the time. Chose only the time less than 31 and delete the rest.
- This should be repeated for the other complications and eventually be able to create a single table with all complication, SA, MOA.

3.4.4.2.4 Age

Children under 18 were then deleted from the dataset with criterion 18 or less. There was a problem with the data results because age less than 1 year is coded as 7001 or more, therefore, data for patients with age below 18 or above 7000 were deleted. Longer term follow-up was assessed by reoperation rate. Hernias can be left or right sided or bilateral and it is therefore important to update the tables with this information, which is included in the HES operative codes. If this information was missing patients were excluded from analysis. I created tables for right, left and bilateral hernia repairs to facilitate the follow up of these patients. This was repeated for all the years.

3.4.4.3 Following patients across time

Each patient operated on between 2002 and 2004 is followed to discover if any underwent repair for a further inguinal hernia on the same side following the index surgery. This means patients who have undergone a left sided hernia will be followed for all years to see if they underwent further surgery on the left side or bilateral surgery and patients who underwent right sided surgery will be followed to see if they underwent a further hernia repair on the right side or bilateral surgery. Whereas for bilateral surgery if they underwent any surgery on any side. Time to reoperation is calculated from date of the index surgery to the date of reoperation. If there is more than one reoperation then the time is calculated till the first reoperation.

The data can be presented in a number of ways, for example the data can be presented in terms of hernias or patients, in terms of the type of surgery, laparoscopic versus open or the type of hernia, unilateral versus bilateral or recurrent versus primary. This can lead to quite complex analyses and this has to be borne in mind when interpreting the data.

In Access

- Click Create and then query design. Select left side hernia in 2002, 2003, 04, 05… 2008 data.
- Link the HESID from 2002 to all other HESID. Select 2002 and drag it to the table below. Click on the linking joint and select number 2.
- Select HESID from 2003 and drag to the table below. Click on the next empty field and then click on expression builder. Select 2003 table and double click on date of admission until it appears on the top box. Enter “- “.
- Select 2002 table and double click on date of admission. Repeat this for every year and run the query. A new table will be formed with new fields for every reoperation followed by time to surgery.

In order to find the first operation a new table is needed as follows.

- Now create a new table with query design. Select the table and drag into table below.
- Click on an empty field and then click on expression builder.
- Select the time to surgery 2003 and double click. Write & and then double click on the time to surgery 2004 and so on then run the query to create a new table.
- Using “&” is mandatory because it will show results as 1 &6 into 16 rather than 7 whereas using + will produce 7. Sort the new table by the new time to surgery and then remove the 6 and keep then one. This is the best and easiest way to get the first time to surgery.

A similar approach was used for all other studies with minimal modifications depends on the aim of the study, a detailed description of each study is discussed in each chapter.

4 Can HES data be used to measure rare complications when there is a code?

Bowel resection is a common elective lower GI surgery and a common surgery carried out under emergency conditions. All general surgeons are, therefore, trained to perform emergency laparotomy and colectomy. One of the rare complications of bowel resection, Venous Thromboembolism (VTE) will be used to measure and assess the factors that are associated with it. VTE is one of the most important complication of bowel resection and all patients should receive prophylactic treatment during their hospital admission and for 28 days following discharge[102, 103]. VTE following bowel resection will be measured and all factors that increase VTE will be identified. Venous Thromboembolism has a specific code in ICD10 codes and it can be measured directly. Therefore, VTE following bowel resection is chosen as an exemplar for this objective.

The research presents the largest dataset studying such an important and fatal complication following surgery and it also study factors that are associated with higher incidence of VTE.

4.1 Venous thromboembolism following colorectal resection

4.1.1 Abstract

Aim: The study investigated the rate of significant venous thromboembolism (VTE) following colorectal resection during the index admission and over one year following discharge. It identifies risk factors associated with VTE and considers the length of VTE prophylaxis required.

Method: All adult patients who underwent colorectal resections in England between April 2007 and March 2008 were identified using Hospital Episode Statistics (HES) data. They were studied during the index admission and followed for a year to identify any patients who were readmitted as an emergency with a diagnosis of deep venous thrombosis (DVT) or pulmonary embolism (PE).

Results: A total of 35,997 patients underwent colorectal resection during the period of study. The VTE rate was 2.3%. Two hundred and one (0.56%) patients developed VTE during the index admission and 571 (1.72%) were readmitted with VTE. Following discharge from the index admission, the risk of VTE in patients with cancer remained elevated for six months compared with two months in patients with benign disease. Age, postoperative stay, cancer, emergency admission, and emergency surgery for patients with inflammatory bowel disease (IBD) were all independent risk factors associated with an increased risk of VTE. Patients with ischaemic heart disease and those having elective minimal access surgery (MAS) appear to have lower levels of VTE.

Conclusion: This study adds to the benefits of MAS and demonstrates an additional risk to patients undergoing emergency surgery for IBD. The majority of VTE occurs following discharge from the index admission. Therefore, surgery for cancer, emergency surgery for IBD, and those with an extended hospital stay may benefit from extended VTE prophylaxis. This study demonstrates that a stratified approach may be required to reduce the incidence of VTE.

4.1.2 Introduction

Venous thromboembolism (VTE) is a major cause of preventable morbidity and mortality. Each year around 25000-32000 patients die in the United Kingdom as a result of VTE related to hospital admission [104]. The incidence of VTE in general surgical patients has been reported to be as high as 25% in patients who did not receive prophylaxis[105]. An international consensus statement recommends that all moderate and high risk general surgery patients undergoing operation should receive VTE prophylaxis.[106] The National Institute for Health and Care Excellence (NICE) in England has issued guidelines that recommend VTE prophylaxis for all patients undergoing major abdominal surgery.[102, 103] Patients undergoing colorectal surgery are considered to be at high risk of VTE.[107-109]

Certain factors such as cancer and major trauma are well known to increase the risk of VTE,[110, 111] but it is not clear whether emergency surgery with colonic resection is a risk factor. Although hospitalization without surgery is a risk factor for VTE,[112] there is little evidence to show that prolonged hospital stay following surgery increases the risk of VTE. Minimal access surgery (MAS) has been suggested to increase the risk of VTE following surgery [113, 114]. The increased risk of VTE following MAS may be due to prolonged operating time, increased intra-abdominal pressure from pneumoperitoneum, and reverse Trendelenburg position.[115] Conversely MAS may reduce the risk of VTE because it is associated with a shorter hospital stay and early mobilization in the setting of enhanced recovery. Recent studies suggest a lower risk of VTE following MAS compared to open colorectal surgery, [108, 116, 117] although these studies investigated the risk during the hospital admission but not following discharge.

The risk of symptomatic VTE following surgery remains high following discharge.[118] In the case of bariatric surgery Steele et al (2011) showed the rate of cumulative VTE increases from 0.88% during a hospital admission to 2.99% at 6 months post-surgery.[119] Because the risk of VTE extends beyond the index hospital admission, recent studies[120] suggest that patients undergoing surgery for cancer should be discharged with 28 days of pharmacological VTE prophylaxis. NICE guidelines were modified in 2010 to recommend pharmacological VTE prophylaxis for 28 days postoperatively for patients having major cancer surgery involving the abdomen or pelvis.[103]

The aim of this study was to investigate the rate of VTE following colorectal resection by laparoscopic or open technique for benign and malignant disease during the index admission and for one year following discharge. The study was also used to identify risk factors associated with VTE.

4.1.3 Method

Hospital Episodes Statistics (HES) data were obtained from the National Health Service Information Centre (NHSIC) and imported into Microsoft 2005 SQL server for analysis. All adult patients who underwent large bowel resection in England between April 2007 and March 2008 were identified by searching all operative fields of the HES dataset using Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (4th revision) codes (OPCS-4).

Patients undergoing laparoscopic repair were identified with the operative code Y75*, converted cases using Y714 and all other patients were considered open. Pelvic surgery was defined as surgery involving the rectum and included anterior resection, abdominoperineal resection, Hartmann's operation (H33) and panproctocolectomy (H04). Abdominal surgery was defined as colectomy (H05 and H11), subtotal colectomy (H29), right hemicolectomy (H06 and H07), transverse colectomy (H08), left colectomy (H09) and sigmoid colectomy (H10).

Patients with a malignant diagnosis of cancer were identified using the diagnostic codes ICD 10 (C18 colon, C19 rectosigmoid, C20 rectum, and C21 anal canal), while all other diagnosis were classified as benign. Patients with benign pathology were sub classified into inflammatory bowel disease (IBD) using ICD10 codes (K50 for Crohn's disease and K51 for ulcerative colitis) and other benign pathology. Patients were also classified according to surgical approach (minimal access surgery (MAS) versus open), mode of admission (elective versus emergency), gender, age, postoperative stay and co-morbidity.

The mode of method was calculated by searching the admimeth (Admission Method) field which identifies how the patient was admitted to hospital (for elective admissions number 11, 12, and 13were selected and 21, 22, 23, 24 for emergency admission). Comorbidity was identified by searching all secondary diagnostic fields for codes for ischaemic heart disease, congestive cardiac failure, hypertension, renal disease, metastatic disease, connective tissue diseases, dementia, diabetes mellitus and complications, chronic pulmonary disease, paraplegia and hemiplegia, liver disease, cerebrovascular accident and peripheral vascular disease. The codes used for comorbidity was obtained from the Dr Foster Charlson comorbidity score.[121]

VTE was identified during the index admission i.e. an admission during which a patient underwent a large bowel resection using ICD-10 codes (International Classification Disease 10th Edition) by searching the HES dataset for the codes for PE (I26*), DVT (I80.2) (thrombophelibitis of deep vessels of lower extremities), and I80.1 (thrombophelibitis of femoral vein) in any diagnostic field except the primary diagnosis.

To identify VTE occurring after the index admission, patients were then followed for a further year using HESID (The HES Patient ID (HESID) provides a way of tracking patients through the HES database without identifying them) to identify any who were readmitted to a hospital as emergency with a diagnosis of VTE in any of the first two diagnostic fields. Of course, not all patients with VTE required admission, but most with a PE and suspected PE did so. Most hospitals also treat patients with extensive DVT, ileofemoral, or bilateral DVT, phlagmasia alba dolens, or phlagamsia cerulosa dolens as inpatients. Therefore, we define significant VTE as patients who presented to a hospital with VTE and required treatment as an inpatient. A flow chart of the methodology is illustrated in Figure 1.

4.1.3.1Statistical analysis

Univariate analysis including Chi square, Mann Whitney, and independent t-test were used as appropriate. Multivariate analysis was carried out with binary logistic regression. Only factors that were statistically significant ($P<0.05$) in univariate analysis were included in the multivariate analysis. All analyses were carried out using SPSS 13.

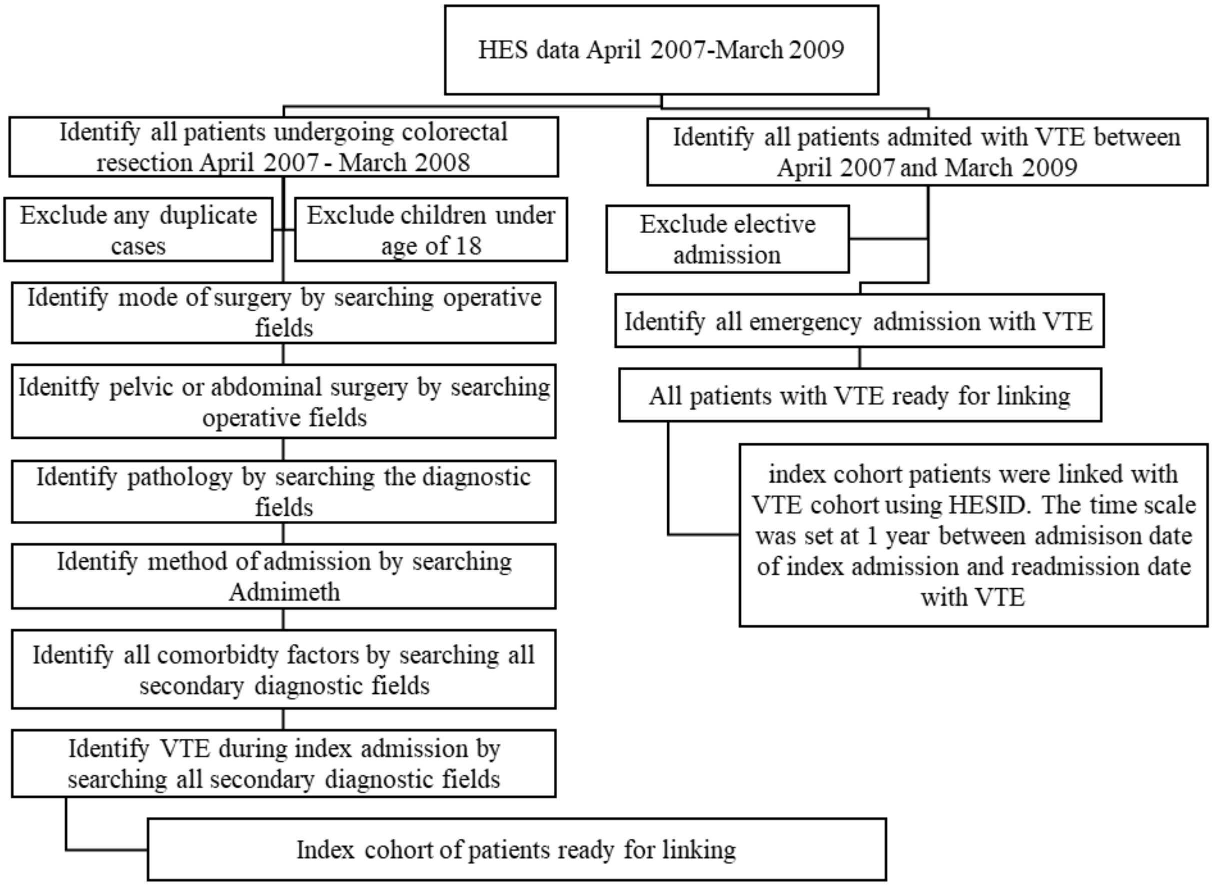

Figure 1: Flow chart of steps used in analysis of data

4.1.4 Results

Thirty-Five thousand and nine hundred and ninety-seven (35 997) adult patients underwent colorectal resection between April 2007 and March 2008. The mean age was 65 years and the male to female ratio was 1:1. The median postoperative stay was 9 (IQR 6-15) days. Two thirds (66.3%) of the patients were admitted electively and one third as an emergency. The majority of patients (86%) underwent open surgery and 14% underwent MAS. More than half the procedures were performed for colorectal cancer (56%) and the rest were for benign pathology. A pelvic operation where surgery involved the rectum was performed in 42.7% of the patients and other types of colectomy were performed in 57.3% of cases. 2710 patients (7.5%) died during the index admission.

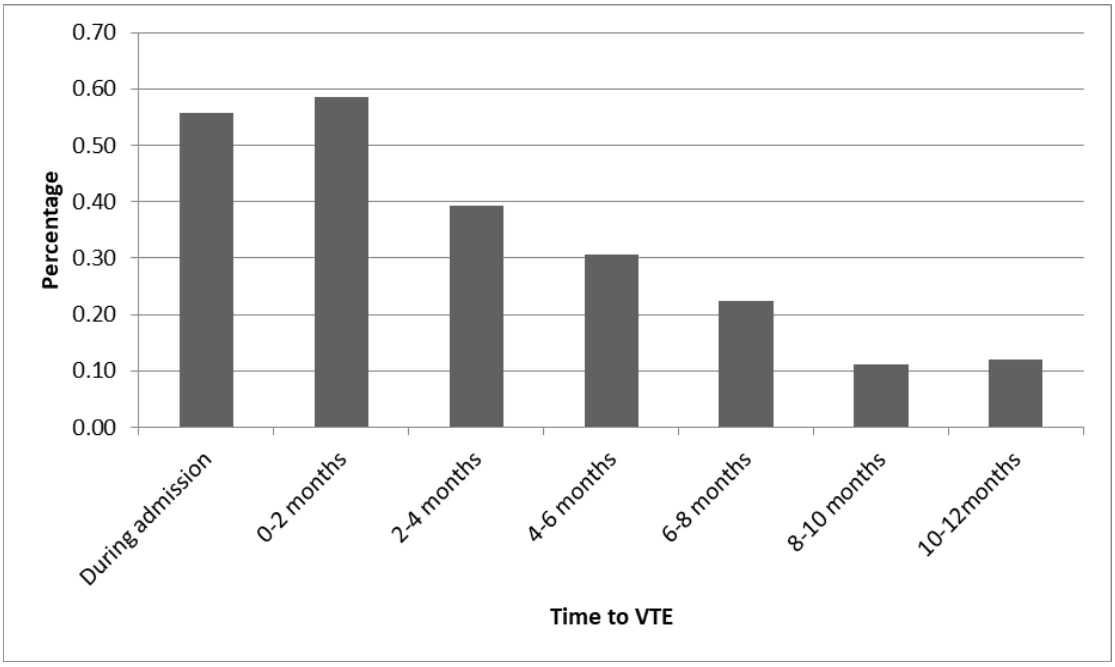

Figure 2: Time from discharge to VTE (all cases)

Factors	Total	VTE	Non VTE	p-value VTE vs non-VTE
Age mean (STD	65 years (15.2)	67 years (11.9)	64.5 years (15.6)	<0.001
Median postoperative duration (IQR)	9 days (8-15)	12.5 day (8-23)	9 days (7-15)	<0.001

Table 1A: Univariate analysis of age and postoperative duration for patients who developed VTE and those who didn't.

Factors		Proportion who had VTE	Percentage	P value
Gender	Male	367/16989	2.2%	NS
	Female	405/16330	2.5%	
Surgical approach	MAS	85/4982	1.7%	0.003
	Open	687/28391	2.4%	
Diagnosis	Benign	280/14273	2.0%	<0.001
	Cancer	492/19046	2.6%	
Site of surgery	Pelvic	341/14416	2.4%	NS
	Abdominal	431/18903	2.3%	
Mode of admission	Elective	458/23172	2.0%	<0.001
	Emergency	314/10147	3.1%	

Table 1B: Univariate analysis showing factors associated with increasing risk of VTE.
SD = standard deviation, IQR = interquartile range, VTE = venous thromboembolism

Two hundred and one (0.56% (95%CI 0.49-0.64%)) patients were coded to have had VTE during the index admission, and 571 (1.72% (95%CI 1.47-1.72%)) were readmitted with VTE as the primary or secondary diagnosis as an emergency within a year of the index admission giving an overall rate of VTE at one year of 2.3% (95%CI 2.13-2.44%), most occurring in the first six months following surgery (Figure 2).

Co-morbidity	Recorded (R) Not recorded (NR)	Percentage of patients who were recorded to have comorbidity	proportion of VTE/total	Percentage	P value
Ischaemic heart disease	R	10%	56/3352	1.7%	0.009
	NR		716/29967	2.4%	
Cerebrovascular accident	R	0.8%	8/263	3%	NS
	NR		764/33056	2.3%	
Congestive Cardiac Failure	R	1.4%	18/460	3.9%	0.022
	NR		754/32859	2.3%	
Connective Tissue disorder	R	1.3%	10/423	2.4%	NS
	NR		762/32869	2.3%	
Dementia	R	0.4%	4/144	2.8%	NS
	NR		768/33175	2.3%	
Diabetes Mellitus	R	9.4%	63/3114	2%	NS
	NR		709/30205	2.3%	
Liver disease	R	1.4%	7/487	1.4%	NS
	NR		765/32832	2.3%	
Peripheral vascular disease	R	2.0%	20/675	3.0%	NS
	NR		752/32644	2.3%	
Pulmonary diseases	R	10.2%	83/3393	2.4%	NS
	NR		689/29926	2.3%	
Paraplegia	R	0.4%	5/116	4.3%	NS
	NR		767/33203	2.3%	
Renal disease	R	2.2%	26/740	3.5%	0.029
	NR		746/32579	2.3%	
Metastatic disease	R	9.6%	97/3204	3.0%	0.005
	NR		675/30115	2.2%	
Hypertension	R	28.7%	243/9352	2.6%	0.033
	NR		529/23967	2.2%	

Table 2: Univariate analysis of comorbidity and the development of VTE.

Increasing age, prolonged postoperative stay, open surgery, cancer and emergency admission were all associated with an increased rate of VTE, whereas pelvic surgery and gender were not associated with higher rate of VTE (Table 1A&B).

Comorbidity including congestive cardiac failure, hypertension, and renal disease were associated with an increased risk of VTE. In contrast, patients with ischaemic heart disease appeared to have a lower rate of VTE (Table 2).

Table 2 showed the percentage of each comorbidity from the total cohort. the proportion and percentage of VTE in each comorbidity and the P value comparing the percentage of VTE in each comorbidity to those with no co-morbidity. For example, 10% of patients were recorded to have ischemic heart disease. Only 1.7% of those developed VTE compared to 2.4% of patients who were not recorded to have ischemic heart disease but developed VTE (P=0.009).

Factors		OR	(95% CI)	P value
Ischaemic heart disease		0.587	(0.443-0.778)	<0.001
Congestive cardiac disease		1.471	(0.902-2.401)	NS
Hypertension		1.116	(0.949-1.313)	NS
Renal disease		1.081	(0.714-1.636)	NS
Metastatic disease		1.166	(0.932-1.460)	NS
Age		0.994	(0.988-0.999)	0.026
Postoperative stay		0.990	(0.987-0.993)	<0.001
Surgical approach	MAS	1		NS
	Open	1.208	(0.957-1.524)	
Pathology	Benign	1		<0.001
	Cancer	1.488	(1.251-1.771)	
Mode of admission	Elective	1		<0.001
	Emergency	1.632	1.390-1.971)	

Table 3: Multivariate analysis (binary logistics regression) shows factors associated with VTE (all cases)

Factors that were significantly associated with VTE on univariate analysis were included in the multivariate analysis (binary logistic regression). When the cohort was analysed as a whole, prolonged postoperative stay, increased age, emergency admission, and cancer were independent factors associated with a higher VTE rate whilst patients wi ischaemic heart disease were less likely to develop VTE. All other factors including surgical approach were not associated with VTE as shown in Table 3.

The proportion of patients admitted as an emergency that underwent MAS was small (10%) compared with open surgery. patient characteristics of MAS vs open surgery are listed in table 4

Factors		MAS	Open	P value
Age (Mean SD)Years		65.2 (50-80)	65.5 (50-80	NS
Postoperative duration (Median IQR) Days		7 (4-10)	10 (7-16)	<0.001
Pathology	Cancer	66.2%	54.3%	<0.001
	Benign	33.8%	45.7%	
Gender	Male	50.8%	50.9%	NS
	Female	49.5%	49.1%	
Site of surgery	Pelvic	40.9%	43.0%	0.004
	Abdomen	59.1%	57.0%	
Mode of admission	Elective	90.0%	62.5%	<0.001
	Emergency	10.0%	37.5%	

Table 4: Characteristics of MAS versus open patients

To eliminate any discrepancy between both groups due to the type of admission, the analysis was repeated for elective cases only. This demonstrated that the surgical approach was an independent factor associated with increased risk of VTE in patients undergoing elective surgery. Open surgery increased the risk of VTE significantly compared with MAS with an odds ratio of 1.307 (1.008-1.693) as shown in Table 5.

The risk of a VTE was high during the index admission and for first few months following discharge. The risk of readmission with VTE following surgery for cancer remained high for six months following discharge, whereas the risk following surgery for benign disease reduced after two months (Figure 3).

Factors		OR	(95% CI)	P value
Ischaemic heart disease		0.520	0.520 (0.351-0.769)	<0.001
Congestive cardiac disease		0.536	0.536 (1.70-1.698)	NS
Hypertension		1.054	1.054 (0.855-1.300)	NS
Renal disease		1.237	1.237 (0.646-2.367)	NS
Metastatic disease		1.394	1.394 (1.064-1.827)	0.016
Age		0.995	0.995 (0.988-1.003)	NS
Postoperative stay		0.990	0.990 (0.986-0.994)	<0.001
Surgical approach	MAS	1	1	0.043
	Open	1.307	(1.008-1.693)	
Pathology	Benign	1	1	0.004
	Cancer	1.412	(1.114-1.789)	

Table 5: Multivariate analysis (binary logistics regression) shows factors associated with VTE (elective cases only)

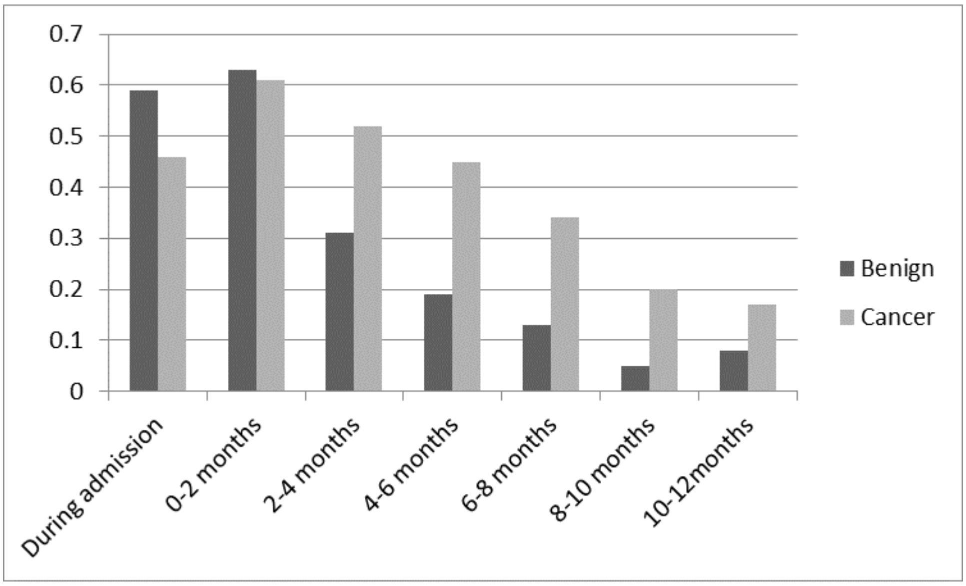

Fig 3: Time from discharge to VTE (Pathology)

Patients who underwent surgery for cancer as an emergency had the highest rate of readmission for VTE, followed by patients who had elective surgery for cancer regardless of the period they spend in hospital following surgery during the index admission (Figure 4).

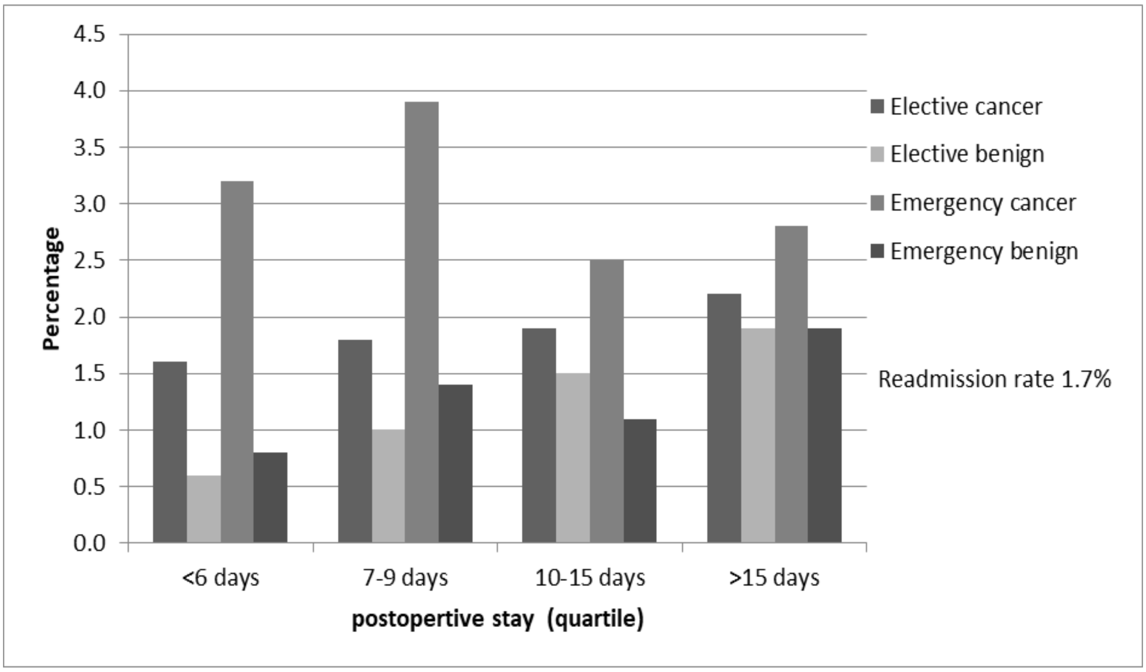

Figure 4: Readmission with VTE and postoperative stay (pathology and mode of admission)

The risk of readmission with VTE for patients who underwent surgery for benign pathology (whether elective or emergency) was low if the patients spent less than a week in the hospital whereas the risk increased significantly if they spent more than a week in the hospital.

When benign pathology was subdivided into IBD and other benign disease, the former appeared to be associated with a higher rate of readmission with VTE compared with other benign disease (2.1% vs 1.7%). Most VTE in IBD patients occurred in patients who underwent emergency surgery as an (Figure 5).

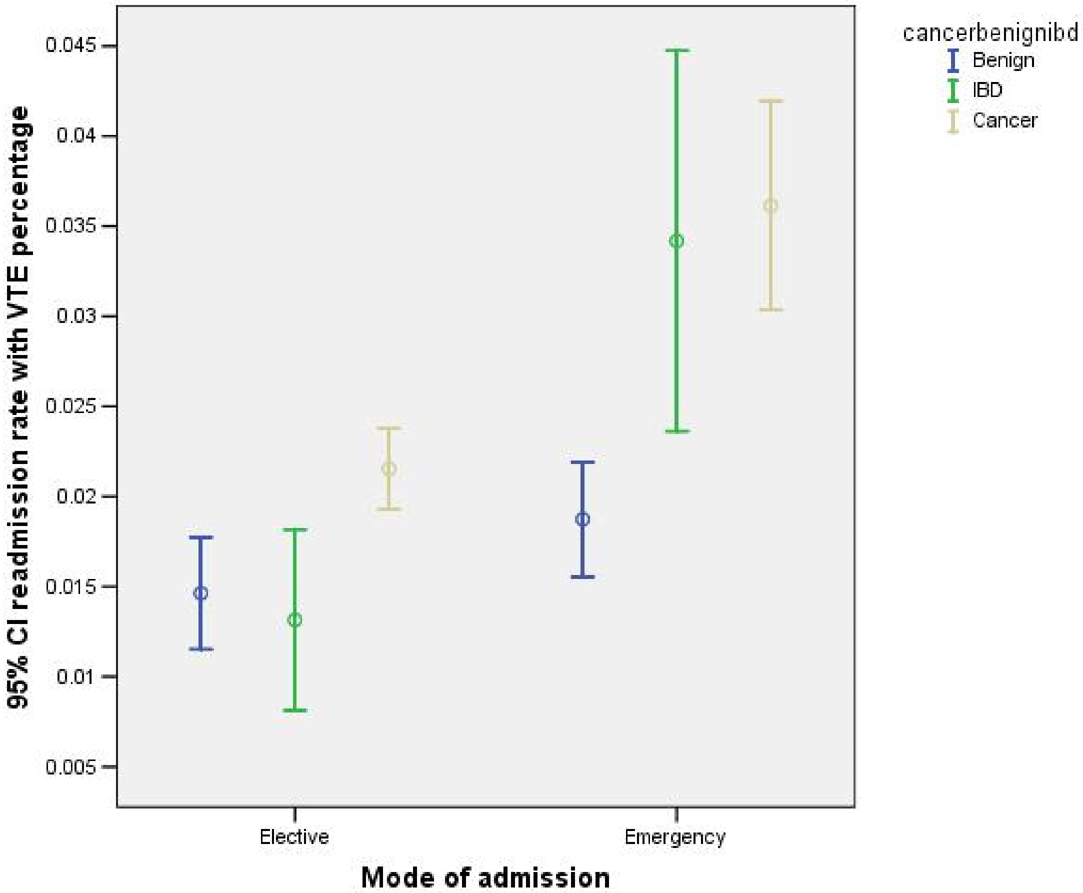

Figure 5: Readmission with VTE method of admission and pathology (cancer, IBD, and other benign disease).

The length of hospital stays remained a major factor in readmission with VTE following discharge for all pathologies (cancer, IBD and benign) as shown in Figure 6. Multivariate analysis was performed for patients underwent emergency surgery for bowel resection and showed patients with IBD are significantly associated with VTE (P= 0.002 and OR 1.999 95%CI (1.353-2.952)) as shown in Table 6.

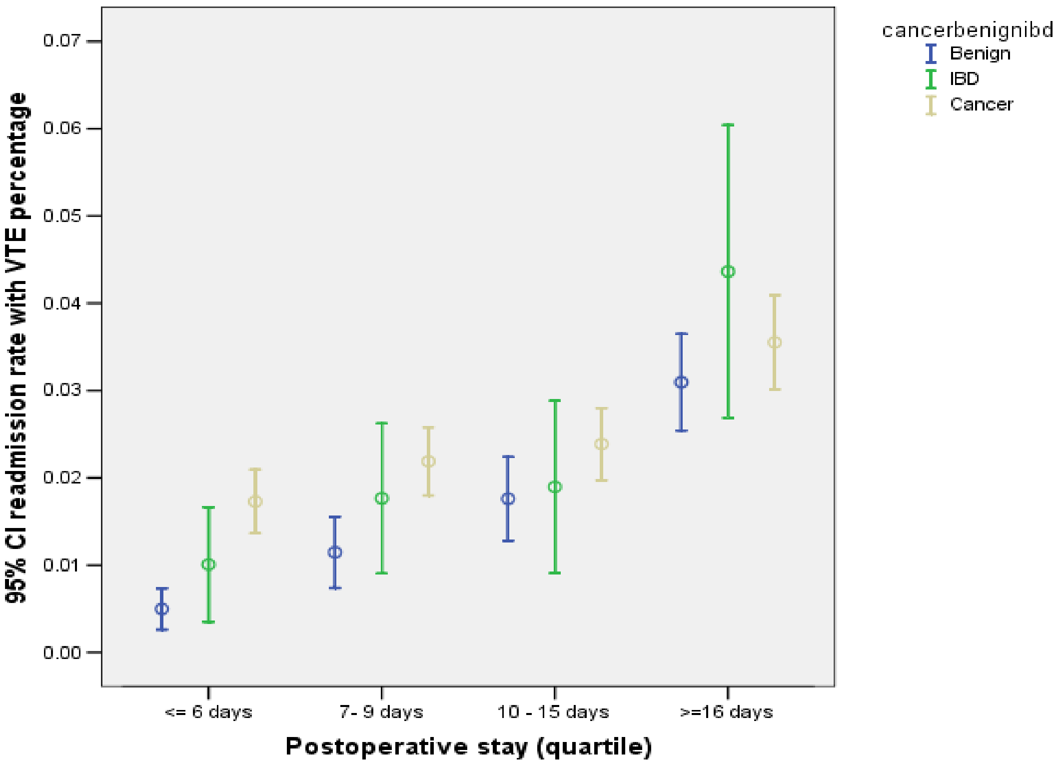

Figure 6: Readmission with VTE postoperative stay and pathology (cancer, IBD, and other benign disease).

<table>
<tr><td colspan="2">Factors</td><td>OR</td><td>(95% CI)</td><td>P value</td></tr>
<tr><td colspan="2">Ischaemic heart disease</td><td>0.451</td><td>(0.257-0.793</td><td>0.006</td></tr>
<tr><td colspan="2">Congestive cardiac disease</td><td>1.424</td><td>(0.944-2.147)</td><td>NS</td></tr>
<tr><td colspan="2">Hypertension</td><td>0.804</td><td>(0.621-1.042)</td><td>NS</td></tr>
<tr><td colspan="2">Renal disease</td><td>0.984</td><td>(0.572-1.693)</td><td>NS</td></tr>
<tr><td colspan="2">Metastatic disease</td><td>1.278</td><td>(0.858-1.904)</td><td>NS</td></tr>
<tr><td colspan="2">Age</td><td>1.010</td><td>(1.002-1.019)</td><td>0.018</td></tr>
<tr><td colspan="2">Postoperative stay</td><td>1.011</td><td>(1.005-1.013)</td><td><0.001</td></tr>
<tr><td rowspan="2">Surgical approach</td><td>MAS</td><td>1</td><td></td><td rowspan="2">NS</td></tr>
<tr><td>Open</td><td>1.245</td><td>(0.743-2.088)</td></tr>
<tr><td rowspan="3">Pathology</td><td>Benign</td><td>1</td><td></td><td rowspan="3"><0.001</td></tr>
<tr><td>IBD</td><td>1.999</td><td>(1.353-2.952)</td></tr>
<tr><td>Cancer</td><td>2.111</td><td>(1.608-2.771)</td></tr>
</table>

Table 6: Multivariate analysis (binary logistics regression) shows factors associated with VTE (Emergency cases only)

4.1.5 Discussion

This study showed that with a year's follow up, the overall VTE rate in England in the year 2007 to 2008 following colorectal surgery was 2.3%. The results from this study were very similar to those from previous publications.[122]

NICE guidelines for the prophylaxis of DVT were introduced in 2007 and then amended in 2010 to recommend prolonged pharmacological prophylaxis in patients undergoing resection for malignancy.[123] As we set out to examine the rates of VTE on the index admission and following discharge and since it was likely that the majority of colorectal resection patients with both benign and malignant disease had received in hospital pharmacological prophylaxis we chose to study the year 2007-2008 because prolonged pharmacological treatment in patients undergoing resection for malignancy was not yet in routine use. We cannot of course say what VTE prophylaxis this cohort of patients had, but we believe that the use of this time facilitated the comparison of the malignant and non-malignant groups.

Only a quarter of patients coded as developing a VTE were identified on the index admission. Further because there was no facility within HES to identify when a patient had suffered a VTE then some of the patients identified as having suffered a VTE on the index admission may have suffered this historically. However, when coders found VTE in the past history taken at admission and they included it in the diagnostic code for completeness, they tended to use the 'Z (Personal history of...) Code'. Therefore, by searching for I codes only, we assumed only those with acute VTE were selected rather than those with a previous history of VTE. Another issue of the study was that other patients may have suffered a VTE many years previously that we could not identify by searching recent preceding years for an admission. We have therefore chosen to present the data in its unabridged form and acknowledge this as a concern, i.e. that the incidence of VTE on the index admission may be an overestimate. Two studies were recently published investigating the risk of VTE and surgery by linking HES data to primary care data. Humes et al[124] investigated the risk of VTE following colectomy but not rectal surgery and Bouras et al [125] investigated VTE rate following a number of surgery including thyroid, breast and hernia. Both studies found similar results. The one year VTE rate was recorded to be 2.5% by the former study and the 90 days VTE rate was 2.11% in the latter. Obesity is a known risk factor for VTE. Searching HES data for obesity codes is feasible, but we think it is significantly under recorded. Therefore, it was not included in the study.

Most VTEs occur in patients who are readmitted during the year after the index admission. We have only included readmissions if the VTE code is in the first or second field making it much more likely that VTE was the reason for the readmission. Another limitation to the present study was it only detected patients readmitted with VTE not those who developed it in the community or who were treated in an ambulatory setting without admission to hospital. The patients who were admitted to the hospital were, however, the high risk group. Patients with significant DVT (e.g. ileofemoral DVT, phlagmasia alba dolens, or phlagamsia cerulosa dolens) and most patients with acute PE or suspected PE were normally admitted to hospital and would have been be included and were at high risk of morbidity and mortality.

Cancer and its treatment is a well-known risk factor for VTE[110] and it is no surprise that this study confirmed this finding. However, in addition, this study demonstrated that the risk of VTE remained elevated for at least six months following discharge.

Prolonged post-operative hospital stay and increasing age were also associated with an increased risk of VTE which may have been due to poor mobility of patients especially in the elderly. Patients admitted as an emergency also had an increased risk of VTE and were likely to be sicker with poorer mobility and in a poor nutritional state compared with patients undergoing elective surgery.

When the full cohort of patients was analysed, binary logistic regression did not find any difference in the rate of VTE between patients undergoing MAS and open surgery. Most patients undergoing MAS were admitted electively, however, whereas a third of open surgical operations was performed following an emergency admission. The analysis was therefore repeated for all patients who were admitted electively. In this subgroup those undergoing MAS were shown to have a lower incidence of VTE than after open surgery. This may be an additional benefit of MAS over open surgery perhaps due in part to shorter hospital stay and early mobilization due to better pain control.

Patients with ischaemic heart disease had a lower incidence of VTE (Odds ratio 0.520 and 95% CI (0.351-0.769)). These patients are routinely started on antiplatelet medication or anticoagulation which may act as a protective factor against developing VTE postoperatively.

The study has other limitations. It is a retrospective population based cohort study using data derived from Hospital Episode Statistics. HES are routinely collected by all hospitals in the NHS in England and the validity of the results therefore depends on the accuracy and depth of coding. Nevertheless, previous studies have suggested that the accuracy of recording of diagnostic and operative codes in England is high,[56] but researchers still have to recognize and account for a degree of coding inaccuracy. HES has been shown to be useful for the assessment of effectiveness, comparative audit, and equity.[126] A recent systematic review showed that coding accuracy was improving and following the introduction of payment by result programme in 2002 the accuracy of primary diagnoses had increased from 73.8% (IQR: 59.3-92.1%) to 96.0% (IQR: 89.3-96.3).[127] Another limitation of this study is that data derived from HES cannot assess whether patients received VTE chemoprophylaxis and for how long although by choosing the time point studied we have tried to reduce the effect of this confounding factor.

In 2010 NICE recommended the use of subcutaneous heparin in patients with malignancy for 28 days following discharge after surgical resection.[103] The study showed that only a quarter of patients who developed VTE did so during index admission and the risk of VTE remained high for six months following surgery. The four week period recommended may, therefore, not be adequate. Further studies to assess the risk of VTE following the introduction of NICE guideline 2010 may be useful to assess the effect of discharging patients with VTE receiving prophylaxis for 28 days.

Patients with benign pathology had a lower rate of VTE than those for malignant disease; however in those with a prolonged stay, the rate of VTE was similar to those seen in patients with a diagnosis of cancer. We would suggest that patients with benign disease undergoing resection who have an inpatient stay for more than 15 days following surgery should therefore be considered for prolonged thromboprophylaxis following discharge.

Patients with IBD were at higher risk of developing VTE compared with healthy controls. [128] This study confirmed increased rates of VTE in IBD although elective surgery for IBD appeared to have a much lower rate of readmission with VTE compared with emergency surgery. This may in part be due to a prolonged hospital stay.

VTE is a preventable condition, hence we believe every effort should be taken to reduce or eliminate the risk. The present study clearly demonstrated that a stratified approach which takes into account hospital stay and pathology may be needed to reduce the incidence of postoperative VTE in patients undergoing colorectal resection. Patients with a diagnosis of cancer and those undergoing colorectal resections for benign condition with extended hospital stay including IBD may benefit from an extended period of chemoprophylaxis.

5 Can HES data be used to identify rare complications of surgery when there is no code available for this complication?

Measuring complications is not difficult if the codes of those complications are available, however, there are times when there are no codes available for complications. In those situations, either the study is abandoned or a different methodology is needed. If the study is deemed to be important and the results of such studies are needed a different approach is necessary. In these situations, a surrogate code is necessary to identify those complications.

Gallstone disease is very common and the incidence is on the rise. Each year over 60000 patients are admitted to an NHS hospital to have their gallbladder removed as illustrated later in this chapter. Laparoscopic surgery was first used to remove gallbladder back in the early 1990 and has since become the standard of care. There are several complications that can develop during gallbladder surgery such as bleeding, infection, bile leak, VTE, retained stone, collections, and bile duct injury.

Bile duct injury is the most important complication following cholecystectomy. Indeed, it is rare but it can cause serious harm to the patient. The average pay-out to patients who suffer from bile duct injury is £102,000[129]. Unfortunately, there is no code in the ICD10 that identifies bile duct injury. I, therefore, created a new system to measure bile duct injury using Bile Duct Reconstruction (BDR) as a surrogate marker for the injury. There is potential for this secondary marker to be confounded and there is a need to create processes to minimise these.

5.1 Bile duct reconstruction following laparoscopic cholecystectomy in England.

5.1.1 Abstract

Objectives: To determine the incidence of bile duct reconstruction (BDR) following Laparoscopic Cholecystectomy (LC) and to identify associated risk factors.

Background: Major bile duct injury requiring reconstruction is a serious complication of cholecystectomy.

Methods: All LC and attempted LC operations in England between April 2001 and March 2013 were identified. Patients with malignancy, a stone in bile duct or those who underwent bile duct exploration were excluded. This cohort of patients was followed for one year to identify those who underwent BDR as a surrogate marker for major BDI. Logistic regression was used to identify factors associated with the need for reconstruction.

Results: A total of 572223 LC and attempted LC were performed in England between April 2001 and March 2013. 500 (0.09%) of these patients underwent BDR. The risk of BDR for Admission with other causes is significantly lower than acute cholecystitis (Odds ratio OR0.48 (95%CI 0.30—0.76). The regular use of On Table Cholangiography (OTC) (OR 0.69 (0.54—0.88) and high consultant caseload >80 LC/year (OR 0.56 (0.39—0.54) reduced the risk of BDR. Patients who underwent BDR were 10 times more likely to die within a year than those who did not require further surgery (6% vs. 0.6%).

Conclusions: The rate of BDR following laparoscopic cholecystectomy in England is low (0.09%). The study suggests that OTC should be used more widely and provides further evidence in support of the provision of LC services by specialised teams with an adequate caseload (>80).

5.1.2 Introduction

Laparoscopic cholecystectomy (LC) is a common operation, with over 60,000 operations undertaken each year in England. Based on conversion rate it has been suggested that LC should be undertaken by high volume surgeons[130].

Bile duct injury (BDI) is a rare but serious complication of cholecystectomy and the reported incidence following LC is between 0.1% and 1.5%[131-137]. Gallrick study[135] showed that the overall incidence of BDI was 1.5%; however, they included patients with bile leaks, partial duct injury, and non-specific injuries that would not have required reconstruction. The rate decreases to 0.1% if only the most serious cases of BDI are included[135]. BDI is associated with significant morbidity and mortality. Early complications include collections or peritonitis and if not treated sepsis, multi-organ failure and death[138]. Patients who sustain a BDI are also at risk of long-term problems including strictures, cholangitis, and secondary biliary cirrhosis requiring multiple hospital admissions, a shortened life expectancy and transplantation[139]. The reported peri-operative mortality rate following BDI varies between 0% and 7.2% [134, 140-142] with a one year mortality of 3.9%[135]. A review of the literature showed (602 BDI from 15 studies) that the adjusted hazard ratio of death in the longer term in those sustaining BDI compared to those without BDI following LC or attempted LC was 2.79 (95% CI 2.77-2.81)[133].

This study investigates Bile Duct Reconstruction (BDR) following LC or attempted LC in England as a surrogate marker for major bile duct injury requiring reconstruction.

5.1.3 Methods

Hospital Episode Statistics (HES) data were obtained from the National Health Service Information Centre (NHSIC) and imported into Microsoft SQL server for analysis. All patients who underwent LC or attempted LC between April 2001 and March 2013 were identified by searching the operative fields for the OPCS-4 (Office of Population Censuses and Surveys 4) codes J18* (cholecystectomy) and the corresponding laparoscopic codes.

Using diagnostic codes, International classification of Diseases Version 10 (ICD 10), patients undergoing surgery for benign biliary disease of the gallbladder were identified. Those who underwent LC or attempted LC for a stone in the bile duct or for a malignant neoplasm of the liver, gall bladder, biliary tree or pancreas were excluded.

There is no specific code for BDI in either ICD-10 or OPCS-4; therefore operative codes that are used for BDR were used to identify patients who required biliary reconstruction following LC or attempted LC. The cohort of patients was followed using HESID (a unique identifier for each patient in HES) to identify patients who underwent BDR within a year of the index operation. If a patient underwent more than one BDR only the first operation was included in the analysis.

A flow chart of the methods is shown in figure 1 and all codes used are summarized in table 1.

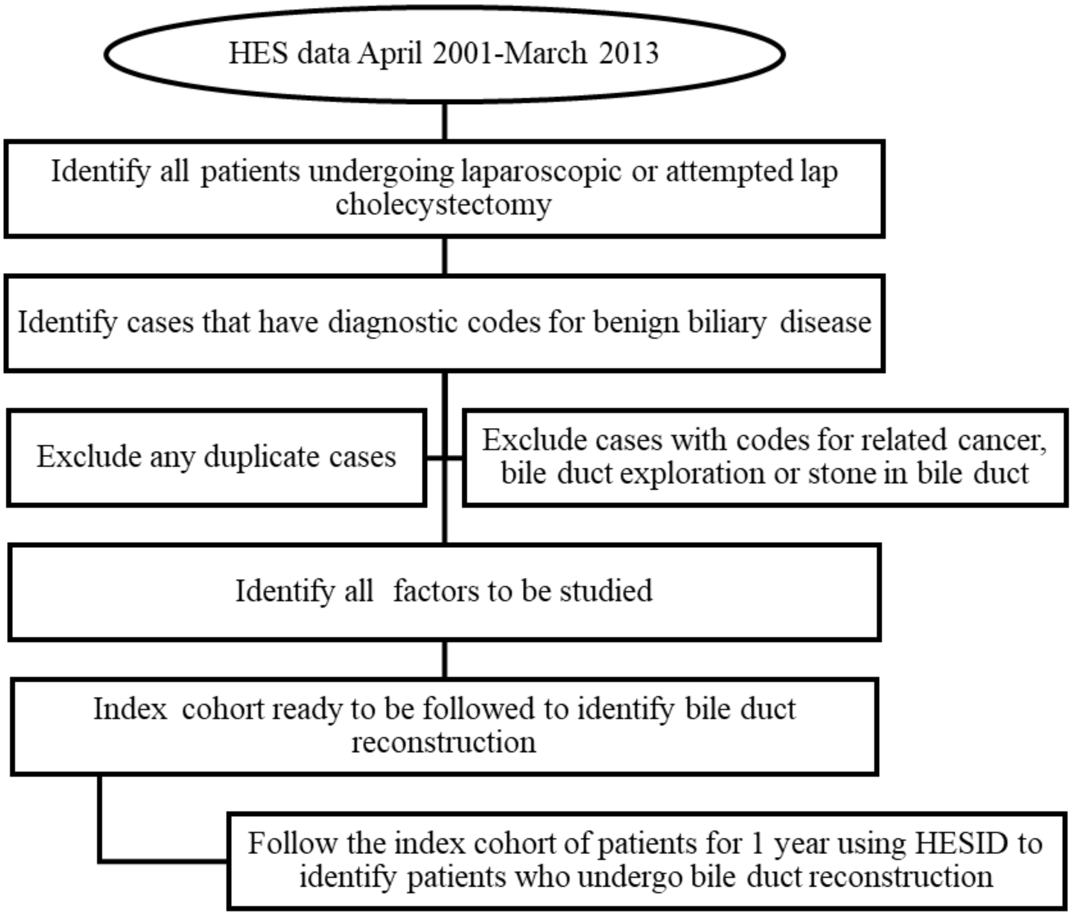

Figure 1: Study design

Factors that may affect the risk of BDR were divided into patient and non-patient groups. Patient related factors studied included age, gender, acute pancreatitis, acute cholecystitis, comorbidity, and deprivation index score. The Charlson comorbidity score was calculated using methods described by Dr Foster.[121] The deprivation index score was used as described in the English indices of deprivation.[143]

Codes used for cholecystectomy	
J181	Total cholecystectomy and surrounding tissue
J183	Total cholecystectomy
J185	Partial cholecystectomy

J188	Other excision of gall bladder
J189	Unspecified excision of gall bladder
Codes used for intraoperative cholangiography	
J372	Operative cholangiography through cystic duct
J373	Direct puncture operative cholangiography
Codes used for laparoscopic surgery and conversion	
Y718	Failed minimal access approach converted to open (before 2006)
Y714	Failed minimal access approach converted to open (after 2006)
Y508	Laparoscopic approach to abdominal cavity (before 2006)
Y75*	Laparoscopic approach to abdominal cavity (assisted, robotic, hand assisted and other approach) (after 2006)
Codes used for diagnosis	
K800	Calculus of gall bladder with acute cholecystitis
K801	Calculus of gall bladder with other cholecystitis
K802	Calculus of gall bladder without cholecystitis
K808	Other cholelithiasis
K810	Acute cholecystitis
K811	Chronic cholecystitis
K818	Other cholecystitis
K819	Unspecified cholecystitis
K82*	Other diseases of gall bladder
K832	Perforation of bile duct
K85*	Acute pancreatitis

Codes used for exclusion in the diagnosis fields	
K803	Calculus of bile duct with cholangitis
K804	Calculus of bile duct with cholecystitis
K805	Calculus of bile duct without cholecystitis or cholangitis
K830	Cholangitis
K823	Fistula of gall bladder
K831	Obstruction of bile duct
K833	Fistula of bile duct
C22*	Malignant neoplasm of liver and intrahepatic duct
C23	Malignant neoplasm of gallbladder
C24*	Malignant neoplasm of other parts biliary tract
C25*	Malignant neoplasm of pancreas
Codes used for exclusions in the operative fields	
J182	Total cholecystectomy and exploration of common bile duct
J184	Partial cholecystectomy and exploration of common bile duct
Codes used to identify bile duct reconstruction	
J27.2	Partial excision of bile duct and anastomosis of bile duct to duodenum
J27.3	Partial excision of bile duct and anastomosis of bile duct to jejunum
J27.4	Partial excision of bile duct and end to end anastomosis of bile duct
J29.1	Anastomosis of hepatic duct to transposed jejunum and insertion of tubal prosthesis HFQ
J29.2	Anastomosis of hepatic duct to jejunum NEC
J30.1	Anastomosis of common bile duct to duodenum
J30.2	Anastomosis of common bile duct to transposed jejunum

J30.3	Anastomosis of common bile duct to jejunum NEC
J32.1	Reconstruction of bile duct
J32.2	Re-anastomosis of bile duct

Table 1: Operative and diagnostic codes used in this study

Non-patient related factors included were consultant caseload, hospital volume, consultant conversion rate, whether a trust was a regional Hepato-Pancreato-Biliary (HPB) centre and consultant rate of use of intraoperative cholangiography (IOC): Definitions are summarized in table 2.

Factors	Definitions
Non-patients related factors	
Consultant caseload	Total number of operations performed under the care of a consultant in the previous year
Consultant conversion rate	Number of laparoscopic cholecystectomies converted divided by the total number of LC and attempted LC under the care of that consultant in the previous year
Hospital volume	Total number of laparoscopic cholecystectomies performed by an NHS Trust in the previous year
Consultant rate of on table cholangiography (OTC)	Number of OTC's performed by a consultant divided by the total number of LC attempted under the care of that consultant in the previous year
Patient related factors	
Acute cholecystitis	Patients admitted as an emergency with diagnostic codes K800 or K810 who undergo cholecystectomy on that admission
Acute pancreatitis	Patient admitted as an emergency with a diagnostic code of

	K85*who undergo cholecystectomy on that admission
Major bile duct injury	Patient who underwent bile duct reconstruction within a year of index admission. i.e hepaticojejunostomy, hepaticodeudenostomy, or resection of injured bile duct and reanastamosis.

Table 2 Definitions used in this study

Mortality was assessed for all patients using data derived from the Office of National Statistics. One-year mortality was then calculated for patients with or without BDR.

5.1.3.1Statistics

Univariate analysis and multivariate analysis (logistic regression) was used to investigate which factors are associated with a risk of bile duct reconstruction.

A funnel plot was used to examine institutional variation and shows the standardised ratio of BDRs at 1-year following LC plotted against the number of expected BDRs. The expected number of BDRs is derived using a multivariate logistic regression model that accounts for patient related factors. The BDR ratio was calculated by dividing observed BDR per year over expected BDR per year multiplied by 100. Each hospital is represented by a blue dot. The dotted lines show the lower and upper 95% control limit and the solid lines the upper and lower 99.8% control limit as described by Eayers[144]. If a hospital falls outside the 99.8% control limit, this is considered to be the result of special cause variation and would usually require further investigation.

5.1.4 Results

572 223 LC or attempted LC were performed in England Between April 2001 and March 2013, Table 3. More than half (56%) were undertaken in patients under 55 years of age while 7.2% were performed in patients above 75 years. Just over three quarters of LC or attempted LC were undertaken in females. The majority of LC was performed electively (89%). Almost a third of emergency LC was performed for acute cholecystitis and 13.3% for acute pancreatitis. The number of LC performed in the NHS in England almost doubled from 32 086 in 2001/02 to 62 020 LC during 2012/13. The overall conversion rate of LC in England is 4.3%. One-year mortality rate following LC in England is 0.6%. Around half of the patients who underwent LC or attempted LC had their surgery under the care of a consultant surgeon who performs between 20 and 80 cases a year and a quarter of patients underwent surgery under care of consultants who perform less than 20 or more than 80 cases a year.

	No of cholecystectomies	Bile duct reconstruction	%
Total	572,233	500	0.09%
Age Group			
<55	319,632	220	0.07%
55-64	119,663	114	0.10%
65-74	90,700	95	0.10%
75+	41,907	71	0.17%
Not recorded	331	0	0.00%
Gender			
Males	135,478	178	0.13%
Females	436,606	322	0.07%
Not recorded	149	0	0.00%
Ethnicity			
White	451,869	405	0.09%
Asian or Asian British	20,106	25	0.12%
Black or Black British	8,128	7	0.09%

Other Ethnic Groups	5,657	9	0.16%
Mixed	2,315	3	0.13%
Chinese	1,059	0	0.00%
Unknown	83,099	51	0.06%
Deprivation (quintile)			
1-Most deprived	122,185	100	0.08%
2	118,715	114	0.10%
3	116,686	101	0.09%
4	110,811	96	0.09%
5-Least deprived	100,190	83	0.08%
Not recorded	3,646	6	0.16%
Tertiary Centre			
No	461,346	386	0.08%
Yes	110,887	114	0.10%
Admission method			
elective	510,260	435	0.09%
emergency	61,406	65	0.11%
transfer	431	0	0.00%
other	136	0	0.00%
Acute cholecystitis (index admission)			
No	551,812	478	0.09%
Yes	20,421	22	0.11%
Acute pancreatitis (index admission)			
No	564,077	493	0.09%
Yes	8,156	7	0.09%
Year of index admission			
2001/02	32,086	28	0.09%
2002/03	37,290	36	0.10%
2003/04	40,824	53	0.13%
2004/05	39,533	33	0.08%
2005/06	42,573	35	0.08%
2006/07	45,049	50	0.11%

2007/08	50,702	43	0.08%
2008/09	50,689	49	0.10%
2009/10	53,748	32	0.06%
2010/11	56,254	49	0.09%
2011/12	61,465	52	0.08%
2012/13	62,020	40	0.06%
Converted			
Yes	25,513	254	1.00%
No	546,720	246	0.04%
No. Procedures per Institution (previous year, exc.2001/02)			
Low volume <200	113,391	82	0.07%
Middle volume 200-500	286,943	258	0.09%
High volume >500	139,813	132	0.09%
No. Procedures per Consultant (previous year, exc.2001/02)			
Low volume <20	144,713	149	0.10%
Middle volume 20-80	254,224	238	0.09%
High volume >80	141,210	85	0.06%

Table 3: Demographics of study cohort

Five hundred patients underwent BDR within one year of a LC (0.09%). Patients who underwent BDR following LC were 10 times more likely to die within a year of the index cholecystectomy (6% vs 0.6%), Table 3. Over the study time period, there is a trend towards a lower rate of BDR (figure 3).

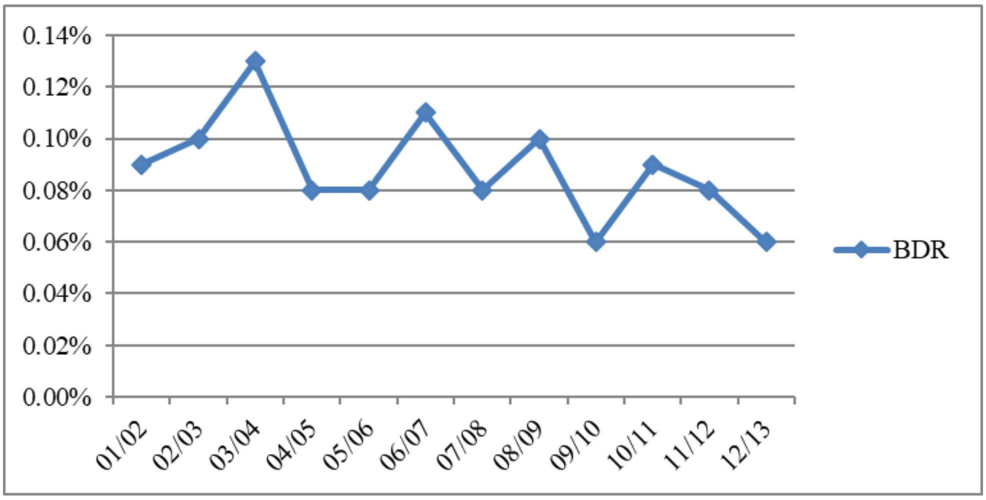

Figure 3: Trend of BDR over the study period

5.1.4.1 Patient related factors

Univariate analysis showed that patient related factors including increasing age, and male sex were significantly associated with bile duct reconstruction. However; multivariate analysis did not confirm these associations suggesting that other factors may be responsible for these findings (Table 4). Only patients with acute cholecystitis who undergo LC on the index admission were found by both univariate and multivariate analysis to have an increased risk of BDR

Odds Ratio - Bile duct Reconstruction		(95% CI)	P Value
Age group <55	1.00		
55-64	0.97	(0.76-1.23)	NS
65-74	0.86	(0.67-1.12)	NS
75+	1.22	(0.91-1.63)	NS
Gender Females	0.89	(0.73-1.09)	NS
Deprivation			
1-Most deprived	1.00		

2	1.24	(0.94-1.64)	NS
3	1.13	(0.85-1.51)	NS
4	1.15	(0.86-1.55)	NS
5-Least deprived	1.11	(0.81-1.51)	NS
Acute cholecystitis	0.48 2.08	(3.33-1.31)	0.002
No acute pancreatitis	0.81	(0.36-1.83)	NS
Charlson score	0.94	(0.80-1.10)	NS
Cholangiography (index admission)	2.73	(2.10-3.56)	<0.001
Converted procedure	22.89	(18.75-27.94)	<0.001
No. of procedures per Consultant (prev year, exc.2001/02)			
Low volume <20	1.00		
Middle volume 20-80	0.80		NS
High volume >80	0.56		<0.001
No. Procedures per Provider (previous year, exc.2001/02)			
Low volume <200	1.00		
Middle volume 200-500	1.07		NS
High volume >500	1.31		NS
Tertiary Hospital	1.19		NS
Consultant conversion rate - quartiles (previous year, exc.2001/02)			
1- lowest quartile	1.00		

2	1.05	(0.72-1.54)	NS
3	1.07	(0.8-1.43)	NS
4- highest	0.95	(0.74-1.24)	NS
Consultant cholangiography rate - tertiles (previous year, exc.2001/02)			
1- lowest tertile	1.00		
2	1.17	(0.86-1.58)	NS
3	0.69	(0.54-0.88)	0.003

Table 4: Multivariate analysis of factors that may be associated with bile duct reconstruction following LC or attempted LC

5.1.4.2 Non patient related factors

Univariate and multivariate analysis showed that high volume consultant caseload >80 LC/year is associated with a lower rate of bile duct reconstruction.

There was a strong association between conversion and BDR OR 22.89 (95%CI 18.75-27.94) p<0.001) which may be due to surgeons converting to open surgery when they suspect a BDI. Therefore, we used consultant conversion rate in the year before rather than conversion in an individual case. There was no association between consultant conversion rate in the previous year and BDR following LC or attempted LC.

Similarly, there was a strong association between the use of OTC and BDR in individual cases (P<0.001). This may be due to surgeons using OTC when they suspect a BDI but when consultants are divided into tertiles on the basis of their use of OTC in the year before the index case, those who use it more frequently have a lower rate of patients subsequently undergoing bile duct reconstruction, odds ratio 0.69 with 95% CI (0.54-0.88).

Trust caseload volume was divided into low volume providers <200 LC/year, intermediate volume provider between 200 and 500 LC/year and high volume providers, which perform more than 500 LC/year. Univariate and multivariate analysis did not show any association between Trust caseload volume and bile duct reconstruction. There was no difference in the rate of BDR following LC or attempted LC if the index procedure was undertaken in an HPB centre as compared to a non-HPB centre.

A funnel plot was used to examine whether some hospitals have a higher rate of BDR following LC/attempted LC. As illustrated in figure 2, all hospital results are within the 95% confidence interval. Most repairs are performed in the hospital in which an injury occurs rather than a regional centre table 5.

Financial Year (index admission)	No. bile duct reconstructions	Number performed at different hospital	% Bile duct repairs not in same Hospital
2001/02	28	10	35.7%
2002/03	36	12	33.3%
2003/04	53	15	28.3%
2004/05	33	14	42.4%
2005/06	35	16	45.7%
2006/07	50	24	48.0%
2007/08	43	13	30.2%
2008/09	49	19	38.8%
2009/10	32	11	34.4%
2010/11	49	18	36.7%
2011/12	52	21	40.4%
2012/13	40	22	55.0%

Table 5: Bile duct repair at index or another hospital

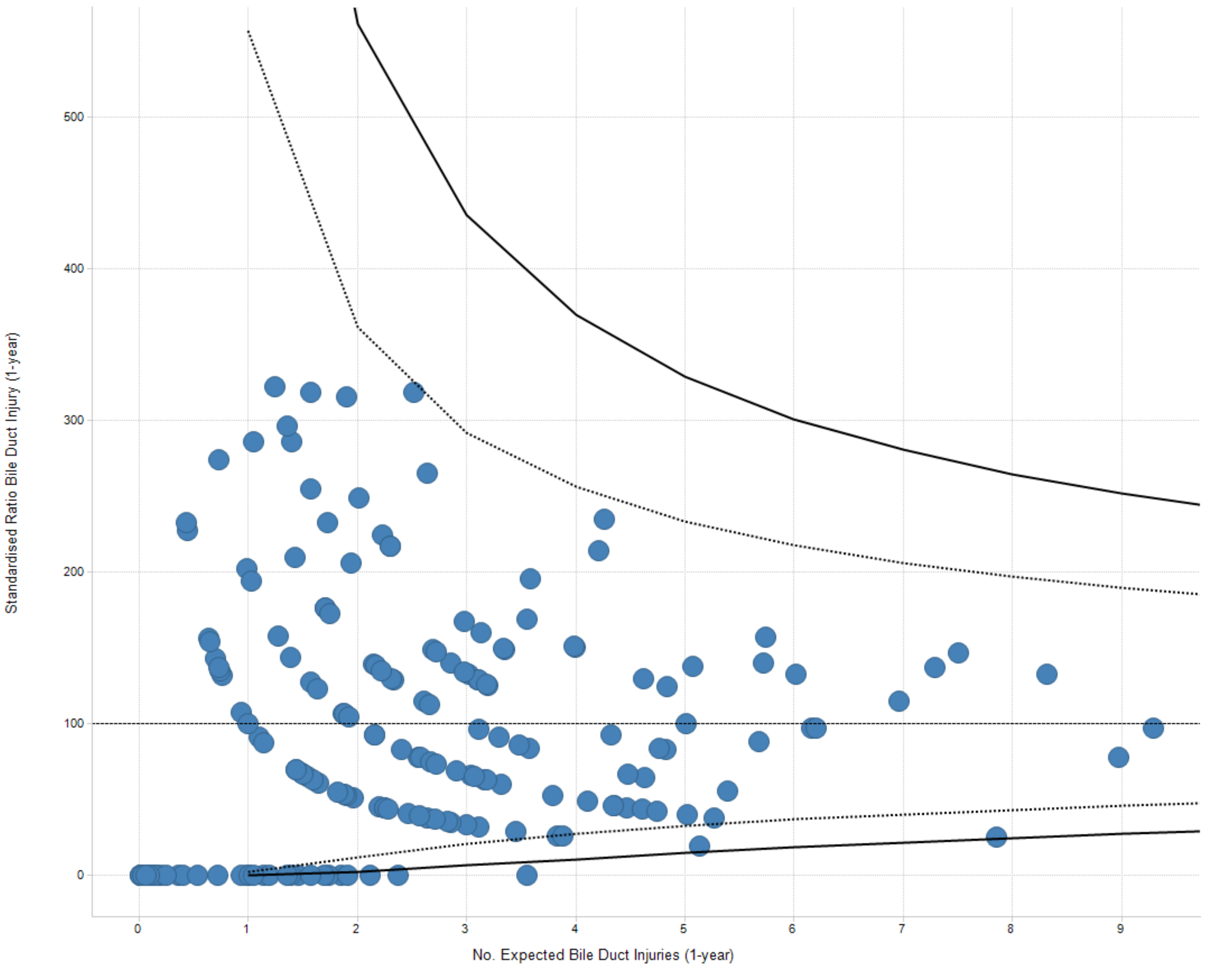

Figure 2: Funnel plot of Institutional Standardised Ratio for BDR following LC or attempted LC

5.1.5 Discussion

This is the largest study of its kind in the literature that examines BDR following LC or attempted LC in England. It investigates all patients who underwent LC surgery in England over a 12 year period which represents 1.1% of the total population of England. The apparent rate of reconstruction and therefore presumed bile duct injury is in keeping with published series (the previous literature for major injuries). Patient related factors associated with BDR include cholecystitis on the index admission. Non-patient related factors associated with a lower reconstruction rate include a high consultant cholecystectomy caseload and regular use of OTC. There is a tenfold increase in mortality at one year in patients who have undergone a BDR (at one year) demonstrating how serious this complication can be.

This study suggests that the incidence of BDR following LC in England is low (0.09%) with only 500 cases over a 12-year period. Data from other registries show that the incidence of BDI in Germany is 0.1% (172 368 LC);[131] in Denmark 0.15% (23 672 LC);[132] in the USA between 0.06%- 0.5%[133, 145]; in Finland 0.82% (6 733 LC)[134]; and in Sweden 1.5% (51 041 LC)[135] although major BDI in this study accounts for only 0.1%. However, researchers have to understand that different definitions of what constitutes BDI make comparative analysis difficult. Other reports from large single centre studies (over 10 000 LC) showed the incidence of BDI is between 0.19%[137] and 0.24%[136]. There was a trend towards a reducing need for BDR during the study period, which may represent an increased awareness of methods of safe cholecystectomy.

The study has a number of limitations. There are no codes for BDI and we therefore used codes for bile duct reconstruction. Other studies using registry data have used similar methodology[131-133, 146]. Patients who sustain a BDI and die without surgical intervention will not be included in this analysis. This study only identifies major duct injuries that require reconstruction, whereas minor injuries that require simple repair, drainage or ERCP and stenting are not included. Therefore, the study underestimates the incidence of BDI. Nevertheless, most minor injuries are associated with a lower rate of complications, and lower long-term morbidity. However, the study does include those patients who fail to respond to ERCP and stenting or who develop stenosis of bile duct that requires delayed (within a year) surgical reconstruction.

The study uses HES data which is administrative data that relies on the accuracy of clinical coding. A recent systematic review shows coding accuracy is improving and following the introduction of payment by results in 2002 the accuracy of coding for primary diagnoses has improved from 73.8% (IQR: 59.3-92.1%) to 96.0% (IQR: 89.3-96.3)[127]. Further studies based on HES are cohort studies; they differ from the usual cohort studies in that they represent almost all activity within the area of study in England. One also has to consider the context of conclusions that are drawn from studies using HES. If findings are of a general nature, then even a relatively high coding error rate at some hospitals or even all hospitals will not detract markedly from the overall conclusions if significant deviation can be shown[147]. Thus studies based on HES data may actually be good at dealing with research questions such as those posed in this study but are less good at identifying variations in care between individual trusts or clinicians[148]. We have not attempted analyse the incidence of minor bile duct injuries as the coding issues are complex and we feel that it would be difficult to draw valid conclusions from the data.

Cholecystectomy is considered by many surgeons to be more difficult in male as compared to female patients and this may lead to a higher complication rates. Our data showed male gender is associated with almost double the rate of BDR (0.13%) compared to female patients (0.07%). However, this difference is not statistically significant when an adjustment is made for other factors.

Age has been shown to be an independent risk factor for BDI[149] and mortality following BDI[133]. Associated co-morbidities, frailty, use of anticoagulants, and previous abdominal surgeries have been postulated to contribute to the increase risk in the elderly [149]. Data from this study showed BDR following LC in elderly patients >75 years (0.17%) was more than that in those below 55 years (0.07%). However, multivariate analysis did not reveal any significant difference, which is due to other factors adjustment.

The calibre of the bile duct increases with age which may make simple repair easier in older patients [150, 151]. Whether simple suture repair of the bile duct can be accomplished depends on many other factors for example the presence of a clean laceration identified at the same time of surgery together with a wide calibre bile duct.

Several studies[152-154] have shown that bile duct injury repaired at an HPB centre is associated with a better outcome as compared to those repaired in a general hospital. Data from this study showed more than half of the injuries were repaired locally.

Centralization of HPB services has progressed rapidly in the UK with most major resections occurring in HPB centres during the study period. Many of those surgeons who used to perform resectional biliary surgery may still practice in their local hospital. Further some regions offer an outreach service where a BDI injury may be treated in the local hospital by a surgeon from the regional unit.

Most surgeons in the UK perform OTC selectively. Large studies based on registry data have produced conflicting results. While some show that the risk of BDI decreases when OTC is performed[135, 146, 155-157], others, including a systematic review[158] show no benefit[159]. The study showed that surgeons who use OTC more frequently have a lower rate of BDR following LC.

The study did not show any difference in BDR following LC between low and high-volume NHS providers or HPB centres and general hospitals suggesting that all NHS providers deliver a satisfactory cholecystectomy service. However, it appears consultant caseload is an independent risk factor for BDR following LC. Surgeons who perform 80 LC/year or more have a lower rate of BDI than low volume surgeons. Further BDI appears to be more common in patients who undergo cholecystectomy on an index emergency admission with acute cholecystitis.

These results suggest that more widespread use of OTC could also help to reduce the incidence of BDI. They do not support centralization of cholecystectomy services; however they do suggest that to avoid major bile duct injury the development of dedicated teams in each hospital with an adequate LC caseload (>80) may help to reduce the incidence of this complication and further suggests that the occasional operator should reconsider their practice especially in emergency patients.

6 *Can HES data be used to compare different types of surgery for the same condition?*

Inguinal hernia is traditionally repaired using open approach. In the last 20 years, laparoscopic approach has been used as an alternative method. Laparoscopic approach has gradually increased in popularity among surgeon. The literature review did not identify research to confirm if the laparoscopic approach is superior to the open approach for inguinal hernia.

There are multiple approaches to study superiority such as superiority studies, equivalence studies and non-inferiority study. In this study it is proposed that a retrospective analysis of HES data with major complication is used as the primary outcome. The rationale being patients are consented for a number of complications. And they can be used as a good marker to measure outcomes of hernia repair. In hernia surgery the main complication is recurrence. However, there is no specific code to say which patient has actually recurred, but a surrogate code can be used instead. Hernia reoperation is an excellent alternative to recurrence.

Fortunately, reoperation can be measured easily. Patients underwent inguinal hernia repair will be followed to identify patients who underwent further surgery on the same side of the previous repair. Most recurrence occurs in the first few years following the original repair. Other complications were used as secondary outcomes. These complications are infections, injury to an organ and readmission with urinary retention. The study will compare both open and laparoscopic techniques and identify factors that are associated with recurrence.

6.1 Laparoscopic versus open repair of inguinal hernia: a longitudinal cohort study.

6.1.1 Abstract

BACKGROUND: Traditionally, repair of an inguinal hernia has been by an open method, but laparoscopic techniques have recently been introduced and are increasing in popularity. This study aimed to compare early and late outcomes following laparoscopic and open repair of inguinal hernia.

METHODS: We performed an analysis of inpatient Hospital Episode Statistics. Early-outcome criteria studied include in-hospital mortality, length of hospital stay, complications (infection, bleeding, injury to an organ, and urinary retention), and readmission. Late outcome was assessed by the need for a further inguinal hernia repair on the same side.

RESULTS: Between April 2002 and April 2004 125,342 patients who underwent inguinal hernia repair were included in the analysis and they were followed until April 2009. There were no differences in postoperative stay between the laparoscopic and open groups except for the laparoscopic bilateral hernia repair patients who had a shorter stay than the open group. Infection and bleeding were more common following open repair, whilst urinary retention and injury to an organ were more frequent after laparoscopic repair. Reoperation for another inguinal hernia was more common after laparoscopic (4.0 %) than after open repair of primary inguinal hernia (2.1 %), mostly in the first year after surgery. There was no difference in reoperation rate following repair of a recurrent inguinal hernia. Consultant caseload was strongly inversely correlated with reoperation following laparoscopic but not open repair of primary inguinal hernia.

CONCLUSIONS: Reoperation is more common after laparoscopic than after open repair of primary but not recurrent inguinal hernia. Surgeons with a low laparoscopic hernia repair caseload have an increased reoperation rate following laparoscopic repair of primary inguinal hernia. The increase in reoperation rate following laparoscopic repair is seen in the first year or two following the initial surgery.

6.1.2 Introduction

Open repair has been the standard surgical approach for the treatment of inguinal hernia for over 100 years. Open hernia can be repaired with mesh or with sutures only. There are a number of techniques used for suture repair such as Shouldice repair and Bassini repair. Tension free mesh hernia repair was first reported by Lichtenstein in 1989[160]. The use of mesh reduces recurrence between 50 and 75%[161] and in this regard is superior to the Shouldice technique, which is the best non-mesh open inguinal hernia repair[162]. The majority of inguinal hernia in the United Kingdom are repaired using tension free mesh repair. Open repair of an inguinal hernia with mesh is therefore considered the standard with which other techniques should be compared.

Over the last 20 years laparoscopic techniques for the treatment of inguinal hernia have been introduced including the transabdominal pre-peritoneal (TAPP) and laparoscopic total extraperitoneal (TEP) approaches, which have become increasingly popular[163].

National Institute for Health and Clinical Excellence (NICE) in the United Kingdom issued new guidelines for the treatment of inguinal hernia and suggested that laparoscopic surgery should be offered as one of the options for repair[164]. This advice was based in part on a meta-analysis of the published randomised trials that were available at that time, which showed a recurrence rate of 2·5% following TAPP as compared to 2·1% following an open repair and a recurrence rate of 2·3% following a TEP as compared to 1·3% with an open technique; these differences were not statistically significant[164]. Earlier NICE had not recommended the widespread introduction of laparoscopic repair because of the lack of evidence but also because of the concern regarding the generalizability of the technique in routine practice rather than in individual series.

However, the literature is not all congruent with the findings of NICE metanalysis of equivalence between open and laparoscopic repair in 2003 [165]. The relative odds of short-term recurrence were increased by 50 per cent for LIHR compared with OIHR, although this result was not statistically significant (odds ratio 1·51 (95% CI 0·81 to 2·79); P = 0·194). Veterans multicentre randomised controlled study comparing open and laparoscopic surgery for the repair of inguinal hernia was published after NICE review and demonstrated a higher recurrence (10·1%) rate using laparoscopic as compared to an open techniques (4·0%)[166]. A multicentre French study also showed higher re-operation rates with the laparoscopic compared to the Shouldice approach[167]. Also higher recurrence rates were reported following TEP repair of unilateral primary inguinal hernia (3·5%) compared to an open tension free repair with mesh (1·2%)[168]. Many other studies have, however, failed to show any difference in recurrence rates between the two techniques for recurrent[169] or primary inguinal hernia[170-172].

Early recurrence can be difficult to assess but a significant recurrent hernia will require reoperation and therefore reoperation rates have been used as a measure of long term outcome.[173, 174]

Due to inconsistency of the findings of published literature, it is suggested a larger dataset analysis is needed to compare both techniques. Using data derived from Hospital Episode Statistics (HES) we have studied all National Health Service (NHS) patients in England who underwent inguinal hernia surgery over a two-year period, and then followed this cohort for a further five years to determine whether any had further inguinal hernia repair on the same side. We have sought to identify factors which may be associated with hernia recurrence including patient related factors such as age, sex, side of surgery (unilateral or bilateral), type of hernia (primary or recurrent), or complications, and non-patient related such as type of surgery, consultant caseload and trust caseload.

6.1.3 Methods

HES data were obtained from the NHS Information Centre and imported into Microsoft 2005 SQL server for analysis. All primary and recurrent inguinal hernia repairs performed in England between April 2002 and April 2009 were identified by searching the first three operative fields of the HES dataset using the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (4th revision) codes (OPCS-4) for T20 (primary inguinal hernia) and T21 (recurrent inguinal hernia). Only patients with a matching diagnostic code, International Classification Disease 10th Edition (ICD-10), K45 (inguinal hernia) in the first three diagnostic fields of the HES dataset were included in the final analysis. (In 2002 this technique eliminated less than 1·2% of all episodes, and we think this technique increases the accuracy of the study by reducing coding errors).

Patients who underwent an inguinal hernia repair between April 2002 and April 2004 were used as the study cohort. These patients were subdivided into primary/recurrent and then into unilateral/bilateral inguinal hernia repairs (Figure 1). If the side of the original operation was not recorded or the patient was under 18 or was admitted as an emergency, then they were excluded from further analysis. To verify the results on a later cohort, patients who underwent an inguinal hernia repair between April 2006 and April 2007 were identified and followed for two years to identify any undergoing re-operation for a further inguinal hernia on the same side.

6.1.3.1Early outcome criteria

Early outcome criteria studied were, in-hospital mortality, length of hospital stay, complications and readmission. Complications were identified using ICD-10 codes by searching the secondary diagnostic fields for infection (T814, T857, and T813), bleeding (T810), injury to an organ (T812), and urinary retention (R33).

Readmission

A readmission was defined as any patient readmitted to a general surgeon as an emergency within 30 days of discharge with bleeding or infection, or if a patient was readmitted with urinary retention within two days of discharge.

6.1.3.2Late outcome criteria

Patients were followed using HES ID until April 2009, to identify those requiring a further inguinal hernia repair on the same side. For example, if a patient had an inguinal hernia repair on the left side during 2002, then the dataset was searched to identify the need for a subsequent inguinal hernia repair on the left side or a further bilateral repair.

Consultant and Hospital Caseload

Consultant caseload, either laparoscopic or open, was defined as the number of patients operated on under a consultant’s care in a year. Hospital caseload, either laparoscopic or open, was defined as the number of patients treated annually in each NHS trust. Both consultant and trust caseloads were divided into quintile groups for analysis.

To stratify patients on the basis of patient related factors such as age, sex, side of surgery (unilateral or bilateral), type of hernia (primary or recurrent), or complications, a model of probability for reoperation was constructed. Predicted probability values for patient related factors likely to lead to reoperation were calculated using logistic regression. This model was then assessed for discrimination using ROC curve analysis. Patients were grouped into three categories low, medium, and high risk of recurrence prior to further analysis based on the lower third, middle third and the higher third risk group.

For bilateral hernia the number of patients rather than hernias was used for data presentation. The reoperation rate was calculated for primary and recurrent hernia then for unilateral and bilateral hernia independently. The time to reoperation is defined as the time between the original operation and the first reoperation.

6.1.4 Statistics

All data analyses were performed using SPSS version 18·0 (SPSS, Inc., Chicago IL). T-test, Chi-square, Fisher Exact test, and Mann Whitney test were used for univariate analysis. Multivariate analysis was performed using binary logistic regression. Where appropriate data is presented with 95% confidence intervals for proportion.

6.1.5 Results

Between April 2002 and April 2004 142,194 patients underwent an inguinal hernia repair in English NHS hospitals. 5·1% (7246) were excluded because the side of operation was not documented. Of the remaining, 5·0% (6705) were undertaken following an emergency admission and 2·1% (2901) were in patients under 18 years leaving 125,342 patients for analysis.

The median age of patients undergoing inguinal hernia surgery was 60 years (IQR 47-71). Patients undergoing a laparoscopic repair of an inguinal hernia were on three years younger (median age 57 years IQR 45-67) than those undergoing open repair, (median age 60 years IQR 47-72) ($P<0.01$).

The proportion of female patients undergoing laparoscopic repair of an inguinal hernia was lower than in the open group, 4·1% versus 6·6% (Table 1). The majority of inguinal hernia repairs were primary (93·5%) and most were unilateral (90·6%) as shown in Figure 1. A laparoscopic approach was used in 8108 (6·1%) and laparoscopic procedures were converted to open surgery in 111 patients (1·4%). The use of the laparoscopic approach for repair of an inguinal hernia increased from 5·8% of cases in 2002 to 17·8% in 2008 (Figure 2).

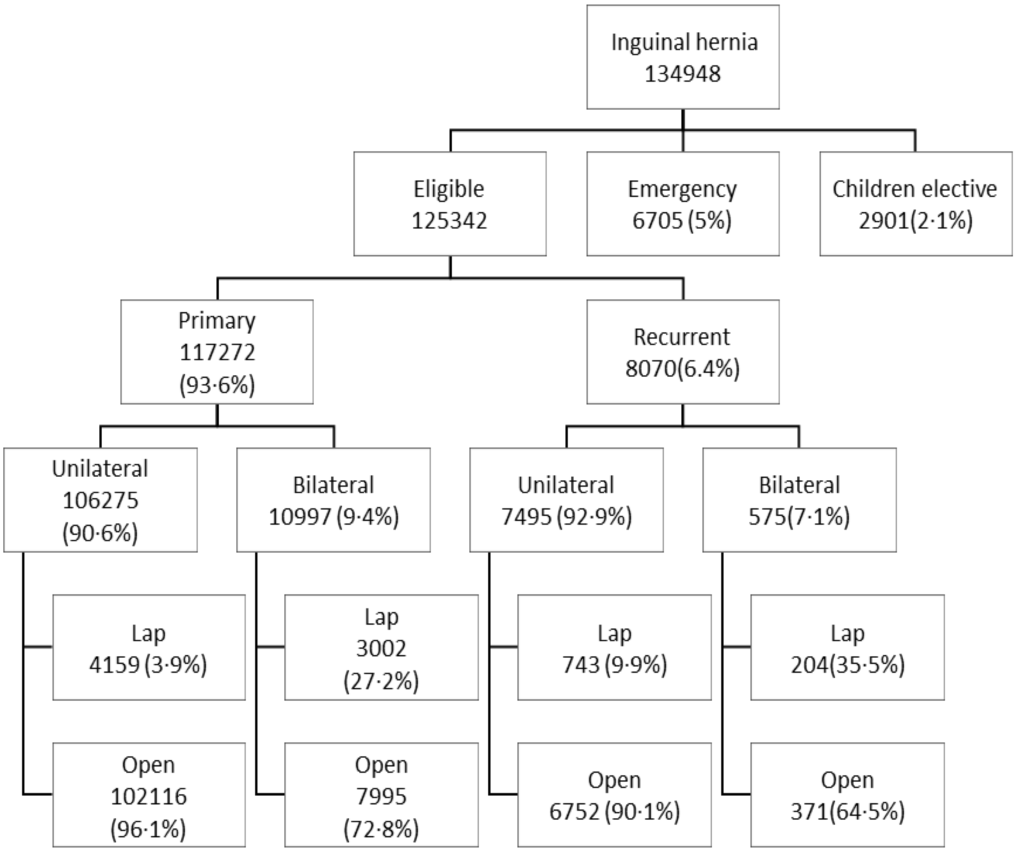

Figure 1: Inguinal hernia repair in England April 2002 - April 2004

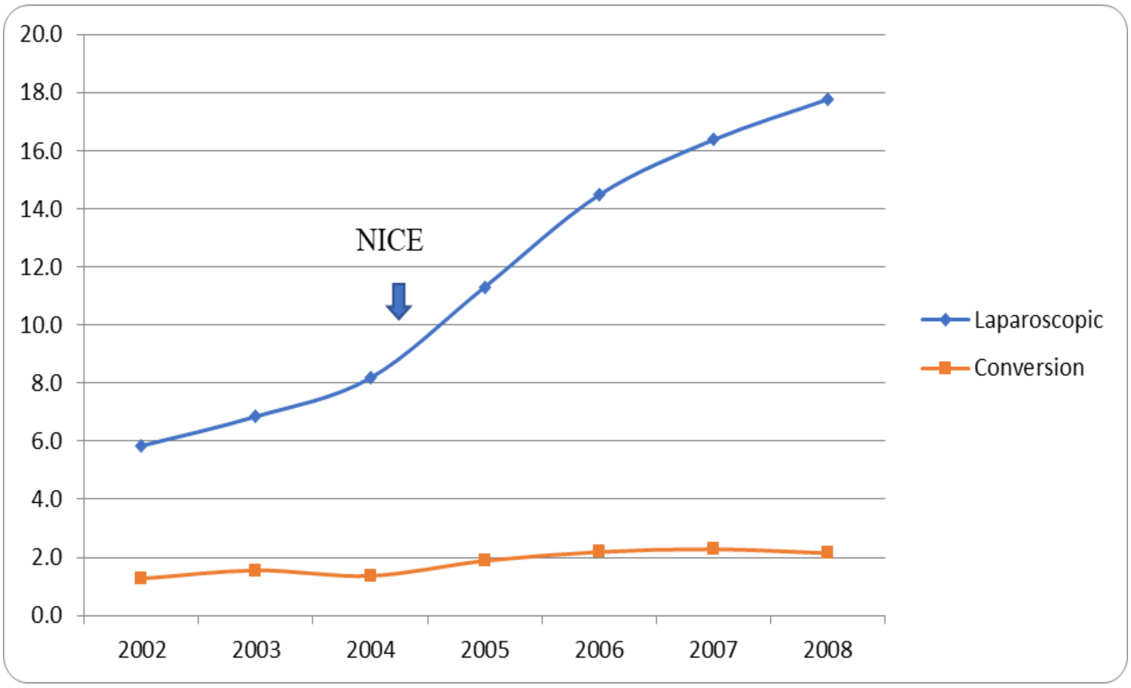

Figure 2: Percentage of inguinal hernias repaired laparoscopically together with conversion rate 2001-2008

6.1.5.1Early outcome

Bleeding or haematoma was recorded as a complication in 1242 operations (1·0%); an injury to an organ followed 61 operations (0·05%); urinary retention followed 900 operations (0·7%), and infection followed 396 operations (0·3%). Following an inguinal hernia repair 1048 patients were readmitted (0·8%). The in-hospital mortality rate was 0·03% (38 patients).

The median length of hospital stay was one day (IQR 0-2). Overall there was no difference in the total length of hospital stay (1-day (0-1) versus 1-day (0-2) P=0.23) or the post-operative hospital stay (1 day (0-1) versus 0 day (0-1) P=0.15) between laparoscopic and open inguinal hernia repair. However, postoperative stay following repair of bilateral inguinal hernia was significantly reduced in the laparoscopic group (1 day (0-2) versus 2 days (1-2)P<0.01). There was no significant difference in the readmission rate between open (0·7%) and laparoscopic hernia repair (0·8%). Laparoscopic surgery was associated with a lower infection rate (0·2% versus 0·3%), and a lower bleeding/haematoma rate (0·8% versus 1·0%). Conversely, the laparoscopic technique had a higher incidence of organ injury during surgery (0·2% versus 0·04%), and of urinary retention (1·5% versus 0·7%) as shown in Table 1.

	LAP	OPEN	P VALUE
Total patients	8108	117234	
Median age	57 years (45-67)	60 years (47-72)	<0·0001^
No of females	334 (4·1%)	7690 (6·6%)	<0·0001*
Recurrent hernias	947 (11·7%)	7123 (6·1%)	<0·0001*
Bilateral hernias	3206 (39·5%)	8366 (7·1%)	<0·0001*
Mortality	3 (0·04%)	35 (0·03%)	0·45$
Length of stay	1 day (0-1)	1 day (0-2)	0·23£
Postoperative stay	1 day (0-1)	0 day (0-1)	0·15£
Length of stay Unilateral	0 day(0-1)	0 day (0-1)	0·26£
Postoperative stay unilateral	0 day (0-1)	0 day (0-1)	0·06£
Length of Stay Bilateral	1 day (0-2)	2 day (1-2)	0·0001£
Postoperative stay bilateral	1 day (0-1)	1 day (1-2)	0·0001£
Readmission	53 (0·7%)	995 (0·8%)	0·062*
Bleeding	61 (0·8%)	1181 (1%)	0·025*
Infection	14 (0·2%)	382 (0·3%)	0·017*
Injury to an organ	13 (0·2%)	48 (0·04%)	<0·0001*
Urinary retention	121 (1·5%)	779 (0·7%)	<0·0001*
Conversion	111 (1·4%)	N/A	

Table 1: Early results of laparoscopic versus open repair of inguinal hernia
*= Chi-square, $=Fisher exact test, £= Mann Whitney test, ^= T test

6.1.5.2 Late outcome

The overall reoperation rate following laparoscopic inguinal hernia repair (4·0%) was higher than open repair (2·1%).

The majority of operations were performed for primary inguinal hernia (117,294 patients, 93·5%). By April 2009 some 2525 (2·2%) of these patients had undergone a further inguinal hernia repair on the same side. The reoperation rate following laparoscopic as compared to open primary inguinal hernia repair was 4·1% versus 2·0%, this difference was less marked after unilateral (2·3% versus 1·9%) than bilateral primary hernia repair (6·5% versus 4·2%) as demonstrated in Table 2.

Patients who underwent surgery for a recurrent inguinal hernia were more likely to require surgery for a further recurrence (3·8%) compared to those who underwent surgery for a primary hernia (2·2%), this high reoperation rate is seen with both the open and laparoscopic techniques (3·8% versus 3·5%) as shown in Table 2.

Primary inguinal hernia repair			P VALUE (X^2)
	Reoperation	Total number	
Laparoscopic	291 (4·1%)	7161	<0·0001
Open	2234 (2%)	110111	
Unilateral primary inguinal hernia repair			
	Recurrence	Total number	
Laparoscopic	97(2·3%)	4159	0·028
Open	1899 (1·9%)	102116	
Bilateral primary inguinal hernia repair			
	Recurrence	Total number	

Laparoscopic	194 (6·5%)	3002	< 0·0001
Open	335 (4·2%)	7995	
Recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	33 (3·5%)	947	0·6
Open	272 (3·8%)	7123	
Unilateral recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	19 (2·6%)	743	0·09
Open	256 (3·8%)	6752	
Bilateral recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	14 (6·9%)	204	0·19
Open	16 (4·3%)	371	

Table 2: Reoperation following repair of inguinal hernia April 2002- April 2004

Factors associated with reoperation

Following open repair of an inguinal hernia: male sex, bilateral hernia, recurrent hernia, and postoperative infection, were all strongly associated with a need for reoperation. There was no association between consultant or trust caseload and reoperation (Table 3).

Factors		Odds Ratio	95% CI	P value
Age for every year		1.001	0.998-1.003	0..45
Hernia	Primary	1		
	Recurrent	1.920	1.686-2.185	<0.001

Gender	Female			
	Male	1.567	1.282-1.916	<0.001
Bleeding during index admission		1.000	1.000-1.000	0.12
Infection during index admission		1.983	1.194-3.291	0.008
Consultant caseload		1.000	0.999-1.001	0.703
Trust Caseload		1.000	1.000-1.000	0.740
Site of operation	Unilateral	1		
	Bilateral	1.920	1.686-2.185	<0.001

Table 3: Factors associated with reoperation following open inguinal hernia repair (binary logistic regression)

Age, consultant caseload, and presence of bilateral hernias were all factors that appeared to be important as regards reoperation following laparoscopic hernia repair (Table 4).

Factors		Odds Ratio	95% CI	P value
Age for every year		1.009	1.001-1.017	0.016
Hernia	Primary	1		
	Recurrent	0.815	0.557-1.194	0.293
Gender	Female	1		
	Male	1.113	0.557-1.194	0.747
Bleeding during index admission		0.545	0.207-1.432	0.218
Infection during index admission		1.292	0.151-11.046	0.815
Consultant caseload		0.987	0.983-0.991	<0.001
Trust Caseload		1.000	0.999-1.001	0.870
Site of operation	Unilateral	1		
	Bilateral	2.365	1.861-3.007	<0.001

Table 4: Factors associated with reoperation following laparoscopic repair of inguinal hernia (binary logistic regression)

Consultant caseload

The effect of consultant caseload on reoperation rates following laparoscopic and open hernia repair is shown in Figure 3. The reoperation rate does not alter with consultant caseload following open repair, whereas, with the laparoscopic technique there is an inverse relationship.

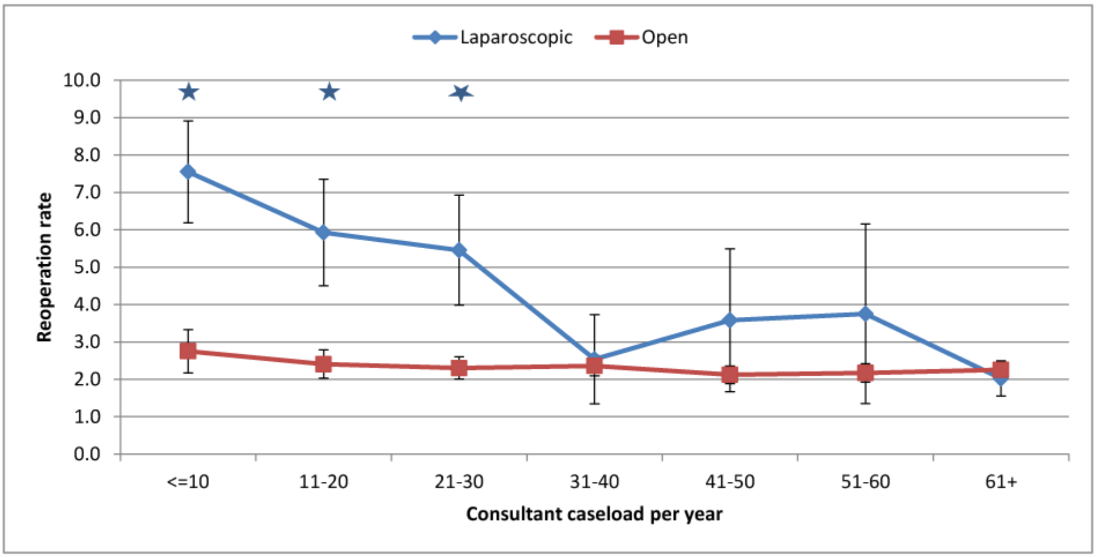

Figure 3: Consultant caseload versus reoperation rate following inguinal hernia repair

Trust caseload

There is no difference in reoperation rate following open repair of an inguinal hernia between high and low caseload trusts (Figure 4). However, trusts performing high numbers of laparoscopic repairs have the lowest reoperation rate (1%), while those with low numbers have an increased reoperation rate.

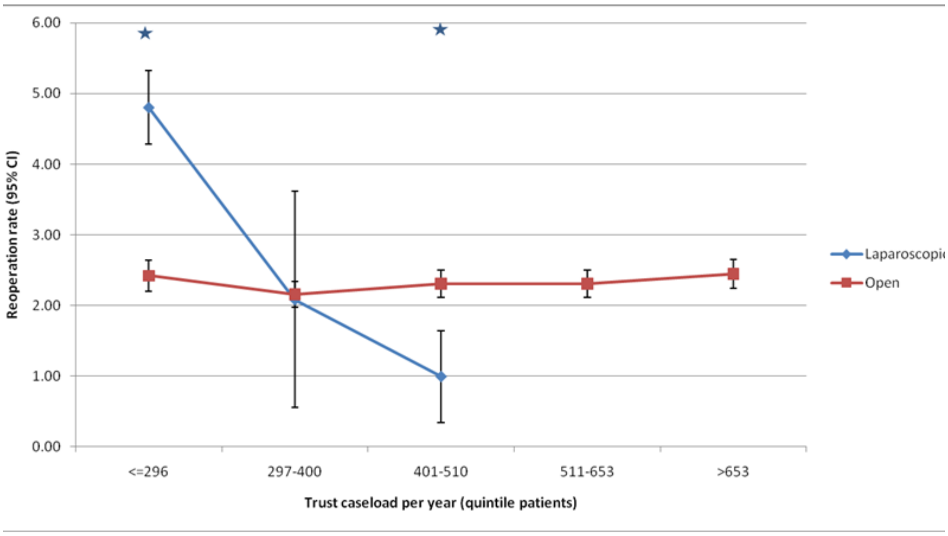

Figure 4: Trust caseload versus reoperation rate following inguinal hernia repair

If patients undergoing laparoscopic inguinal hernia repair are stratified into low, medium and high risk of reoperation, based on patient related factors and then analysed on the basis of consultant and trust caseload as shown in Table 5; patients with similar risk can be seen to have up to a fivefold difference in re-operation rate depending on where and by whom they are operated on.

Risk of reoperation	CONSULTANT CASELOAD				
	Trust load	<20	20-40	40 +	P value X^2
Low risk <2·42	<250	3.6%	3.9%	1.8%	0·029
	>250	0	6.3%	0.5	0.018
Medium risk 2·42-5·64	<250	N/A	3.5%	1.3%	0.0001
	>250	N/A	7.7%	1%	0.062
High risk 5·64+	<250	10.2%	4.7%	5.2%	0·0001
	>250	18.4%	7.7%	2.1%	0·0001

Table 5: Consultant and trust caseload versus reoperation stratified by patient risk of reoperation

Time to reoperation

The reoperation rate following laparoscopic unilateral primary inguinal hernia was higher than that following open repair during only the first year of follow up (Figure 5). There was no difference in reoperation rates following repair of a recurrent inguinal hernia repair by either a laparoscopic or open technique at any time (Figure 7).

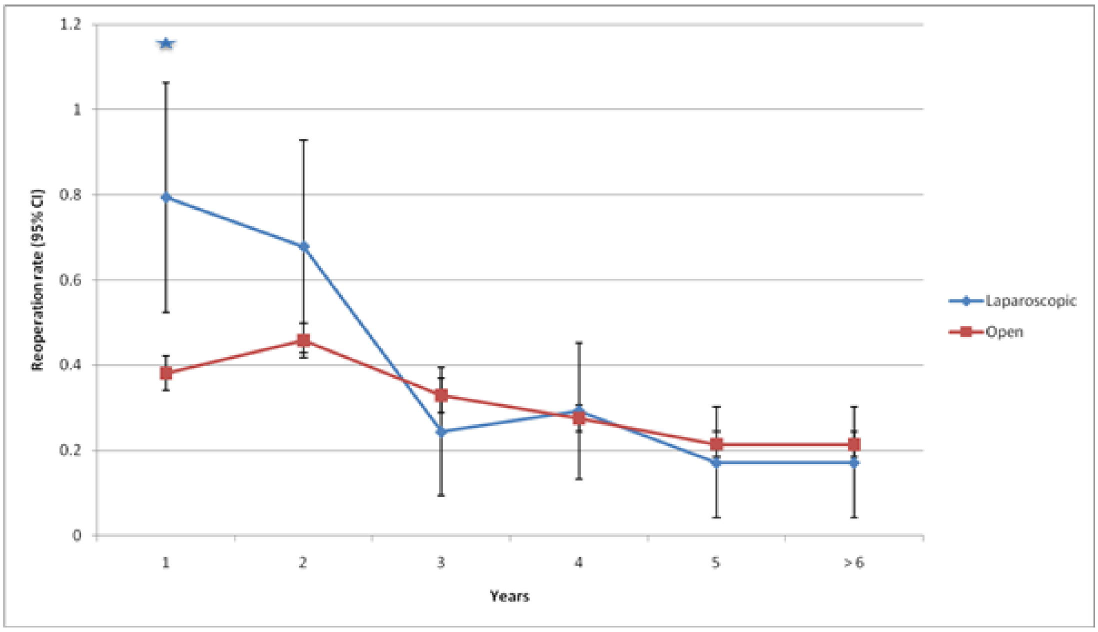

Figure 5: Time to reoperation following operation for primary unilateral inguinal hernia repair

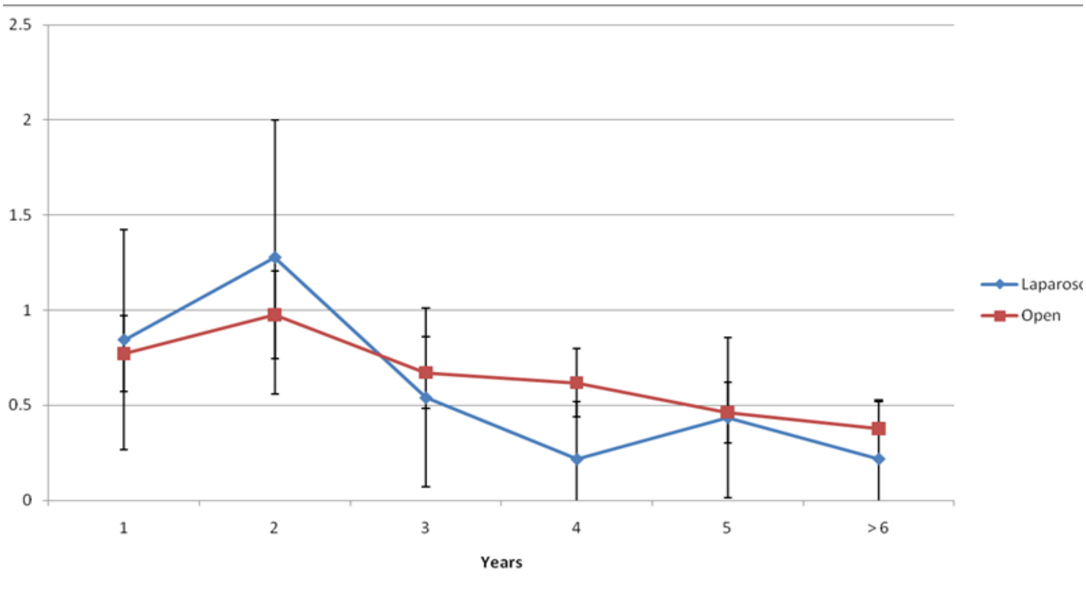

Figure 7: Time to reoperation following operation for recurrent inguinal hernia

To confirm these results with a later cohort, patients undergoing surgery between April 2006 and April 2007 were analysed in a similar manner to the initial cohort but with two further years of follow up. An increased reoperation rate following laparoscopic as compared to open repair of inguinal hernia was again seen (Table 6).

Primary inguinal hernia repair			P VALUE X^2
	Reoperation	Total number	
Laparoscopic	200 (2.5%)	8026	<0·0001
Open	684 (1.4%)	49146	
Unilateral primary inguinal hernia repair			
	Recurrence	Total number	
Laparoscopic	101(2·0%)	5067	<0·0001
Open	593 (1·3%)	45845	
Bilateral primary inguinal hernia repair			
	Recurrence	Total number	
Laparoscopic	99 (3·3%)	2959	0.184
Open	91 (2·8%)	3301	
Recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	36 (3·2%)	1125	0·688
Open	102 (3·0%)	3444	
Unilateral recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	24 (2·9%)	829	0·906
Open	87(2·8%)	3122	
Bilateral recurrent inguinal hernia repair			
	Reoperation	Total number	
Laparoscopic	12 (4·1%)	296	0·844
Open	15(4·7%)	322	

Table 6: Reoperation following repair of inguinal hernia, April 2006- April 2007

6.1.6 Discussion

This study uses national administrative data to report on the early and late outcomes of surgery for inguinal hernia in England over a two-year period with a further five years of follow-up. A unique identifier HESID has been used to follow individual patients in England for up to 7 years postoperatively to detect those who underwent surgery for recurrence and this constitutes the biggest study of outcome following surgery for inguinal hernia in the literature and reports results as they have actually occurred following the introduction of laparoscopic hernia repair in the United Kingdom.

It is, however, a retrospective study using data collected routinely by the NHS. Thus there could be differences between the groups that are being compared, causing bias, for example it is likely complex hernias will be operated on by an open technique and that the laparoscopic approach will often be used preferentially for earlier and less technically demanding hernias.

Another criticism of studies of this type is that data may not have been coded or coded incorrectly. Previous studies have shown that the accuracy of recording of diagnostic codes in England is high (median 91%), but researchers still have to recognize and account for a degree of coding inaccuracy[56]. HES data can, however, be used usefully for assessment of effectiveness, comparative audit, and equity[126].

The consultant code identifies only the consultant in charge of a patient's care. It does not necessarily identify the operating surgeon. Teams in English NHS hospitals are consultant led rather than consultant delivered. Some operations, such as inguinal hernia repair, may be undertaken by middle grade doctors or trainees working under a consultant's direct or indirect supervision. High-caseload consultants are, however, likely to be undertaking or directly supervising a large number of hernia operations. Paradoxically, assessing the results of the consultant firm rather than those of individual consultant surgeons may thus be advantageous because the former fully reflects real practice.

Increased infection and haematoma rates are seen following open as compared to laparoscopic repair, a difference which is consistent with other published studies[169, 175, 176]. Rates in this study are, however, lower and may be a result of under coding.

Urinary retention following open inguinal hernia repair reported rates vary between 0·37% and 3·0%[177]. Urinary retention rates have been shown to be higher following laparoscopic repair, 2·3% versus 1·1%[178] and up to 22·0% in a single retrospective study[179]. In this study the rate of urinary retention is increased following laparoscopic as compared to open repair (1·5% versus 0·7%).

There was no overall difference in the post-operative stay following laparoscopic and open unilateral hernia repair, but following bilateral hernia repair discharge was quicker with the laparoscopic technique suggesting an advantage for the laparoscopic technique in this regard.

Injury to an organ is rare during a hernia repair but has been reported to be higher with a laparoscopic technique[180], our study confirms this. It also shows there was no difference in mortality or readmission rate between the two techniques. Thus in terms of early outcome laparoscopic and open inguinal hernia repair would seem to be broadly comparable, with minor advantages for each technique.

Multivariate analysis shows that undergoing surgery for bilateral hernia increases the risk of reoperation with both techniques, but this is obvious as a patient with two hernias will have an increased risk of recurrence in comparison to a patient undergoing repair for a unilateral hernia. Post-operative infection may increases the chance of recurrence following open repair, but not after laparoscopic repair. This may be because infection following laparoscopic repair usually occurs at the port site of operation which is far away from the mesh.

Non-patient related factors such as technique, open versus laparoscopic, consultant caseload and trust volume also appear to be important as regards failure of an inguinal hernia repair. Specifically reoperation rates are higher following laparoscopic as compared to open repair of primary inguinal hernia. Following open repair consultant caseload appear to have no influence on reoperation rate; however, consultants who perform a large number of laparoscopic inguinal hernias have lower reoperation rates than surgeons with a low laparoscopic caseload.

Further reoperation rates are higher with the laparoscopic technique in the early postoperative years, but return to the rates seen with open repair after this. This suggests that technical failure (poor placement of mesh, fixation of mesh, small mesh, or small pocket to place the mesh) at the time of laparoscopic inguinal hernia repair may be the cause of a recurrent hernia in these patients and is consistent with general perception of surgeons that laparoscopic repair is technically more demanding than the open technique.

Studies have suggested that surgeon experience is related to hernia recurrence following laparoscopic repair,[168, 181] and it may be argued that the results of laparoscopic repair have improved with increasing laparoscopic experience. However, when a cohort of patients undergoing repair of an inguinal hernia in 2006 were analysed, the re-operation rate following laparoscopic repair (2·5%) was still significantly higher than open (1·3%) repair (Table 6).

It is interesting that no differences were seen in reoperation rate following repair of a recurrent hernia by the open or the laparoscopic route. It is therefore clear that open surgery is as effective as laparoscopic surgery for the treatment of recurrent inguinal hernia and this is consistent with the latest meta-analysis[169].

This study demonstrates that reoperation rates are higher following laparoscopic as compared to open repair of primary inguinal hernia, but we would suggest that they do not show laparoscopic technique is inferior to the open procedure, as reoperation rates from high caseload surgeons undertaking laparoscopic repair of inguinal hernia are similar to those seen following open surgery. Similarly, results from units undertake a large number of laparoscopic hernia repairs are as good as and possibly better than those seen following open surgery. Further we have not been able to assess other advantages of laparoscopic repair such as early return to work[182-185] and a reduced incidence of post-operative pain[185-187]. We would, however, suggest that these results provide powerful evidence for specialisation of surgeons undertaking laparoscopic repair of inguinal hernia together with the development of dedicated units.

Early outcome following open and laparoscopic repair of inguinal hernia is broadly similar. Reoperation is, however, more common with the laparoscopic approach and may be due to early failure in patients operated on by low caseload surgeons. These results provide evidence for increased specialisation of surgeons undertaking laparoscopic repair of inguinal hernia.

7 Can HES data be used to measure changing trends in surgical practice?

Over the last 30 years surgical practice has changed considerably and continued to evolve. New surgical techniques are always under development. Some procedures get popular and become the standard of care such as laparoscopic cholecystectomy and other techniques become popular for a period of time then loose its momentum and eventually fades away when other procedures developed. In order to plan for future service and train future surgeons, it is always important to know the current practice and predict the future changes. This will help health care providers to identify specific skills needed when they appoint new surgeons.

HES data is available and not expensive. It can be used to assess the practice and measure the changing trends in surgery. This will help develop future service and advice planner about the results of surgery and the need to train future surgeon and the skills required when appointing new surgeons by health care providers.

Rectal prolapse is a common surgical problem but the exact incidence is not known. While some patients may benefit from conservative management, surgical repair is the only definitive treatment. Surgery for rectal prolapse is divided into abdominal and perineal repair. The former is subdivided into open and laparoscopic approach. All surgical techniques can be divided into resection and fixation. The study will illustrate how these approaches changed over the years and what is their outcome.

7.1 Epidemiological trends in surgery for rectal prolapse in England 2001-2012

This paper was submitted for publication during thesis writing. The reviewers requested a number of changes which lead to minor amendment to this version. The published paper is attached as appendix 1.

7.1.1 Abstract

Background:

The UK incidence of rectal prolapse is uncertain and there is little international consensus about best surgical management. This study analysed trends in admission and surgery for rectal prolapse in adults in England between 2001 and 2012 as well as prolapse reoperation rates.

Methods:

Analysis of data derived from a comparative longitudinal population-based cohort study using Hospital Episode Statistics.

Results:

During the study period, a total of 25,238 adults underwent a total of 29,379 operations for rectal prolapse (mean 2,670 per annum) [median age 73 years (IQE 58-83) years; female to male ratio: 7:1]. Median LOS was 3 days (IQR 1-7) with an overall in-hospital mortality rate of 0.9%. Numbers of total admissions (2001: 4,950 vs. 2012: 8,927) and of patients undergoing prolapse surgery (2001: 2,230 vs. 2012: 2,808) significantly increased ($P < 0.001$ for trends) throughout the study period. The overall increase in surgery (up about 1/3rd overall and 44% for elective) was dwarfed by an increase in popularity of laparoscopic surgery (increased 15-fold during the period). Overall prolapse reoperation rate (as a surrogate of recurrence) was 12.7%. The lowest recurrence rate was observed for elective open resection (9.1%) but this had the highest

mortality (1.9%) Laparoscopic and perineal fixations were also associated with low reoperation rates (<11%) but lower mortality rates of approx. 0.3% for elective surgery. The data refute a trend toward subspecialisation (by surgeon or hospital) during the study period.

Conclusions:

Admissions for rectal prolapse increased in England between 2001-2012 with parallel increases in surgery. Surgical decision making has changed over the period and may be reflected in the outcome.

7.1.2 Introduction

Rectal prolapse is an uncommon but highly morbid condition in which a full-thickness intussusception of the rectal wall extrudes through the anal canal[188-190]. The only potentially curative treatment is surgery with exceptions being patients considered medically unfit for surgery and those with minor degrees of prolapse. Over 100 operations for rectal prolapse repair have been described and none has achieved primacy following attempts to provide high quality evidence[20]. Rectal prolapse can be repaired via the abdomen or perineum with several alternatives for each described. Abdominally, posterior rectopexy (sacral fixation of the rectum) is generally considered to have a low recurrence rate but may result in poor function especially constipation[191]. Alternatively, the rectum may be fixed with concomitant segmental colonic resection (resection rectopexy) but there is a risk of anastomotic leak 1-5.9%[192, 193] even though some data suggest it has the lowest recurrence rate[20]. Perineal approaches (principally Delormes and Altemeier's) are less invasive and are considered a better option for elderly and medically unfit patients. However these may have higher recurrence rates 10 -30% compared to 0-11% for rectopexy[194].

Laparoscopic rectopexy was first reported in 1992 by Berman and has re-popularised the abdominal approach[195]. Laparoscopic ventral mesh rectopexy (LVMR) uses an anterior rectal dissection with fixation of the anterior rectal wall to a mesh, which is then anchored to the sacrum. The operation theoretically preserves pelvic nerves avoiding the 'rectal inertia' caused by posterior dissection and reportedly better functional outcome [196]. Several large series have now been published suggesting low recurrence rates and lower short-term morbidity[197-199], however this operation has recently become the subject of media scrutiny in relation to long-term complications from the use of pelvic mesh in general[200, 201].

The current study evaluated trends in surgery for rectal prolapse in England from 2001 to 2012 with a focus on type of operation performed and estimates of recurrence based on incidence of re-operation.

7.1.3 Methods

7.1.3.1 Data sources

Hospital Episode Statistics (HES) data were obtained from the National Health Service Information Centre (NHSIC) and imported into Microsoft SQL server. All patients admitted with rectal prolapse over an 11-year period (April 2001 and March 2012) were identified by searching the primary diagnostic codes (K622 for anal prolapse and K623 for rectal prolapse) using the International classification of Diseases Version 10 (ICD 10). Data were then imported into Microsoft Access [Microsoft Corp. USA] for analysis. Patients who underwent surgery for rectal prolapse were then selected by searching the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (4th revision) codes (OPCS-4). Codes used are listed in table 1. Patients under the age of 16 were excluded from analysis.

Open fixation	H35 or H36	
Open resection	H04, H05, H09, H10, H33, H29	except H337
Laparoscopic surgery	Y75 or Y508	
Conversion codes	Y714 or Y718	
Perineal fixation	H421, H422, H423, H425, H426, H428, H429, H414	
Perineal resection	H337, H411, H415	

Table 1: Operative codes for surgery (OPCS4)

Patients were subdivided by type of surgical repair into 6 categories using OPCS codes. Open fixation, open resection, laparoscopic fixation (laparoscopic codes plus open fixation), laparoscopic resection (laparoscopic codes plus open resection), perineal fixation, and perineal resection. Codes for each group are described in suppl. table 1. Laparoscopic repair was identified by searching all operative codes for Y75* or Y508* using the OPCS code 4. Converted cases were included with the laparoscopic approach by searching for the codes Y714* or Y718*. Patients were then subdivided into elective and emergency repair by mode of admission using the “admimeth” field to identify how the patient was admitted to hospital (for elective admissions: numbers 11, 12, and 13; and for emergency admission: numbers 21, 22, 23, 24).

Patients identified as having surgery within the 11 year period were followed up until March 2012 using HESID to investigate any who underwent further rectal prolapse procedures (as a surrogate for recurrence). The HES ID is a unique identifier for every patient that is calculated using NHS number, local hospital number and date of birth. Using HESID permitted follow-up of patients across time and place and was used to calculate reoperation rate for each surgical procedure type. In addition, Consultant caseload was identified by searching all patients who underwent surgery by a specific consultant per year. The “Pconsult” code is a pseudo-anonymised code for each consultant based on their GMC number that permitted identification of individual caseloads. Similarly, hospital surgical volumes were calculated by searching the “SiteTreat” field.

7.1.3.2Data analysis

Data have been presented descriptively with summary statistics based on data distribution. Population statistics were derived from Office of National Statistics census 2011 [202] to allow incidence rates per 100,000 population to be calculated for both rectal prolapse admission and rectal prolapse surgery. Limited statistical analyses were performed for time trends using regression of moving averages. All analyses were performed using SPSS version 18·0 (SPSS, Inc., Chicago IL).

7.1.4 Results

Tables 2 and 3 [Figure 1] show the main results by year from 2001 to 2012 with 25,238 adult patients undergoing a total of 29,379 operations for rectal prolapse over this period (mean 2,662 per annum). There were obvious upward trends (P<0.001 for both) in total numbers of patients admitted and of those undergoing surgery of any type for rectal prolapse over this time.

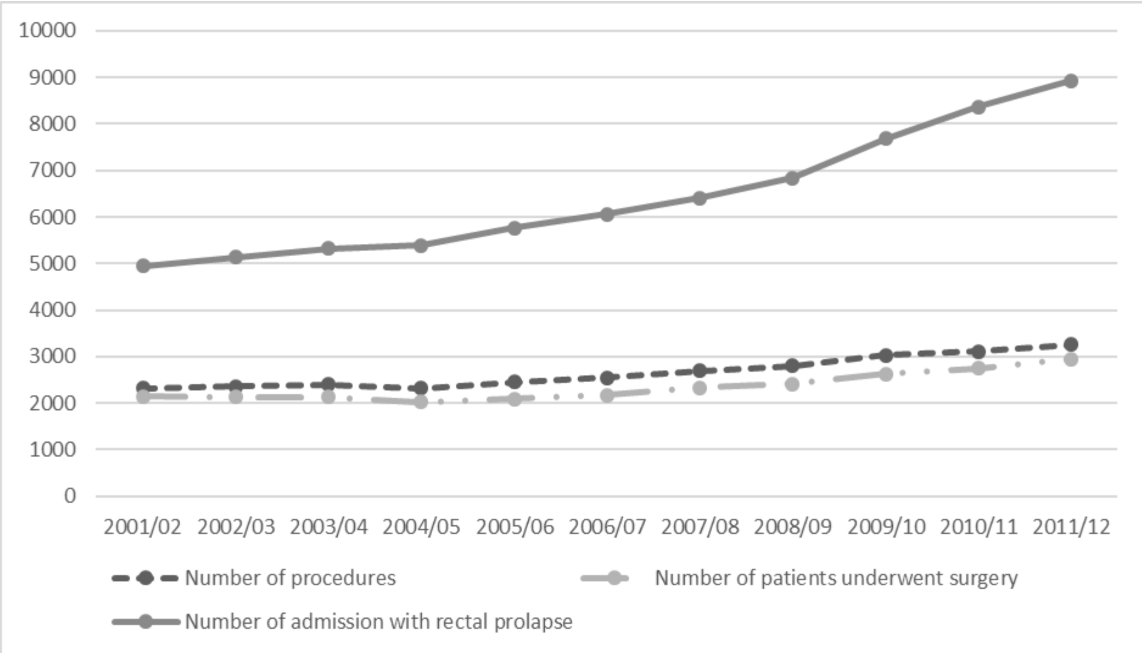

Figure 1: Trend of total number of admissions of rectal prolapse and patients underwent surgery and total number of procedures per year.

The number of patients admitted to hospital with rectal prolapse in 2011 was 8,927 providing an annual incidence rate of 18.5 per 100,000 for this year; 2,808 underwent rectal prolapse surgery providing a statistic of 6.1 per 100,000 per year. For patients over the age of 75, these rates were much higher (106 per 100,000 and 31 per 100,000 per year respectively). Over the same time period, population statistics showed the English population increased by about 3.9 million (8.0%) from around 49.1 million in 2001 to 53 million in 2011[203]. The number of people over the age of 65 years increased by 851,000 (10.9%) for England over the same period. Nevertheless, patient age at surgery remained remarkably constant (median 73 years) over the same period.

Year	Total admissions	Total pts undergoing surgery	Total surgical procedures	Total surgeons	Procedures / surgeon: median (IQR)	Total hospitals	Procedures / hospital: median (IQR)	Age: median (IQR)
01/02	4,950	2,230	2,320	384	4 (3-7)	195	8 (5-13)	73 (58-82)
02/03	5,135	2,085	2,352	391	4 (2-6)	185	8 (4-13)	73 (57-82)
03/04	5,322	2,102	2,404	408	4 (3-6)	200	8 (5-12)	73 (58-82)
04/05	5,389	1,988	2,321	417	4 (2-6)	197	9 (5-14)	73 (59-81)
05/06	5,763	2,060	2,451	432	4 (3-6)	212	10 (6-13)	73 (59-82)
06/07	6,058	2,162	2,543	461	4 (3-6)	186	9 (5-14)	74 (61-84)
07/08	6,411	2,251	2,612	487	4 (2-6)	192	10 (6-15)	73 (59-82)
08/09	6,838	2,404	2,798	483	4 (2-6)	191	10 (5-15)	73 (59-81)
09/10	7,685	2,532	3,031	518	4 (3-6)	200	11 (6-17)	73 (58-83)
10/11	8,371	2,616	3,159	521	4 (2-7)	222	11 (5-16)	73 (58-83)
11/12	8,927	2,808	3,293	533	4 (2-7)	222	11 (5-17)	73 (58-83)

Table 2: Trends in numbers of admissions and procedures for rectal prolapse 2001-2012.

The number of operations performed per year increased by approximately one third from 2,320 in 2001 to 3,253 in 2011. The number of surgeons providing rectal surgery for prolapse increased from 384 in 2001 to 533 surgeons in 2011/2012 keeping the median number of operations performed by individual consultants relatively static at only 4 (IQR 2-7) per year. The number of hospitals providing rectal prolapse surgery increased marginally from 195 in 2001 to 222 in 2011 with a median increase in number of surgeries/hospital/per year from 8 (IQR 5-13) to 11 (IQR 5-17) in the final year of data analysis. Females were seven times more likely to undergo surgery for rectal prolapse compared to males. Median length of stay (LOS) was 3 days (IQR 1-7). Overall in-hospital mortality rate was 0.9%. Just over 10% of the operations (2,692/25,238 patients, 3,063/29,379 procedures) were performed as an emergency.

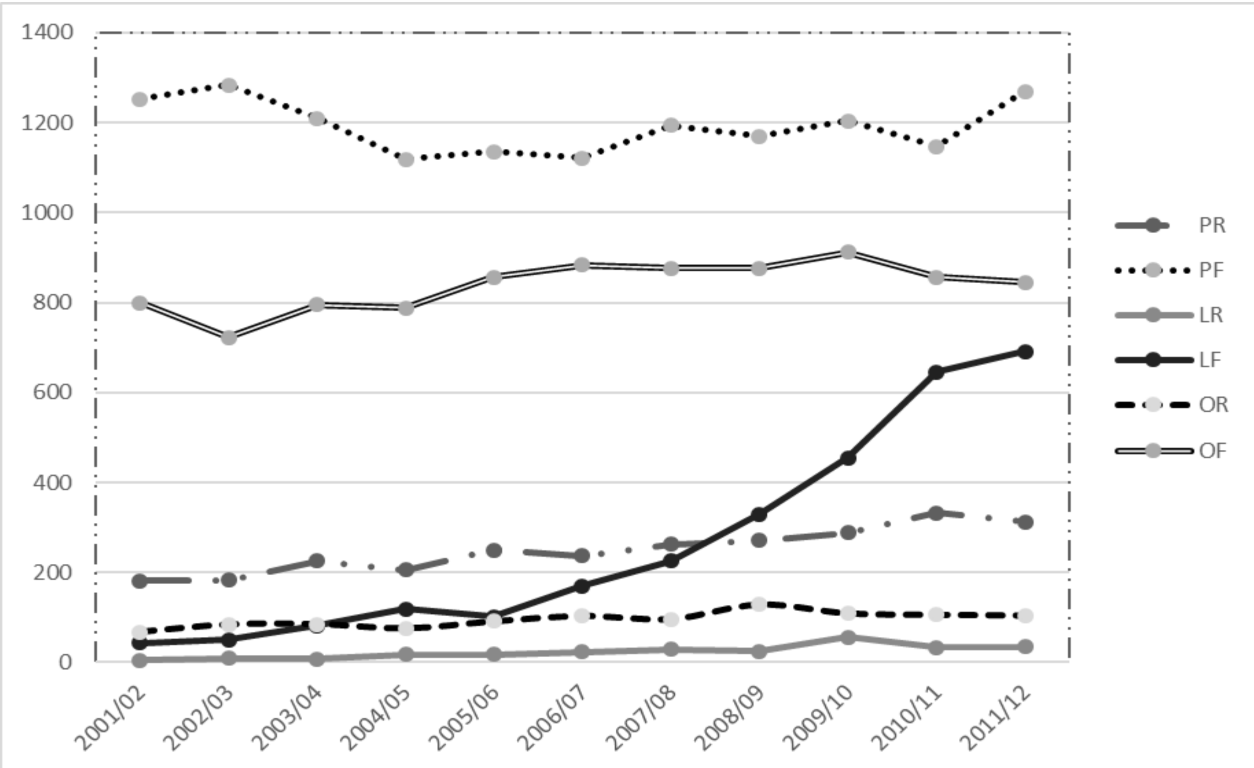

Figure 2: Trend of surgical procedures for rectal prolapse

Over the 11-year study period, perineal fixation remained the most popular surgical approach for both elective or emergency rectal prolapse repair [Table 3, Figure 2].

However, the number of patients undergoing laparoscopic surgery (repair/resection) increased more than 15-fold from only 48 (2.1% of total cases) in 2001/02 to 725 operations (22.3% of total) in 2011/12. Over the whole time period, patients selected for laparoscopic surgery were significantly younger than patients selected for other types of surgery with a mean age of 67 years (IQR 52-79) [Figure 3]. In contrast, older patients were more likely to be offered perineal resection: median age 81 years (IQR 73-86). In the final year of data analysis, the mean age for laparoscopic surgery was 65 years (IQR 50-78).

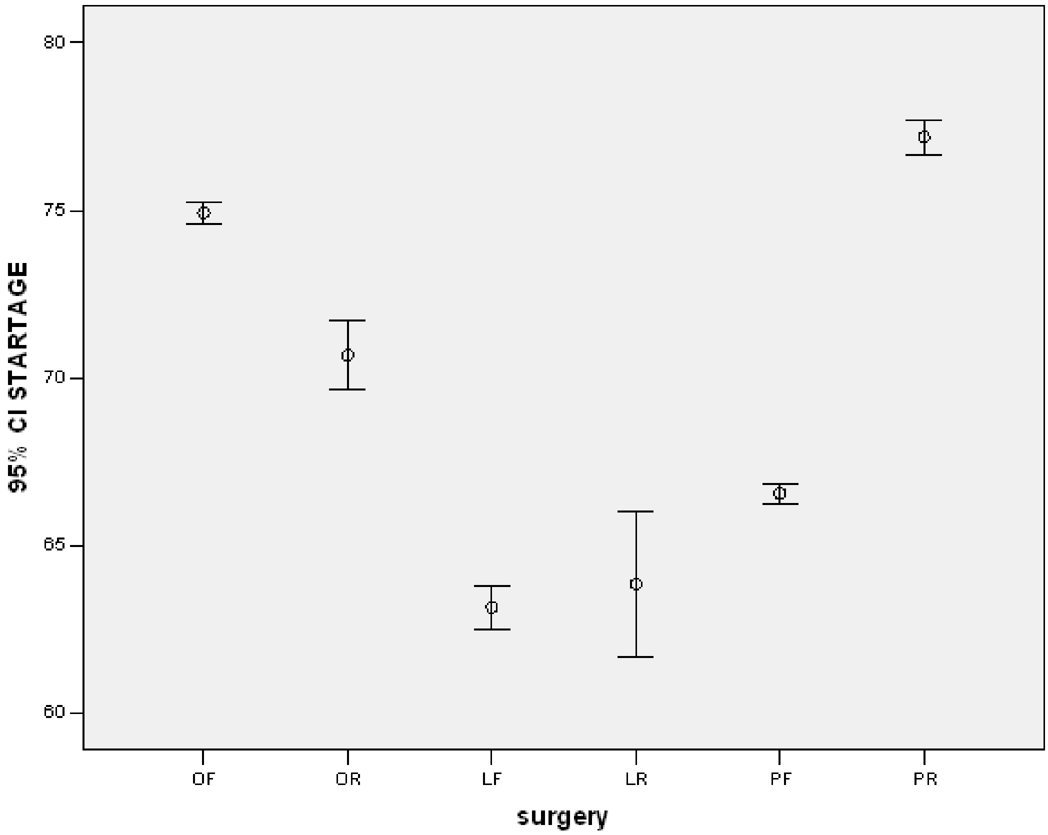

Figure 3: Mean age and 95% CI range for surgical repair

Elective surgery for rectal prolapse was associated with a significant shorter hospital LOS as compared to emergency surgery for all types of surgical repair [table 2]. Laparoscopic and perineal fixations were associated with the shortest hospital stay. Elective surgery was also associated with significant lower mortality rate (0.5%)

compared to emergency surgery (2.5%). Patients who underwent open resection were at higher risk of death compared to other types of surgical repair with a mortality of 14.7% in the emergency setting and 3.4% in the elective setting. Elective laparoscopic and perineal fixations were associated with the lowest mortality of just 0.3%.

Type of repair	Total patients	Total procedures	Age: median (IQR)	LOS: days median (IQR)	Total deaths (%)	Total reoperation (%)	% change total procedures 2001 to 2012
Open fixation	7,838	7,919	78 (68-85)	4 (2-7)	49 (0.6)	1279 (16.3)	+ 9%
Open resection	774	886	75 (58-82)	7 (4-11)	15 (1.9)	70 (9.1)	+ 56%
Lap fixation	2,303	2,780	65 (50-77)	3 (2-4)	7 (0.3)	244 (10.4)	+ 1,624%
Lap resection	179	248	67 (51-77)	6 (4-9)	1 (0.6)	19 (10.6%)	+ 660%
Perineal fixation	9,804	11,965	68 (54-79)	1 (0-4)	26 (0.3)	979 (9.9)	+ 4%
Perineal resection	1,548	2,322	80 (72-85)	4 (2-6)	10 (0.7)	262 (16.9)	+ 170%
Total all procedures	22,446	26,120	72 (57-82)	3 (1-5)	109 (0.5)	2853 (12.7)	+ 44%

Table 3: Data by type of procedure for whole time period
A: Elective procedures

Using HESID-derived data, 3,241 (12.8%) patient underwent reoperation for rectal prolapse. The majority (2622; 80.9%) underwent one further surgery; 489 (15.1%) underwent two further surgeries and a small proportion (n = 99; 3.1%) underwent three or more further procedures. Procedure type influenced reoperation rate [Table 3] with open resection rectopexy having the lowest reoperation rate (9.1% elective and 4.3% emergency) compared to higher rates for perineal resection (16.9% elective and 13.7%

emergency) and open fixation (16.3% elective and 14.3% emergency). Laparoscopic fixation had an intermediate outcome in terms of re-operation (10.4% elective and 13.3% emergency).

Type of repair	Total patients	Total procedures	Age: median (IQR)	LOS: days median (IQR)	Total deaths (%)	Total reoperation (%)	% change total procedures 2001 to 2012
Open fixation	1,023	1,093	84 (79-87)	14 (8-22)	26 (2.5)	146 (14.3)	-13%
Open resection	164	164	82 (75-88)	15 (9-28)	23 (14.0)	7 (4.3)	+ 50%
Lap fixation	113	132	81 (77-85)	11 (6-22)	4 (3.5)	15 (13.3)	+ 1,250%
Lap resection	3	7	706 (64-92)	29 (16-31)	0 (0)	1 (33.3)	+100%
Perineal fixation	1,198	1,344	82 (75-88)	13 (5-21)	24 (2.0)	129 (10.7)	-25%
Perineal resection	291	424	84 (82-86)	12 (8-21)	12 (4.1)	40 (13.7)	+ 189%
Total all procedures	2,792	3,164	83 (77-83)	13 (7-23)	89 (3.2)	338 (12.1)	+ 4%

Table 3: Data by type of procedure for whole time period

B: Emergency cases

7.1.5 Discussion

To our knowledge, we present the largest dataset to date of patients undergoing surgery for rectal prolapse with over 25,000 patients included. Several findings merit discussion: (1) the incidence of rectal prolapse and surgical repair increased year on year between 2001 to 2012 at a rate greater than that anticipated by population growth alone; (2) there appears to be little evidence of subspecialisation for rectal prolapse surgery with unchanged and low numbers of procedures per surgeon per annum; (3) laparoscopic fixation has increased dramatically in popularity over the period and this procedure has favourable outcomes in terms of LOS, mortality and reoperation compared to several other procedures; (4) there is no compelling evidence of superiority of abdominal procedures over perineal in general; and (5) data confirm the previous assertion of higher risk but lower reoperation (recurrence) rate after resection rectopexy[204].

The reported incidence of rectal prolapse in our study was 18.5 per 100,000 per year which is much higher than a previous report of only 2.5 per 100,000 in a Finnish population [205]. The overall in-hospital mortality rate for all types of surgery was less than 1% which is comparable to the reported mortality in the literature 0 – 6.5%[206-209]. Reported recurrence rates in the literature vary from 3- 33%[209-212] depending on type of surgical repair and length of follow up. Our overall reoperation rate was approximately 12% for both elective and emergency cases.

There are several limitations to this study. The study used the HES database which contains administrative data reliant on the accuracy of clinical coding. A recent systematic review shows coding accuracy is improving and following the introduction of payment by results in 2002 the accuracy of coding for primary diagnoses has improved from 73.8% (IQR: 59.3-92.1%) to 96.0% (IQR: 89.3-96.3)[127]. It has been suggested that researchers should consider the context of conclusions that are drawn from HES data. If findings are of a general nature, then even a relatively high coding error rate at some hospitals or even all hospitals will not detract markedly from the overall conclusions if significant deviation can be shown[147, 148]. Thus, studies based on HES data may actually be good at dealing with research questions such as those posed in this study but are less good at identifying variations in care between individual trusts or clinicians[148]. Another limitation of this study was the use of reoperation rate rather than actual recurrence rate. Thus some patients who had recurrence but declined (or were unfit) for further repair will not have been included in the analysis. This indicates that recurrence rates might be underestimated in this study. Finally, we acknowledge the time expiration on the data presented (only up to 2012). While, sometimes it is normal for HES data to be presented several years after initial entry[213, 214], our data are now 7 years old. We do however feel that these still have value in understanding trends in surgical strategy, lack of subspecialisation / centralisation to at least this point in time and in providing surrogate outcomes on much larger numbers of patients than for instance widely cited single centre cohort studies and an under-recruited trial from the same time period[20].

In summary, this population-based cohort study demonstrates an increasing trend in both numbers of admissions and operations for rectal prolapse over the studied decade. Despite there being little or no evidence of service centralisation, there has been a significant change to laparoscopic fixation during this period and this operation appears safe with acceptable reoperation rates.

8 *Can HES data be used to measure adherence to national guidelines?*

National guidelines are written by national bodies to advice health care providers about the effective model of care. They are very important to keep a consistent and safe standard of care provided to patients. It also helps managers at health care providers to bench mark their service and costs.

In this chapter HES data is to be examined to assess the feasibility of using HES data as a national tool to monitor adherence to national guidelines. HES will be used to monitor the national adherence to the national guideline for definitive management of acute gallstone pancreatitis. The study will also assess the benefit of the national guideline if they were adhered to.

Acute gallstone pancreatitis is a common surgical emergency. These patients are at risk of readmission with the same problem if they didn't undergo definitive management. The British Society of Gastroenterology guideline recommends that these patients should undergo definitive management within acute admission or within 14 days of discharge[62]. The definitive management of gallstone pancreatitis is defined as the removal of gallbladder in terms of Cholecystectomy or if the patient is not fit for surgery to undergo endoscopic sphincterotomy of the ampulla of Vater. In order to investigate whether hospitals are following this guideline or not, a national audit has to be completed. Such an audit is feasible but is resource and labour intensive.

8.1 Definitive management of Gallstone pancreatitis in England

8.1.1 ABSTRACT

Aim:

The aim of this study was to investigate whether definitive treatment of gallstone pancreatitis (GSP) by either cholecystectomy or endoscopic sphincterotomy in England conforms with British Society of Gastroenterology (BSG) guidelines and to validate these guidelines.

METHODS:

Hospital Episode Statistics data were used to identify patients admitted for the first time with GSP between April 2007 and April 2008. These patients were followed until April 2009 to identify any who underwent definitive treatment or were readmitted with a further bout of GSP as an emergency.

RESULTS:

A total of 5,454 patients were admitted with GSP between April 2007 and April 2008, of whom 1,866 (34.2%) underwent definitive treatment according to BSG guidelines, 1,471 on the index admission. Patients who underwent a cholecystectomy during the index admission were less likely to be readmitted with a further bout of GSP (1.7%) than those who underwent endoscopic sphincterotomy alone (5.3%) or those who did not undergo any form of definitive treatment (13.2%). Of those patients who did not undergo definitive treatment before discharge, 2,239 received definitive treatment following discharge but only 395 (17.6%) of these had this within 2 weeks. Of the 505 patients who did not undergo definitive treatment on the index admission and who were readmitted as an emergency with GSP, 154 (30.5%) were admitted during the 2 weeks immediately following discharge.

CONCLUSIONS:

Following an attack of mild GSP, cholecystectomy should be offered to all patients prior to discharge. If patients are not fit for surgery, an endoscopic sphincterotomy should be performed as definitive treatment.

8.1.2 Introduction

Acute pancreatitis is associated with considerable morbidity and mortality[215-217]. Gall stones are the aetiological factor in 30 to 50% of cases[216, 218, 219]. Stones less than 5 mm in diameter, a wide cystic duct, and a longer common channel between the bile and pancreatic duct are predisposing factors[220].

United Kingdom guidelines for the management of GSP were first published by the British Society of Gastroenterology (BSG) in 1998[221] and then amended in 2005[222]. These guidelines suggest that all patients with mild GSP should be offered the following programme:

On index admission if the condition is not severe (necrotising pancreatitis) and the patient is clinically fit for surgery cholecystectomy should be performed

On index admission if the condition is not severe (necrotising pancreatitis) and the patient is not fit for surgery, then endoscopic sphincterotomy (ES) should be performed.

If the above two condition are met and the patient is discharged then the appropriate treatment should be carried out within 2 weeks of discharge.

Following severe GSP, the guidelines suggests cholecystectomy should be delayed until a patient is fully recovered.

Patients with predicted severe GSP or with cholangitis should have an early ES as part of their initial management[223-225] in addition to the routine treatment of GSP.

Published studies suggest that adherence to the BSG guidelines in the UK is variable, and compliance with the guideline varies from 6.6% to 89%[226-229]. While in the US it is 50%[230]. There are no national data available on the definitive treatment of gall stones following an attack of GSP or on readmission/mortality rates amongst patients in whom there was a delay in definitive management.

The evidence of the appropriate timing of definitive treatment following discharge is not well established, one study found that 31% of recurrent GSP occurred in the first 2 weeks following discharge[231], but another suggests that this figure is 6.5%. A further study suggests that performing definitive treatment during the index admission increases the length of hospital stay.

Our study investigated current practice and compared this against the definitive treatment of GSP in England as recommended by the BSG guidelines[62]. It also investigated the effectiveness of cholecystectomy and ES in preventing a further attack of GSP and the consequences of delayed treatment.

8.1.3 Method

Hospital Episode Statistics (HES) data for the financial year April 2007 to March 2008 were imported into Microsoft SQL server for analysis. HES contain information on all patients treated in England in National Health Service (NHS) hospitals and those NHS patients treated in the private sector. Patients admitted with gallstones and acute pancreatitis as an emergency was identified by searching the admission method, diagnostic and operative fields.

To identify an emergency admission the method of admission was searched for codes 21, 22, 23, 24 and 28. The International Classification of Diseases (ICD-10) codes K85* and K80* were used to identify acute pancreatitis and cholelithiasis respectively. Operative procedures were identified using the Office of Population Censuses and

Surveys (OPCS-4) codes: J18* was used to identify cholecystectomy and J38* to identify ES. Individual patients were followed across time and place using 'HESID', a unique number generated by combination of the patient's NHS number, local patient identifier, postcode, sex and date of birth.

The index cohort consisted of patients admitted as an emergency for the first time with GSP between April 2007 and April 2008. Any patients admitted with GSP or who had an intervention (ES or cholecystectomy) between April 2005 and April 2007 were excluded from this cohort. The cohort was followed until April 2009 (median duration: 18 months, range: 12–24 months) to identify those who underwent cholecystectomy or ES or those who were readmitted with GSP as an emergency.

If the patients didn't undergo definitive treatment during index admission, then the time to definitive treatment was defined as the time from discharge until ES or cholecystectomy was performed. If a patient underwent ES and cholecystectomy, the date of the first treatment was used. If a patient was readmitted with a further bout of GSP as an emergency, the time from initial discharge until the first emergency readmission was used as the time until the second attack. Patients were stratified into four groups based on LOS. All statistical analyses were performed using SPSS® version 18.0 (SPSS, Chicago, IL, US).

8.1.4 Results

A total of 5,878 patients were admitted as an emergency with acute GSP between April 2007 and April 2008. After excluding patients who had been admitted with GSP or who had undergone a cholecystectomy/ES during the period April 2005 to April 2007, 5,454 patients remained for the final analysis (Fig 1).

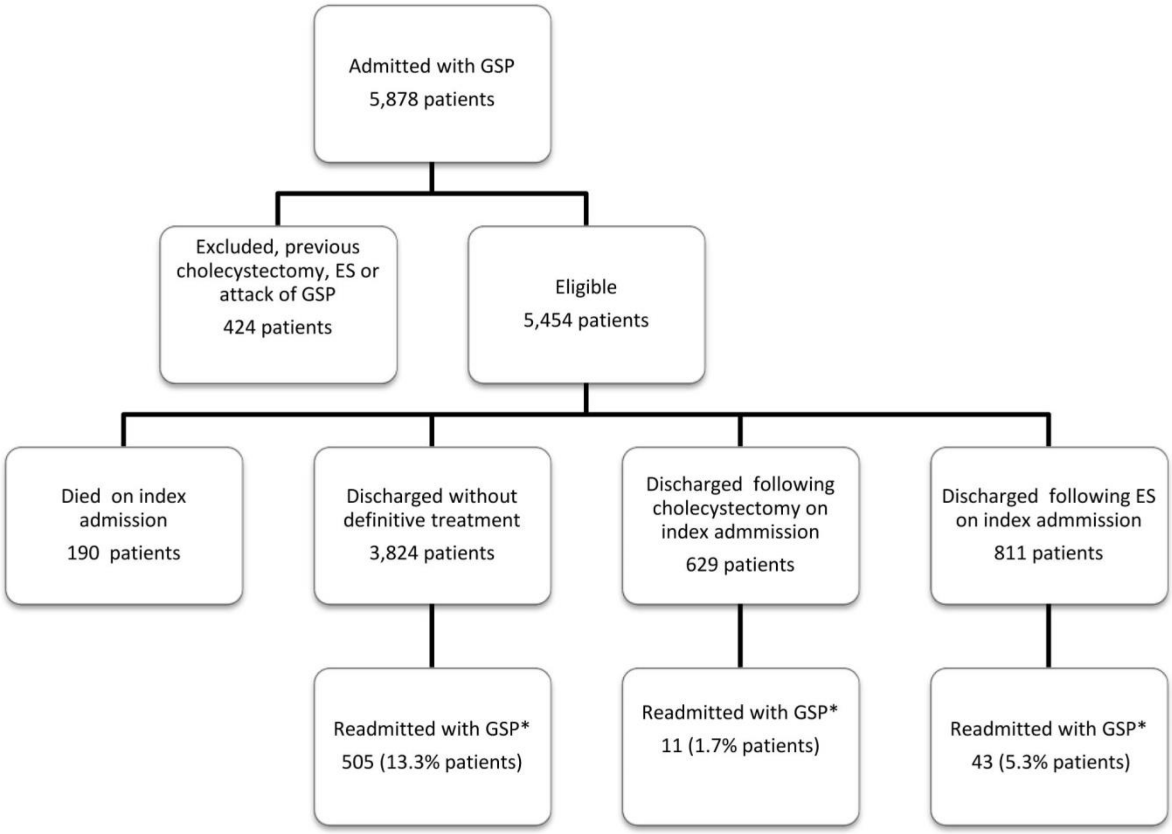

Figure 2 Study flowchart

The median age of the cohort was 63 years. Women were nearly twice as likely to be admitted with GSP as men and the median LOS was one week. During the index admission, 190 patients (3.5%) died. Of these, 25 had already undergone an ES, 6 a cholecystectomy and 159 no definitive treatment. The median number of patients admitted with GSP to each NHS trust was 35 patients per year (interquartile range [IQR]: 25–51) (Table 1).

The majority (4,105 patients) underwent definitive treatment either within BSG guidelines (n=1,866) or at a later date outside the guideline(n=2,239). Two-thirds (n=2,706, 65.9%) underwent a cholecystectomy while 713 patients (17.3%) had an ES and 686 (16.7%) underwent both procedures. Patients who underwent a cholecystectomy (median age: 56 years, IQR: 39–68 years) were significantly younger than those who underwent an ES alone (median age: 78 years, IQR: 69–84 years) and those who did not undergo definitive treatment (median age: 72 years, IQR 56–83 years). On the index admission, 1,471 patients underwent definitive treatment. Of those who were discharged, 811 underwent an ES alone and 629 a cholecystectomy (28 of these underwent both an ES and a cholecystectomy).

Number of patients	5454
Age, median (IQR)	63 years (45-76)
Gender M: F	1:1.73
Length of stay, median (IQR))	7 days (4-12)
In-hospital mortality	190 patients (3.5%)
Admissions per Trust, median (IQR)	34 patients (24—51)
Number receiving definitive treatment on the index admission	1471
Number receiving definitive treatment during study period	4105
Readmission as an emergency with GSP	559
Deaths following readmission	22
Readmissions with GSP, median (range)	1 (1-3)

Table 3 Demographics of patients admitted with GSP during the year April 2007 until April 2008 and followed until April 2009.

A total of 559 patients, 505 of whom had not undergone definitive treatment on the index admission, were readmitted 655 times with a further attack of GSP by April 2009 (median number of readmissions: 1, range: 1–3 readmissions) and 22 patients (3.9%) died following a readmission with GSP (Table 1). Patients who underwent a cholecystectomy during the index admission had a significantly lower readmission rate (1.7%) compared with those who underwent an ES alone (5.3%) and those who did not have any form of definitive treatment during the index admission (13.2%) as shown in Fig 2.

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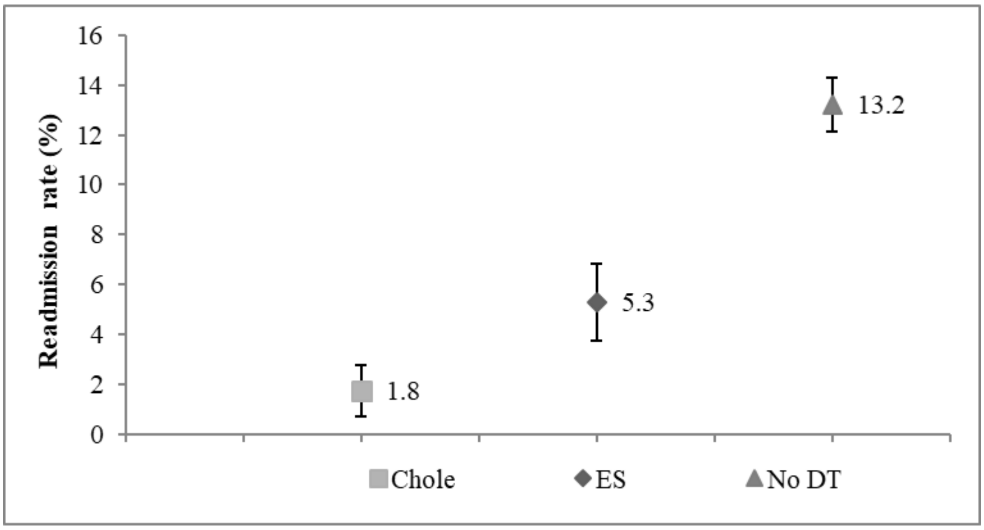

Figure 2 Re-admission rate following definitive treatment mean and confidence interval.

Approximately a third of patients (n=1,866, 34.2%) underwent definitive treatment according to BSG guidelines (ie on the index admission or within two weeks of discharge). The majority of these patients (n=1,471) had definitive treatment during the index admission. Of the 3,824 patients discharged without definitive treatment, only 10.3% underwent definitive treatment within the next two weeks and only 32.4% had undergone definitive treatment by eight weeks (Fig 3).

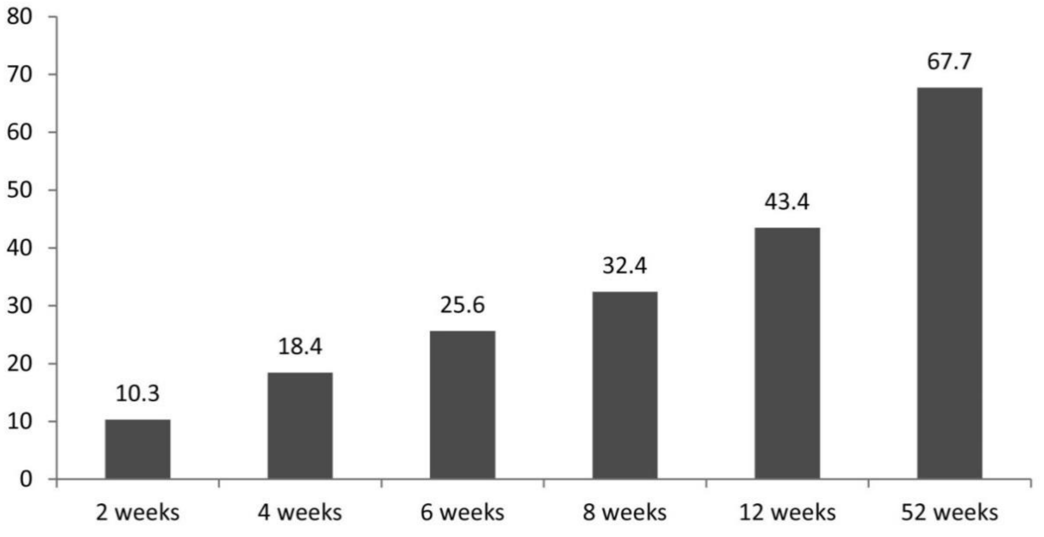

Figure 3: Cumulative percentages of patients who undergo definitive treatment in those who did not receive definitive treatment on the index admission

Of the 505 patients who did not undergo definitive treatment and who were readmitted with a further diagnosis of GSP, about a third of these (n=154, 30.5%) were readmitted during the first two weeks following discharge and seven died during this readmission. By eight weeks, the cumulative readmission rate in patients who did not undergo definitive treatment on the index admission was 8.5% (Fig 4).

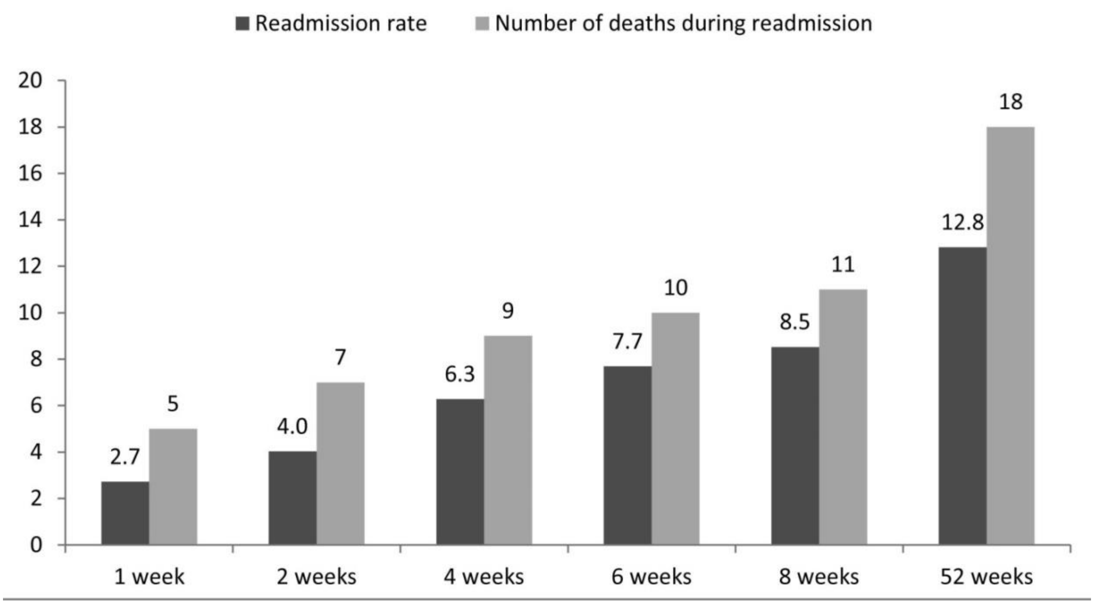

Figure 4: Cumulative readmission rates for gallstone pancreatitis and number of deaths in patients who did not receive definitive treatment on the index admission.

In Figure 5 patients are stratified into four groups according to their LOS. Only 9.3% of those who stayed four days or less underwent definitive treatment on the index admission compared with 41.2% of those who stayed more than twelve days.

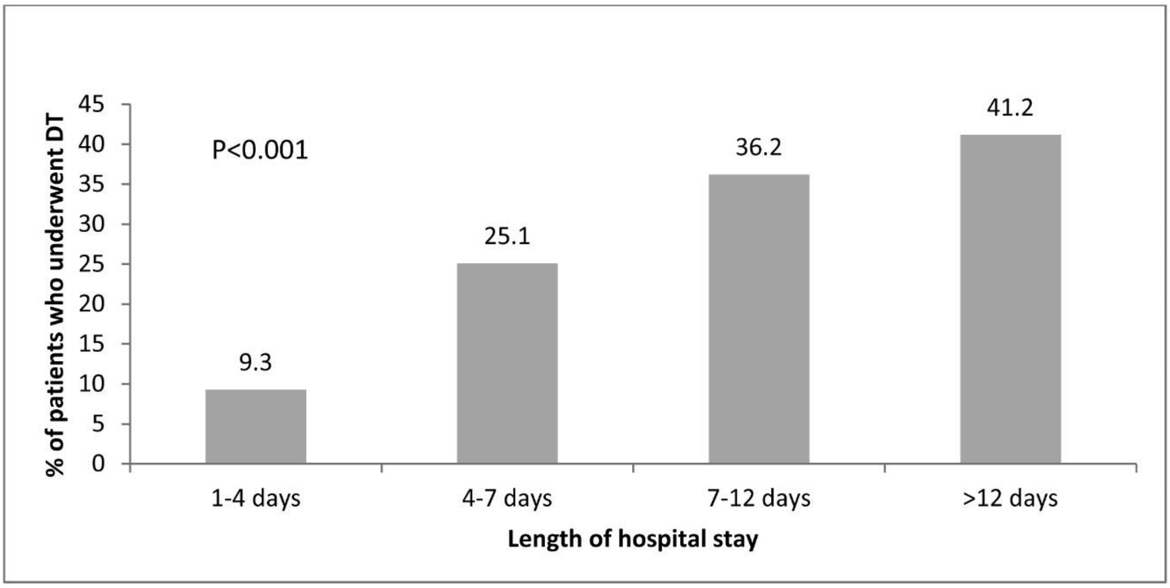

Figure 5: The proportion of patients who underwent definitive treatment during the index admission stratified by length of stay

8.1.5 Discussion and Conclusion

Data derived from HES are used increasingly to investigate delivery of care in England. The validity of studies using these data depends on the accuracy and depth of coding, and this has been questioned. Campbell et al showed in a systematic review that there is generally a high level of accuracy (91%) for diagnosis although the accuracy for coding of operations or procedures was only 69.5%[56]. There may have been an improvement in the accuracy of coding in the NHS in England in the ten years since this study due to the introduction of the payment by results scheme, which relies on data derived from OPCS-4 codes.

Since 2007–2008, the Audit Commission has conducted an annual audit of clinical coding in England. Results from the first of these audits suggest that 10.5% of primary procedures are coded incorrectly although there was wide variation between different trusts and the inaccuracies did not necessarily mean that patients were categorised incorrectly [232, 233]. Another study looking at aortic aneurysm surgery found that coding accuracy appeared to be high if diagnostic, operative and administrative codes were compared, and accuracy could be improved further if they were combined[234] similar to our study.

Despite improvements, HES data need careful interpretation. Variations in coding are usually ignored when large aggregations of data are used, for example at national level as in this study. In this situation, the variations in coding are likely to occur randomly and therefore to cancel each other out. Conversely, if comparisons were made between individual providers, then variation in coding could not be ignored in this way[126, 147]. We have not attempted any such comparisons.

This national audit shows that current practice in England with regard to the definitive management of patients with GSP falls well short of that suggested by the BSG[222]. In fact, only a third of patients received definitive treatment on the index admission or within two weeks of discharge.

HES data lack many clinical details that have been used in other comparative studies of acute pancreatitis to stratify patient populations into predicted severe and mild disease, and this is a limitation of our study.

This study demonstrates that patients who had definitive treatment during the index admission are less likely to be readmitted with GSP than those who did not. When the issue of timing is addressed, the study also reveals that a third of readmissions with GSP occur in the two weeks following discharge and that some of these patients died. Furthermore, only 10% of the patients discharged following an index admission with GSP who did not undergo definitive treatment on this admission underwent definitive treatment in the two weeks following discharge (Fig 2). This suggests that clinicians are not making proper use of the facility provided by the BSG guidelines to undertake a cholecystectomy within two weeks of discharge on a routine list.

Although there was a general consensus among clinicians who prepared the BSG guidelines that definitive treatment was best performed during the index admission or within two weeks of discharge, this recommendation was based on expert opinion and not objective data. It may be that definitive treatment during the index admission is advisable and that patients suffering an attack of mild GSP should have a cholecystectomy or ES before discharge. Subsequent guidelines in acute pancreatitis should possibly take this into account.

In addition, it appears that once patients were discharged without definitive treatment, only a third had undergone definitive treatment within two months of discharge. This may reflect the lack of available operating time on routine lists together with poor prioritisation. On the other hand, this and other observational studies[235, 236] have shown that the LOS during the index admission increases if patients undergo definitive treatment during that admission. It may be necessary to book patients with mild GSP for a cholecystectomy once the diagnosis has been made, even if they are still settling, as this has been shown to be safe and reduce LOS[237, 238]. In severe pancreatitis early cholecystectomy should be avoided while the patient is recovering; there may, however, be a role for initial treatment of these patients with an ES to modify this attack and to prevent further attacks with interval cholecystectomy at a later date[239-241].

There is still considerable debate as to whether an ES reduces the risk of a further bout of GSP to the same level as a cholecystectomy[242-246]. This study has shown that cholecystectomy is superior to ES with regard to the prevention of further attacks of GSP. Furthermore, cholecystectomy is a lower risk procedure and the later biliary complications attributable to gallstones in the gallbladder such as cholecystitis are avoided[236]. There is therefore general agreement that all patients with acute GSP who are fit enough should undergo a cholecystectomy. Delaying surgery will not save treatment costs although it may decrease LOS on the index admission. Delaying definitive treatment will, however, increase the possibility of a further emergency readmission with GSP with the associated costs, morbidity and mortality, and this will increase the burden on emergency services.

The median number of patients admitted as an emergency with GSP per NHS trust is 35 (IQR: 25–51). Therefore, for the majority of NHS trusts, the extra theatre time required is less than one operation per week, which in most cases should be managed easily if treatment of GSP were given the appropriate clinical priority[247].

Following an attack of mild GSP, cholecystectomy should be offered to all patients prior to discharge and these should be prioritised appropriately on emergency or elective lists. If a patient is not fit for surgery, endoscopic sphincterotomy should be performed in line with the BSG guideline.

9 Discussion

This thesis set out to evaluate the use of HES data to measure surgical outcomes. 5 objectives were identified to answer such a question.

The first objective was to identify rare complications when the code of such complication is available. Venous thromboembolism was used as an example of rare complications following bowel resection. The study showed that rare complications can be easily identified whether during index admission or subsequent admissions.

The second objectives showed the ability of HES data to lend itself to measure rare complications when the codes for such complications are not available. Bile duct reconstruction was used as a surrogate for bile duct injury following laparoscopic cholecystectomy. The study showed the feasibility and benefit of such techniques.

The third objective was to compare different types of surgery for the same conditions. Laparoscopic versus open inguinal hernia was used as an example. Early and late complications following inguinal hernia repair were used to compare both techniques. Direct codes for complications were used for early complications and reoperation rate was used as a surrogate for recurrence.

The fourth objective was to measure changing trends in surgical practice. Surgery for rectal practice was used as an example. The study showed the ability of HES data to identify changing trends and the rise of laparoscopic surgery compared to other types of surgery.

Finally, HES data was used as a national tool to identify adherence to national guidelines. HES was used to monitor the national adherence to the national guideline for definitive management of acute gallstone pancreatitis. The study showed the benefit of adherence to the national guideline as well the number of patients who are being treated within those guidelines.

9.1 Can meaningful clinical recommendations be made from research using HES data?

HES was used to identify Venous Thromboembolism VTE following bowel resection as an example of this objective. It was feasible to calculate the incidence of VTE at one year follow up. The study showed a VTE rate of 2.3% at one year follow up which was comparable to findings of other research[248]. The risk of developing VTE during index admission represents only a quarter of the total number of VTE the patients may develop at one year. These findings were first to be reported in colorectal surgery and it is comparable to the risk of VTE shown previously from bariatric surgery[119]. Two further researches were published from different institutions investigating the risk of VTE and surgery by linking HES data to primary care data. Humes et al[124] investigated the risk of VTE following colectomy but not rectal surgery and Bouras et al[125] investigated VTE rate following a number of surgery including thyroid, breast, hernia, and bowel surgery. Both studies found similar results to our findings which credence to our methods. The study confirmed what was little known before that the risk of VTE following prolonged hospital stay is increased for cancer patients, Inflammatory Bowel Disease (IBD) patients, and for benign patients. Policy to reduce length of stay is not only important to save money but to speed up recovery and reduce the incidence of VTE in those patients following discharge. Enhanced Recovery After

Surgery (ERAS) was first introduced by Henrick Kehlet in 1995[249] and since it has evolved and become the standard of care across different specialities[250]. NHS Trusts should further enhance the use of ERAS and reduce hospital stay.

Laparoscopic surgery is well-known approach to reduce hospital stay[251]. Study for HES data showed a new benefit of laparoscopic approach compared to open surgery by reducing the incidence of VTE. Training in laparoscopic surgery is very important and the NHS commissioned LAPCO training in 2009[252] which was directed at training colorectal surgeon the laparoscopic approach. The majority of colorectal surgery can be performed by laparoscopic approach and it should become the standard of care to all patients.

Studying each comorbidity individually to assess their association with VTE was essential to identify factors associated with VTE. The risk of VTE was found lower among patients with ischaemic heart disease. This is most likely due to the fact that these patients tend to be on antiplatelets agents which act as prophylactic measure. Aspirin is the most common antiplatelet and Aspirin was found to reduce the recurrence of cancer[253]. It may be a good idea to start all patients on date of diagnosis on Aspirin but further studies are warranted.

The rate of Bile Duct Reconstruction (BDR) and therefore presumed bile duct injury is in keeping with published series. This study suggests that the incidence of BDR following LC in England is low (0.09%) with only 500 cases over a 12-year period. Data from other registries show that the incidence of Bile Duct Injury (BDI) in Germany is 0.1% (172 368 LC)[131] in Denmark 0.15% (23 672 LC);[132] in the USA between 0.06%- 0.5%[133, 145]; in Finland 0.82% (6 733 LC)[134]; and in Sweden 1.5% (51 041 LC)[135] although major BDI in this study accounts for only 0.1%. However, researchers have to understand that different definitions of what constitutes BDI make comparative analysis difficult. Other reports from large single centre studies (over 10 000 LC) showed the incidence of BDI is between 0.19%[137] and 0.24%[136].

The study confirmed what was known before about the importance of Bile Duct Injury following laparoscopic cholecystectomy[254]. The study showed that there is a tenfold increase in mortality at one year in patients who have undergone a BDR

A similar methodology was used in this study to the one that was used previously by Ballal et al 2009 of reporting patients related factors and non-patients related factors for risk of conversion following laparoscopic cholecystectomy[83]. Patient related factors associated with BDR include cholecystitis on the index admission. Non-patient related factors associated with a lower reconstruction rate include a high consultant cholecystectomy caseload and regular use of OTC.

The study was able to compare incidence of BDI between different centres and after adjustment to all factors, all hospitals in England were within the 99 percentiles during the study period. This finding confirms the ability to of HES to compare hospital performance in complications of surgery. Several studies[152-154] have shown that BDI repaired at an Hepato-Pancreatico-Biliary (HPB) centre is associated with a better outcome as compared to those repaired in a general hospital. Data from this study showed more than half of the injuries were repaired locally. Centralization of HPB services has progressed rapidly in the UK with most major resections occurring in HPB centres during the study period. The policy planners should draw up from these findings and all patients should be transferred to HPB unit when bile duct injury is diagnosed.

Most surgeons in the UK perform On Table Cholangiogram (OTC) selectively. Large studies based on registry data have produced conflicting results. While some show that the risk of BDI decreases when OTC is performed[135, 146, 155-157], others, including a systematic review[158] show no benefit[159]. The study showed that surgeons who use OTC more frequently have a lower rate of BDR following Laparoscopic Cholecystectomy (LC). On Table Cholangiogram should be used more widely and all surgeons should be trained to use it. Training is needed to understand the anatomy of the biliary tree and the OTC procedure during Registrar's training and regional courses for the Consultants. Hospital system should encourage the use of OTC by providing the necessary equipment.

The study confirms the ability to record rare complications of surgery from HES data when there are no codes for such complications. The Study also confirms the ability of HES data to compare hospitals across the country and study factors associated with such a complication. The study confirmed the importance of Bile Duct Injury in terms of risk of death to patients. The study was able to add to the evidence of subspecialisation of laparoscopic cholecystectomy is needed and that occasional surgeon should consider their practice. The study was able to add to the growing evidence that on table cholangiogram is associated with a lower risk of BDI.

Inguinal hernia was used as an example of comparing two different surgical approaches for surgery. The reoperation rate was used as a surrogate for recurrence as the primary outcome. HES was able to identify surgical approaches and the reoperation rate as well as early complications such as bleeding, injury and urinary retention. Because of the complexity of inguinal hernia, a different approach in methodology was needed. Inguinal hernia was divided into primary and recurrent and then each of them was subdivided into unilateral and bilateral. Each group was then followed across time and place to identify if any patient was re-operated on and it appeared in any of the other group later in life. The study showed that laparoscopic repair was associated with higher incidence of reoperation compared to open repair for the overall group and for the primary group. HES also showed that laparoscopic repair has a similar reoperation rate to open surgery for recurrent inguinal hernia.

The results were revalidated by repeating the same methodology for a different timing period and the outcome was similar to the original cohort of patients.

HES data analysis was able to monitor infection, hematoma formation, urinary incontinence, and injury to an organ. Injury to an organ is rare during a hernia repair but has been reported to be higher with a laparoscopic technique[180]. Increased infection and haematoma rates are seen following open as compared to laparoscopic repair, a difference which is consistent with other published studies[169, 175, 176].The rate reported in HES were lower than published literature and it is probably due to under reporting.

The study showed that consultant caseload of laparoscopic approach is inversely associated with recurrence of hernia. This result informs surgical society about the importance of volume of their cases and their results in benign pathology. Subspecializing appears to be important not only in cancer surgery but even in common pathology such as gallbladder and hernia surgery. These findings should be taken into account with the current policy of NHS Improvement and Getting It Right First Time (GIRFT).

The study from HES was able to identify factors associated with recurrence. Non patients related factors in terms of consultant caseload was significantly inversely associated with higher reoperation rate in the laparoscopic group but not in the open group. These findings reaffirms other Studies which suggested that surgeon experience is related to hernia recurrence following laparoscopic repair,[168, 181].

Research from HES can compare different types of surgery for the hernia and it can also be used to identify factors associated with poor outcome of hernia. HES can also be used to monitor outcomes of inguinal hernia in the country.

HES data was used to measure changing trends in prolapse surgery. The study showed rectal prolapse surgery is increasing year on year at a rate faster than the increase in population. HES also showed new techniques in terms of laparoscopic surgery increased exponentially during the study period. The study showed that there is little evidence of subspecialisation for rectal prolapse surgery with unchanged and low numbers of procedures per surgeon per annum.

Data from HES allowed us to measure the incidence of rectal prolapse. The incidence was 18.5 per 100,000 per year which is much higher than a previous report of only 2.5 per 100,000 in a Finnish population [205]. The overall in-hospital mortality rate for all types of surgery was less than 1% which is comparable to the reported mortality in the literature 0 – 6.5%[206-209].

Similar to the methodology used in the inguinal hernia repair, It was feasible to measure the reoperation rate of different surgical approach for rectal prolapse. The overall reoperation rate was approximately 12% for both elective and emergency cases which is similar with the reported recurrence rates in the literature 3-33%[209-212]

Limitation of this study was the use of reoperation rate rather than actual recurrence rate. Therefore, some patients who had recurrence but declined (or were unfit) for further repair will not have been included in the analysis. This indicates that recurrence rates might be higher than the data provided.

Studies from HES data have value in understanding trends in surgical strategy, lack of subspecialisation and/or centralisation and in providing surrogate outcomes on much larger numbers of patients than for instance widely cited single centre cohort studies and an under-recruited trial from the same time period[20].

HES data was used as a National Audit Tool to investigate the national adherence to the British Society of Gastroenterologists (BSG) guideline of definitive management of gallstone pancreatitis[62]. This national audit shows that current practice in England with regard to the definitive management of patients with GSP falls well short of that suggested by the BSG. In fact, only a third of patients received definitive treatment on the index admission or within two weeks of discharge.

Although there was a general consensus among clinicians who prepared the BSG guidelines that definitive treatment was best performed during the index admission or within two weeks of discharge, this recommendation was based on expert opinions and not based on objective data. It may be that definitive treatment during the index admission is advisable and that patients suffering an attack of mild GSP should have a cholecystectomy or endoscopic sphincterotomy (ES) before discharge. Subsequent guidelines in acute pancreatitis should possibly take this into account. This is the first study to provide the evidence to support the BSG guideline.

In addition, it appears that once patients were discharged without definitive treatment, only a third had undergone definitive treatment within two months of discharge. This may reflect the lack of available operating time on routine lists together with poor prioritisation. On the other hand, this and other observational studies[235, 236] have shown that the length of stay during the index admission increases if patients undergo definitive treatment during that admission. It may be necessary to book patients with mild GSP for a cholecystectomy once the diagnosis has been made, even if they are still settling, as this has been shown to be safe and reduce LOS[237, 238].

There is still considerable debate as to whether an ES reduces the risk of a further bout of GSP to the same level as a cholecystectomy[242-246]. This study has shown that cholecystectomy is superior to ES with regard to the prevention of further attacks of GSP. Furthermore, cholecystectomy is a lower risk procedure and the later biliary complications attributable to gallstones in the gallbladder such as cholecystitis are avoided[236]. There is therefore general agreement that all patients with acute GSP who are fit enough should undergo a cholecystectomy. Delaying surgery will not save treatment costs although it may decrease LOS on the index admission. Delaying definitive treatment will, however, increase the possibility of a further emergency readmission with GSP with the associated costs, morbidity and mortality, and this will increase the burden on emergency services.

The study was also able to calculate the workload to each trust and this will help the management to make the necessary arrangement to provide such service. The median number of patients admitted as an emergency with GSP per NHS trust is 35 (IQR: 25–51). Therefore, for the majority of NHS trusts, the extra theatre time required is less than one operation per week, which in most cases should be managed easily if treatment of GSP were given the appropriate clinical priority[247].

HES data lack many clinical details that have been used in other comparative studies of acute pancreatitis to stratify patient populations into predicted severe and mild disease, and this is a limitation of our study

9.2 Strength and weaknesses of HES data.

There are many benefits of using HES data in measuring surgical outcome compared to other types of data. However, HES does have weaknesses and limitations which are summarised below.

9.2.1 Strength of HES data

9.2.1.1 Overview of practice and changing trends

HES is one of the best tools readily available to evaluate the changing trend in practice and to give a clear overview of current practice. It is reliable and accurate in measuring the primary diagnosis and primary procedure. The degree of error from coding inaccuracy is likely to be diluted due to the large number of practices. HES compared to other databases are readily available and free. Whereas any other attempt to perform such database will need millions of pounds and a lot of effort, such as the National

Emergency Laparotomy AUDIT (NELA) [255]. HES will help planners to predict the future resources needed. For example, the rising use of laparoscopic surgery 10 years ago in inguinal hernia surgery has shown the need for more training and resources by hospitals to keep up with the demand. Hospitals who did not plan for changing trends will always find themselves in a difficult position in the future if they did not assess the changes and did not make a plan. For example, in my department, there was a limited attempt to introduce laparoscopic surgery in the last 10 years. Therefore, up to 2015 only 30% of all colorectal resections were performed laparoscopically. When this became evident, their aim was to recruit a laparoscopic colorectal surgeon to boost the number of laparoscopic cases.

In surgery for rectal prolapse paper, the laparoscopic ventral mesh rectopexy (VMR) surgery is rising exponentially. This will again help the heath authorities to start training surgeons to perform the surgery so patients will benefit from this kind of surgery without post code lottery.

9.2.2 Weaknesses of HES data

9.2.2.1Coding accuracy

The previous systematic reviews and the current one in my study showed coding accuracy of about 85% for both primary diagnosis and primary procedures. These figures are good and researchers can conclude researches from HES data are reliable. Most coding inaccuracy appears to occur in the fourth character codes and for complex diagnosis such as self-harm or non-specific abdominal pain. When studying an overview or changing trends, inaccuracy tends to be homogenous and its effect tends to be negligible due to the high number of cases studied. However, when assessing individual surgeons, the number of cases is small and coding inaccuracy may potentially play a significant role in skewing the data. Research from HES is a good tool to study the overall practice rather than investigate a particular case because the error margin is high in those circumstances.

9.2.2.2 Codes insufficiency

Some procedures and diagnoses lack the relevant codes. There are very few new procedures that a code can be found for it. This is clearly evident in Patrick and colleagues paper which was published in 2013[256]. They published their findings of assessing the HES data to measure the activity of new procedures and devices as per NICE guideline. They looked at 12 new technologies and compared only 9. They contacted relevant registries, hospitals, and manufacturers to compare the data. They found HES have the potential to provide evidence about new devices and procedures. However, achieving this potential requires improvement in the simplicity and specificity of coding procedures (particularly when they are being used for particular indications). A higher priority should be given to the development of a reactive coding system with improved specificity of its codes. The study has confounding factors as it compare HES data to non-approved databases. Some comparisons of HES data were made with the sale figures of manufacturers, which is probably not the best indicator. Others compare HES to local hospital database. It is not clear how accurate these local hospital databases are and whether they are validated. The final comparison was made with national Central Cardiac Audit Database (CCAD). They looked at 5 procedures. When they compared HES with CCAD they found high sensitivity of 83.3 (35.9–99.6) to 100.0 (75.3–100.0). However, they found HES to be significantly under reporting these procedures. When they compared HES to registry, they found a much lower sensitivity of 29.2 (21.6–37.8) to 81.3 (54.4–96.0). The study made many assumptions on how they calculated their results and what they are comparing to in order to complete their findings.

The bile duct injury paper in chapter 5 is another example of coding insufficiency. In order to measure the bile duct injury, surrogate code was used instead. Bile duct reconstruction codes were used as a surrogate marker for the bile duct injury. This is a very good and reliable method to measure major bile duct injury. However, it has several drawbacks, it doesn't include minor bile duct injury when the surgeon simply sutures the repair at time of surgery. It doesn't include patients who underwent conservative management for bile duct injury with ERCP. This can be measured but it is very difficult to distinguish between injury and stone. It doesn't include patients who died prior to the repair. However, other studies using registry data have used similar methodology[131-133, 146] and our result are consistent with their findings. Nevertheless, most minor injuries are associated with a lower rate of complications, and lower long-term morbidity. However, the study does include those patients who fail to respond to ERCP and stenting or who develop stenosis of bile duct that requires delayed (within a year) surgical reconstruction.

9.2.2.3 Codes overlapping

HES depend on clinical codes. Clinical codes are mainly derived from OPCS and ICD 10 codes. Unfortunately, these codes are not designed by clinicians and they are completely out of date. For example, there are over 10 codes for ERCP. Many of these codes are not valid and no one uses them. The OPCS codes are not based on operation but they are based on IT protocols. Codes should be simplified and mimics true surgery. Laparoscopic reversal of Hartmann's for example is complex procedure where clinical coders have to combine multiple clinical codes, which unfortunately may vary between different NHS trusts. Sometimes there are more than one code for the same conditions. For example, when searching for Delorme procedure for rectal prolapse, there are many codes in the OPCS system that can be used. For example, excision of mucosal prolapse of rectum NEC, Perineal repair of prolapse of rectum NEC, Other specified perineal operations for prolapse of rectum, and Preanal mucosal proctectomy and endoanal anastomosis. All these codes should be used when searching for Delorme procedure.

Multiple and duplicate codes can increase the error and mess the data. However, if the right steps are taken this can be minimised. Anyone attempting to search HES should undergo extensive training in clinical coding, statistics and database management before embarking on any research on HES.

9.2.2.4 Data structure such as comorbidity and events

One of the main problems of HES data structures are the secondary diagnosis and secondary operations fields. These fields combine the primary diagnosis, comorbidities, and complications. Some patients have a single diagnosis but many others have multiple primary diagnoses. This is evident when a patient is admitted with multiple conditions such as diabetic ketoacidosis due to sepsis or exacerbation of heart failure due to sepsis or anaemia. The coders may find it very difficult to code the primary diagnosis. This is often recorded as inaccurate diagnosis because the original coders decide it is the heart failure which is the main cause and the reviewers disagree and think it is the sepsis.

In the procedure codes, it is even more evident. If the patient undergoes a laparoscopic gastric bypass with laparoscopic cholecystectomy, the coders may code either as the primary procedure. Other patients may undergo emergency laparotomy and adhesiolysis and small bowel resection or other procedure. Again, the coders may choose laparotomy as the main codes, but the auditor may think it is the adhesiolysis or the small bowel resection. That is why when searching for a particular procedure, the researcher should look at the first three codes and then search manually for the ones where the procedure coded on the second diagnostic fields to decide whether this is correct or not.

Another problem is the comorbidity and complications. There is no way of knowing if the heart failure recorded in the secondary fields occurred during admission or it is one of the comorbidities. Similarly, patients who develop myocardial infarction during admission will be recorded in the secondary diagnostic fields, however, it is impossible to distinguish this from patients admitted to the hospital with a history of myocardial infarction as both events will be recorded in the secondary diagnostic fields.

9.2.3 Suggestions for HES data analysis

Understanding the data and codes are one of the most important aspects of any analysis. Different methodology can lead to different results. One of the main problems of HES is the methodology used to identify patients. The first step is to understand the subject very carefully. A lot of work has to be undertaken to analyse the broad subject, the aim, expected results and outcome. Some subjects are difficult to be undertaken from HES and their results are probably misleading.

Once the subject is accepted and deemed to be feasible to be analysed through HES data, the method should be written. The first decision is to decide whether one should search by diagnostic codes or operative codes or both of them. Should the researcher search the primary codes only or the secondary codes as well? I performed an Audit of clinical codes in 108 surgical patients at Leighton hospital in 2010. The audit was performed by the clinical coding manager and she found the operative codes accuracy was 80% and 85% for diagnostic codes. However, I found the majority of inaccuracy was not in the actual codes but in the sequence of the codes. For example, the accuracy of clinical codes increased to 90% and 95% respectively, if we search for codes in the first three fields rather than simply the first field.

For simple procedures such as inguinal hernia, performing such analyses can lead to certain problems. A patient can be admitted for major surgery and at the same time, the surgeon decided to repair the hernia. Therefore, searching for inguinal hernia repair in the second or third operative fields will select those patients as well. Adding those patients to the analysis will skew the results of length of stay, mortality, infections etc. To overcome such a problem, researchers should probably assess these cases manually. All patients who were recorded to have an inguinal hernia repair in the second and third operative fields should be inspected individually to decide whether to include them or exclude them.

The second step once the original cohort is identified is to compare the diagnostic fields for the relevant diagnosis. For example, searching the inguinal hernia in the diagnosis should be performed on the original cohort. This will eliminate any coding inaccuracy in the final cohort. It will however, eliminate some patients who did undergo surgery, but I believe it is an excellent method to make sure our cohort is almost 100% accurate by searching and linking both diagnostic and operative fields. In the inguinal hernia study when this method was performed, only 1.2% of patients were eliminated from the study resulted in almost 100% accuracy. Because it is extremely unlikely for coders to give the wrong clinical codes twice.

Identify certain factors in each episode such as method of admission (emergency or elective). The best method is to create a new field and use the update table query. Searching the “admimethod” field for 11, 12, and 13 should be performed, and then use the update table to update the new field to elective. The same method should be repeated for every field required for the study.

Charlson comorbidity score can be calculated in the same update query table by searching the secondary diagnostic fields for each item such as heart failure. Then a new field should be formed in the update table query and is used again to add all scores to form the final Charlson comorbidity score by using express builder in Access.

One of the main problems of HES data analysis is the spells and episodes. Each spell composes of one or more episodes. For some reason hospitals may record the same clinical codes for each episode and others do not. By searching for duplicates (multiple episodes) to remove them and keep only one record for that surgery. I described the methods in full in the methodology chapter, but it worth noting that certain steps should be considered.

Researchers should use the find duplicate query by using the query wizard in Access.

Records should be selected based on HESID and date of admission.

Fields of interest should be selected for example, Charlson comorbidity score and type of surgery. This will create a query where all duplicate records are listed.

Once HESID are listed ascending or descending, duplicate cases can be deleted manually. If there is discrepancy in the Charlson comorbidity fields or surgical fields between different episodes (duplicate), then the correct number can be chosen manually and the unwanted ones deleted.

9.3 Proposed changes to HES data

There are many changes to HES data that can be implemented very easily, but can results in ground breaking improvement. Many of the criticisms of HES can be resolved in few easy steps.

The first is to divide the diagnostic fields into three categories. The first is the presenting diagnosis or symptoms (three fields). This will tell any future researcher that a patient presented with right iliac fossa pain and vomiting for example. The second part of diagnosis is the main diagnosis. This part represents the main diagnosis of the patient such as Appendicitis or ovarian cyst. A combination of both presenting diagnostic fields and the main diagnosis can help future researchers that a patient was admitted with right iliac fossa pain and a diagnosis was made of appendicitis.

The third diagnostic fields are the comorbidity. There has been a great deal of emphasis on the Charlson comorbidity score in HES data. The current strategy is searching the secondary diagnostic fields, but it is very difficult to know whether those diagnoses represent the comorbidity or complications. Up to 10 fields of comorbidity should be coded comorbidity and a set of particular comorbidities should be used. For example, any patient with a history of VTE, COPD, Asthma, Heart failure etc should be coded under this section. Therefore, the researchers can identify that this patient presented with right iliac fossa pain and the main diagnosis was appendicitis and the patient had a history of COPD.

The next fields should be labelled as further diagnoses. For example, this patient developed myocardial infarction and DVT during his stay in the hospital. Therefore, a researcher can identify those as conditions developed during the patient stay, rather than the patient having a history of them.

Currently, some coders in some hospitals use the operative codes to record investigations. These are not measured and highly unreliable. If HES introduce investigation fields to HES data, HES data users can monitor the use of investigations by each hospital. Researchers can understand how the current practice is changing and what can be done to improve it. HES data team should however, identify what type of investigations should be recorded. For example, HES should probably record all ultrasound, CT scan, MRI scan, and PET scan. The radiology department can be connected directly to the codes by sending what scan was performed, without the need for the coders.

Back to our example of appendicitis patient, if this patient underwent CT scan, future research can quantify the use of CT scan in diagnosing appendicitis. This is a very important question as CT scan involves a large dose of radiations. Policy makers should a identify if a certain hospital is over using scans in making a diagnosis of appendicitis.

Such practice is widely used in the NHS and can result in unnecessary exposure to radiation and potentially those patients may be at higher risk of cancer development in the future.

Finally, the operative codes. The current practice is highly misleading and ambiguous. The use of multiple codes to represent an operation is probably not ideal. The OPCS codes are very primitive and complex, that is very difficult to master by both coders and clinicians. It is probably a good idea if clinicians play a significant part in the new codes. BUPA codes for example is a better code system than OPCS codes. For example, BUPA use H3390 to represents reversal of Hartmann's procedure, whereas the OPCS coders have to use H15.4 + Y16.2 + Z29.1. This is highly complicated and often junior coders get them wrong. If researchers and planner are to continue using HES data to measure NHS practice, a new system is needed. Each OPCS code comes with several other operation or non-specific operation. For example, in rectal prolapse surgery H35 codes are one of the codes for this procedure. H358 and H359 represent other specific fixation of rectum for prolapse and unspecific fixation of rectum for prolapse. Many coders and clinicians do not understand the difference between both of them and what they actually mean. Are they meant to be used for Delorme procedure, Altemeier's procedure, abdominal fixation or laparoscopic rectopexy? Of course, experienced clinical coders will know which one to use, but a busy or inexperienced coder will use any of them. Therefore OPCS codes should be changed, simplified and become clinically oriented based on actual surgery rather than Information technology (IT).

Another suggestion is to divide the operative fields in several categories. For example, category one is proposed surgery. Category two is performed surgery/procedures on that specific day. Category three represents second or subsequent operation/procedures performed in another day. Category four represents any interventional radiology.

To put this into context of our original example of appendicitis, the proposed procedure was appendectomy, but the surgeon performed right hemicolectomy instead of appendicectomy. Therefore, the researcher will understand and be able to identify that from the HES data. The patient was then taken back to theatre because of anastomotic leak and exteriorisation of bowel was carried out. Therefore, this should be categorised into the third fields rather than into the current system which is very difficult to identify and measure. This patient later developed a collection and a radiological drainage was carried out. Therefore, researcher should be able to measure this from the fourth category in the future.

The fifth category should be kept for complications of surgery. For example, anastomotic leak, bowel injury, bladder injury etc. The current system does not allow this to be recorded in detail. But there is a very primitive codes for misadventure. By forming category 5 for operative complication, both planners and researchers can identify those complications and will be able to measure outcome in a much better way than the current system.

By making those simple changes to just how the fields are grouped can transform the HES from the current style data to the 21st century. Researchers will be able to identify the patient pathway and story in a very easy systematic method that cannot be measured with the current data. Government can use the data to monitor hospital performance like never before.

9.4 Conclusion

Hospital Episode Statistics can be used to measure surgical outcome in a number of useful and reproducible ways. HES can be used to measure mortality, complications, compare different surgical approaches, assess the effect of changes in practice, and assess caseload outcome association. Those metrics can be used to inform health care planners, develop guidelines, and inform patients. The use of HES, however, has weaknesses which to a certain extent could be overcome easily with minor alteration in the way the diagnostic, consultant/operator and procedure fields are recorded.

10 References

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11 Appendix

11.1 Appendix 1

Published paper in chapter 7

Epidemiological trends in surgery for rectal prolapse in England 2001-2012: An adult hospital population-based study.

Authors: Y. El-Dhuwaib[1,2], A. Pandyan[2], C.H Knowles[3]

1- East Sussex Healthcare NHS Trust, East Sussex, UK

2- FMHS, Keele University, Stoke-on-Trent, UK

3- Blizard Institute, Barts and London SMD, Queen Mary University of London, London, UK

Correspondents
Mr Yesar EL-Dhuwaib
Consultant General and Laparoscopic Colorectal Surgeon
Conquest Hospital, East Sussex Healthcare NHS Trust, Hastings, UK
Email: yesar@doctors.org.uk
Tel: 0300 131 4500

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Abstract
Background: This study analysed trends in admission and surgery for rectal prolapse in adults in England between 2001 and 2012 as well as prolapse reoperation rates.

Methods: Analysis of data derived from a comparative longitudinal population-based cohort study using Hospital Episode Statistics (HES).

Results: During the study period, a total of 25,238 adults underwent a total of 29,379 operations for rectal prolapse (mean 2,662 per annum) [median age 73 years (IQE 58-83) years; female to male ratio: 7:1]. Median length-of-stay was 3 days (IQR 1-7) with an overall in-hospital mortality rate of 0.9%. Total number of admissions (2001: 4,950 vs. 2012: 8,927) and of patients undergoing prolapse surgery (2001: 2,230 vs. 2012: 2,808) significantly increased over the study period (P < 0.001 for trends). The overall increase in prolapse surgery (up by 1/3rd overall and 44% for elective) was dwarfed by an increase in popularity of laparoscopic surgery (increasing 15-fold). Overall prolapse reoperation rate was 12.7%. The lowest recurrence rate was observed for elective open resection (9.1%) but this had the highest mortality (1.9%). Laparoscopic and perineal fixations were also associated with low reoperation rates (<11%) but lower mortality rates, in the order of 0.3% for elective surgery. These data refute a trend toward subspecialisation (by surgeon or hospital) during the study period.

Conclusions: Admissions for rectal prolapse increased in England between 2001-2012 together with increases in surgery. Surgical decision making has changed over the period and may be reflected in outcome.

What does this paper add to the existing literature?

This is the largest dataset of patients undergoing surgery for rectal prolapse, studying over 25,000 patients. The incidence of rectal prolapse and surgical repair in England has increased between 2001 and 2012. Laparoscopic fixation has increased dramatically in popularity and has favourable outcomes in terms of length-of-stay, mortality and reoperation rates.

Introduction

Rectal prolapse is an uncommon but highly morbid condition in which a full-thickness intussusception of the rectal wall extrudes through the anal canal [1-3]. The only potentially curative treatment is surgery with exceptions being patients considered medically unfit for surgery and those with minor degrees of prolapse. Over 100 operations for rectal prolapse repair have been described and none has achieved primacy following attempts to provide high quality evidence[4]. Rectal prolapse can be repaired via the abdomen or perineum with several alternatives for each described. Abdominally, posterior rectopexy (sacral fixation of the rectum) is generally considered to have a low recurrence rate but may result in poor function especially constipation [5]. Alternatively, the rectum may be fixed with concomitant segmental colonic resection (resection rectopexy) but there is a risk of anastomotic leak 1-5.9% [6, 7] even though some data suggest it has the lowest recurrence rate[4]. Perineal approaches (principally Delormes and Altemeier's) are less invasive and are considered a better option for elderly and medically unfit patients. However these may have higher recurrence rates 10 -30% compared to 0-11% for rectopexy[8].

Laparoscopic rectopexy was first reported in 1992 by Berman and has re-popularised the abdominal approach[9]. Laparoscopic ventral mesh rectopexy (LVMR) uses an anterior rectal dissection with fixation of the anterior rectal wall to a mesh, which is then anchored to the sacrum. The operation theoretically preserves pelvic nerves avoiding the 'rectal inertia' caused by posterior dissection and reportedly better functional outcome [10]. Several large series have now been published suggesting low recurrence rates and lower short-term morbidity[11-13], however this operation has recently become the subject of media scrutiny in relation to long-term complications from the use of pelvic mesh in general[14, 15].

The current study evaluated trends in surgery for rectal prolapse in England from 2001 to 2012 with a focus on type of operation performed and estimates of recurrence based on incidence of re-operation.

Methods

Study design

The study examined a national dataset (below) to obtain data pertaining to trends in incidence of rectal prolapse diagnosis and operations performed for prolapse by year. Patients undergoing an index prolapse procedure were followed up longitudinally to determine if they underwent further operations for rectal prolapse. As such, the study had elements of a multiple cross-sectional and retrospective cohort design.

Data sources

Hospital Episode Statistics (HES) data were obtained from the National Health Service Information Centre (NHSIC) and imported into Microsoft SQL server. All patients admitted with rectal prolapse over an 11-year period (April 2001 and March 2012) were identified by searching the primary diagnostic codes (K622 for anal prolapse and K623 for rectal prolapse) using the International Classification of Diseases Version 10 (ICD 10). Data were then imported into Microsoft Access [Microsoft Corp. USA] for analysis. Patients who underwent surgery for rectal prolapse were then selected by searching the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (4th revision) codes (OPCS-4). Codes used are listed in suppl. table 1. Patients under the age of 16 were excluded from analysis. It is noted that there are no HES diagnostic codes for internal prolapse (intussusception) and the cohort will almost certainly have included some patients undergoing procedures for this diagnosis e.g. those undergoing stapled rectal resection (STARR) procedures. These patients represented less than 1% of the whole cohort (n=201).

Patients were subdivided by type of surgical repair into 6 categories using OPCS codes. Open fixation, open resection, laparoscopic fixation (laparoscopic codes plus open fixation), laparoscopic resection (laparoscopic codes plus open resection), perineal fixation, and perineal resection. Codes for each group are described in suppl. table 1. Laparoscopic repair was identified by searching all operative codes for Y75* or Y508* using the OPCS code 4. Converted cases were included with the laparoscopic approach by searching for the codes Y714* or Y718*. Patients were then subdivided into elective and emergency repair by mode of admission using the "admimeth" field to identify how the patient was admitted to hospital (for elective admissions: numbers 11, 12, and 13; and for emergency admission: numbers 21, 22, 23, 24).

Open fixation	H351 H352 H353 H354 H358 H359 H361 H368 H369	Anterior fixation of rectum Posterior fixation of rectum using prosthetic material Posterior fixation of rectum NEC Fixation of rectum using fascia lata Other specified fixation of rectum for prolapse Unspecified fixation of rectum for prolapse Abdominal repair of levator ani muscles Other specified abdominal operations for prolapse of rectum Unspecified other abdominal operations for prolapse of rectum
Open resection	H04 H05 H09 H10 H29 H33 Except H337	Panproctocolectomy Total Colectomy Left Hemicolectomy Sigmoid colectomy Subtotal colectomy Anterior resection or proctectomy or Hartmann's Perineal resection of rectum
Laparoscopic surgery	Y75 Y508	Laparoscopic or robotic approach to abdominal cavity Laparoscopic or robotic approach to abdominal cavity
Conversion codes	Y714 Y718	Failed minimal access surgery Failed Minimal access surgery prior to 2007
Perineal fixation	H421 H422 H423 H425 H426 H428 H429 H414	Insertion of encircling suture around perianal sphincter Perineal plication of levator ani muscles and anal sphincters Insertion of supralevator sling Excision of mucosal prolapse of rectum NEC Perineal repair of prolapse of rectum NEC Other specified perineal operations for prolapse of rectum Unspecified perineal operations for prolapse of rectum Peranal mucosal proctectomy and endoanal anastomosis
Perineal resection	H337 H411 H412 &Y263	Perineal resection of rectum Rectosigmoidectomy and peranal anastomosis Peranal resection of rectum using staples

Supplementary table 1: Operative codes for surgery (OPCS4)

Patients identified as having surgery within the 11-year period were followed up until March 2012 using HES patient ID (HESID) to investigate any who had undergone further rectal prolapse operations (as a surrogate for recurrence). The HESID is a unique identifier for every patient that is calculated using NHS number, local hospital number and date of birth. Using HESID permitted follow-up of patients across time and place and was used to calculate reoperation rates for each surgical operation type. In addition, Consultant caseload was identified by searching all patients who underwent surgery by a specific consultant per year. The "Pconsult" code is a pseudo-anonymised code for each consultant, based on their GMC number, that permitted identification of individual caseloads. Similarly, hospital surgical volumes were calculated by searching the “SiteTreat” field.

Data analysis

Data have been presented descriptively with summary statistics based on data distribution. Population statistics were derived from Office of National Statistics census 2011 [16] to allow incidence rates per 100,000 population to be calculated for both rectal prolapse admission and rectal prolapse surgery. Limited statistical analyses were performed for time trends using regression of moving averages. All analyses were performed using SPSS version 18·0 (SPSS, Inc., Chicago IL).

Results

Year	Total admissions	Total pts undergoing surgery	Total operations	Total surgeons	Operations/ surgeon: median (IQR)	Total hospitals	Operations / hospital: median (IQR)	Age: median (IQR)
01/02	4,950	2,230	2,320	384	4 (3-7)	195	8 (5-13)	73 (58-82)
02/03	5,135	2,085	2,352	391	4 (2-6)	185	8 (4-13)	73 (57-82)
03/04	5,322	2,102	2,404	408	4 (3-6)	200	8 (5-12)	73 (58-82)
04/05	5,389	1,988	2,321	417	4 (2-6)	197	9 (5-14)	73 (59-81)
05/06	5,763	2,060	2,451	432	4 (3-6)	212	10 (6-13)	73 (59-82)
06/07	6,058	2,162	2,543	461	4 (3-6)	186	9 (5-14)	74 (61-84)
07/08	6,411	2,251	2,612	487	4 (2-6)	192	10 (6-15)	73 (59-82)
08/09	6,838	2,404	2,798	483	4 (2-6)	191	10 (5-15)	73 (59-81)
09/10	7,685	2,532	3,031	518	4 (3-6)	200	11 (6-17)	73 (58-83)
10/11	8,371	2,616	3,159	521	4 (2-7)	222	11 (5-16)	73 (58-83)
11/12	8,927	2,808	3,293	533	4 (2-7)	222	11 (5-17)	73 (58-83)

Table 1: Trends in numbers of admissions and operations for rectal prolapse 2001-2012

Tables 1 and 2 [Figure 1] show the main results by year from 2001 to 2012 with 25,238 adult patients undergoing a total of 29,379 operations for rectal prolapse over this time period (mean 2,662 per annum). There were obvious upward trends ($P<0.001$ for both) in total numbers of patients admitted and of those undergoing surgery of any type for rectal prolapse over time.

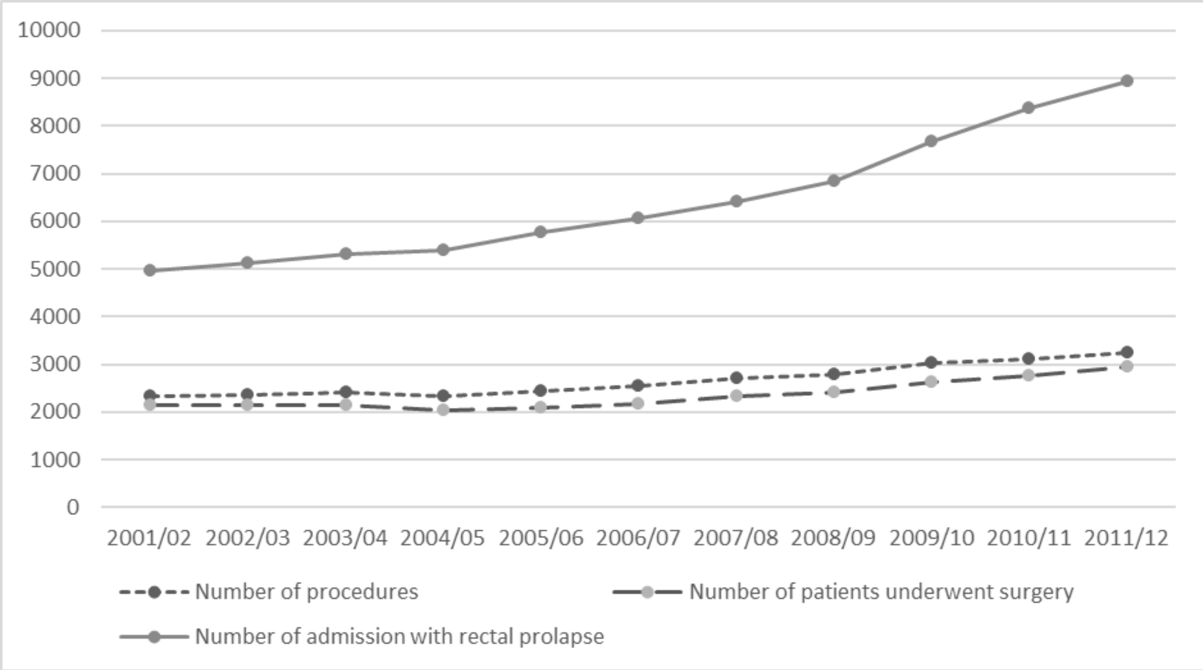

Figure 1: Trend of total number of admission of rectal prolapse and patients underwent surgery and total number of procedure per year.

The number of patients admitted to hospital with rectal prolapse in 2011 was 8,927 providing an annual incidence rate of 18.5 per 100,000 for this year; 2,808 underwent rectal prolapse surgery providing a statistic of 6.1 per 100,000 per year. For patients over the age of 75, these rates were much higher (106 per 100,000 and 31 per 100,000 per year respectively). Over the same time period, population statistics showed the English population increased by about 3.9 million (8.0%) from around 49.1 million in 2001 to 53 million in 2011[17]. The number of people over the age of 65 years increased by 851,000 (10.9%) for England over the same period. Nevertheless, patient age at surgery remained remarkably constant (median 73 years) over the same period.

Type of repair	Total patients	Total operations	Age: median (IQR)	Ratio: M: F	LOS: days median (IQR)	Total deaths (%)	Total reoperation (%)	% change total operations 2001 to 2012
Open fixation	7,838	7,919	78 (68-85)	1:14.0	4 (2-7)	49 (0.6)	1279 (16.3)	+ 9%
Open resection	774	886	75 (58-82)	1:9.4	7 (4-11)	15 (1.9)	70 (9.1)	+ 56%
Lap fixation	2,303	2,780	65 (50-77)	1:12.8	3 (2-4)	7 (0.3)	244 (10.4)	+ 1,624%
Lap resection	179	248	67 (51-77)	1:14.3	6 (4-9)	1 (0.6)	19 (10.6%)	+ 660%
Perineal fixation	9,804	11,965	68 (54-79)	1:3.7	1 (0-4)	26 (0.3)	979 (9.9)	+ 4%
Perineal resection	1,548	2,322	80 (72-85)	1:14.6	4 (2-6)	10 (0.7)	262 (16.9)	+ 170%
Total all operations	**22,446**	**26,120**	**72 (57-82)**	**1:6.3**	**3 (1-5)**	**109 (0.5)**	**2853 (12.7)**	**+ 44%**

Table 2: Data by type of operation for whole time period
a. elective operations

Type of repair	Total patients	Total operations	Age: median (IQR)	Ratio: M:F	LOS: days median (IQR)	Total deaths (%)	Total reoperation (%)	% change total operations 2001 to 2012
Open fixation	1,023	1,093	84 (79-87)	1:16.5	14 (8-22)	26 (2.5)	146 (14.3)	-13%
Open resection	164	164	82 (75-88)	1:6.4	15 (9-28)	23 (14.0)	7 (4.3)	+ 50%
Lap fixation	113	132	81 (77-85)	1:37	11 (6-22)	4 (3.5)	15 (13.3)	+ 1,250%
Lap resection	3	7	706 (64-92)	All female	29 (16-31)	0 (0)	1 (33.3)	+100%
Perineal fixation	1,198	1,344	82 (75-88)	1:7.2	13 (5-21)	24 (2.0)	129 (10.7)	-25%
Perineal resection	291	424	84 (82-86)	1:28.5	12 (8-21)	12 (4.1)	40 (13.7)	+ 189%
Total all operations	**2,792**	**3,164**	**83 (77-83)**	**1:11.9**	**13** (7-23)	**89 (3.2)**	**338 (12.1)**	**+ 4%**

b. emergency operations

The number of operations performed per year increased by approximately one third from 2,320 in 2001 to 3,253 in 2011. The number of surgeons providing rectal surgery for prolapse increased from 384 in 2001 to 533 surgeons in 2011/2012 keeping the median number of operations performed by individual consultants relatively static at only 4 (IQR 2-7) per year. The number of hospitals providing rectal prolapse surgery increased marginally from 195 in 2001 to 222 in 2011 with a median increase in number of operations/hospital/per year from 8 (IQR 5-13) to 11 (IQR 5-17) in the final year of data analysis. Females were more than six times more likely to undergo surgery for rectal prolapse compared with males, with some operations having a very high female predominance compared to others (Table 2). Median length of stay (LOS) was 3 days (IQR 1-7). Overall, in-hospital mortality rate was 0.9%. Just over 10% of the operations (2,692/25,238 patients, 3,063/29,379 operations) were performed as an emergency.

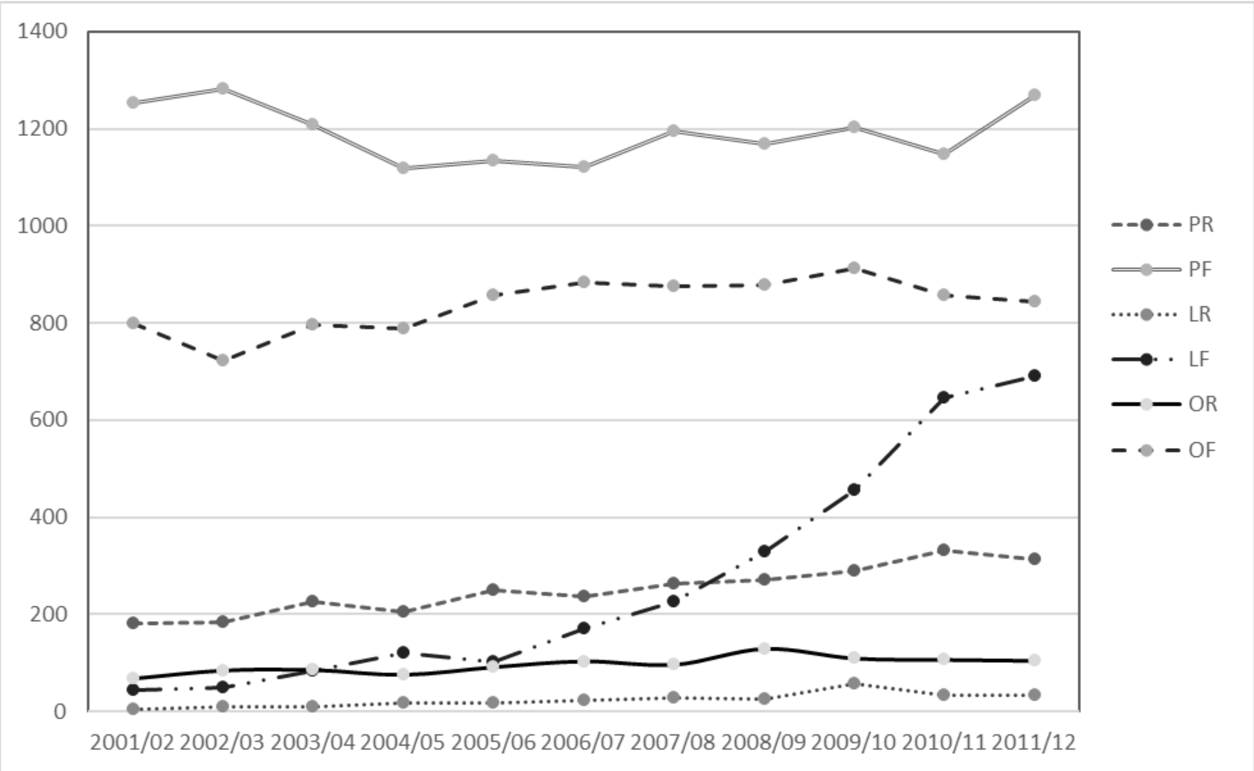

Figure 2: Trend of surgical procedures for rectal prolapse

Over the 11-year study period, perineal fixation remained the most popular surgical approach for both elective and emergency rectal prolapse repair [Table 2, Figure 2].

However, the number of patients undergoing laparoscopic surgery (repair/resection) increased more than 15-fold from only 48 (2.1% of total cases) in 2001/02 to 725 operations (22.3% of total) in 2011/12. Over the whole time period, patients selected for laparoscopic surgery were significantly younger than patients selected for other types of surgery with a median age of 67 years (IQR 52-79) [Figure 3]. In contrast, older patients were more likely to be offered perineal resection: median age 81 years (IQR 73-86). In the final year of data analysis, the median age for laparoscopic surgery was 65 years (IQR 50-78).

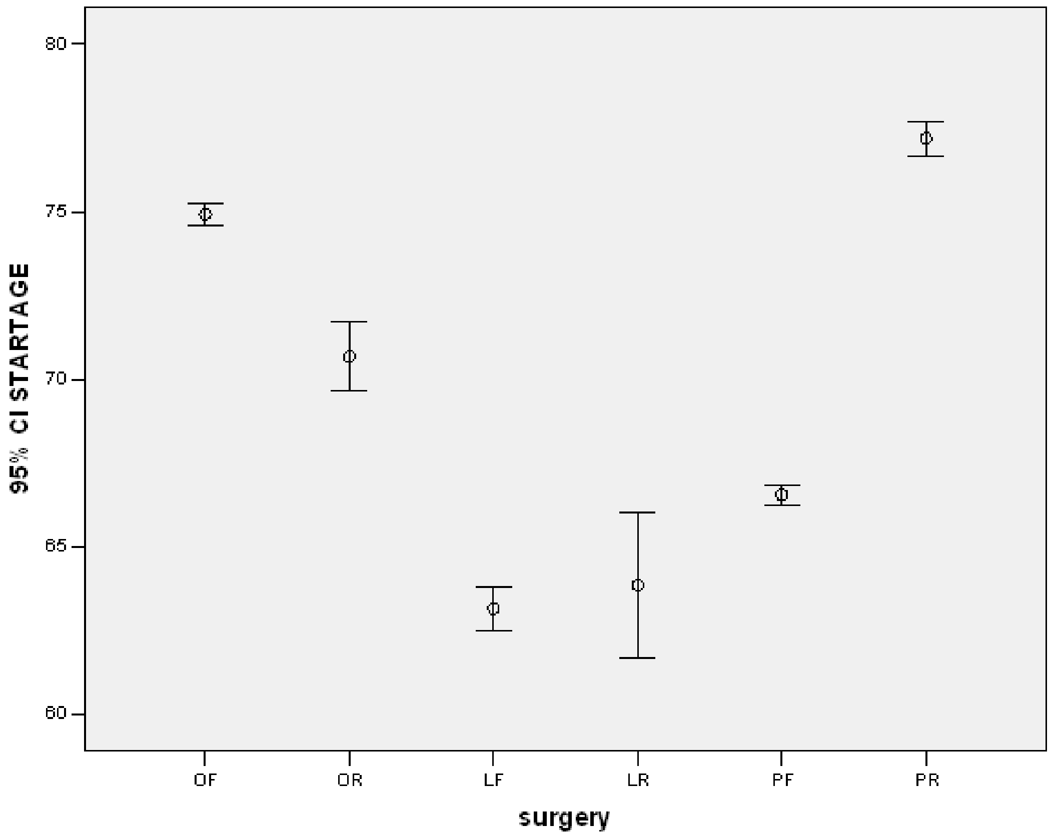

Figure 3: Mean and 95%CI for surgical repair age

Elective surgery for rectal prolapse was associated with a significant shorter hospital LOS as compared with emergency surgery for all types of surgical repair [table 2]. Laparoscopic and perineal fixations were associated with the shortest hospital stay. Elective surgery was also associated with a significantly lower mortality rate (0.5%) compared with emergency surgery (2.5%). Patients who underwent open resection were at a higher risk of death compared with other types of surgical repair, with a mortality of 14.7% in the emergency setting and 3.4% in the elective setting. Elective laparoscopic and perineal fixations were associated with the lowest mortality of just 0.3%.

Using HESID-derived data, 3,241 (12.8%) patient underwent reoperation for rectal prolapse. The majority (2622; 80.9%) underwent one further surgical procedure; 489 (15.1%) underwent two further operations and a small proportion (n = 99; 3.1%) underwent three or more further operations. Operation type influenced reoperation rate [Table 2] with open resection rectopexy having the lowest reoperation rate (9.1% elective and 4.3% emergency) compared with higher rates for perineal resection (16.9% elective and 13.7% emergency) and open fixation (16.3% elective and 14.3% emergency). Laparoscopic fixation had an intermediate outcome in terms of re-operation (10.4% elective and 13.3% emergency).

Discussion

To our knowledge we present the largest dataset to date of patients undergoing surgery for rectal prolapse, with over 25,000 patients included. Several of the findings merit discussion: (1) the incidence of rectal prolapse and surgical repair increased year on year between 2001 and 2012 at a rate greater than that anticipated by population growth alone; (2) there appears to be little evidence of subspecialisation for rectal prolapse surgery with unchanged and low numbers of operations per surgeon per annum; (3) laparoscopic fixation has increased dramatically in popularity over the period and this operation has favourable outcomes in terms of LOS, mortality and reoperation compared with several other operations; (4) there is no compelling evidence of superiority of abdominal operations over perineal in general; and (5) data confirm the previous assertion of higher risk but lower reoperation (recurrence) rate after resection rectopexy[18].

The reported incidence of rectal prolapse in our study was 18.5 per 100,000 per year which is much higher than a previous report of only 2.5 per 100,000 in a Finnish population[19]. The overall in-hospital mortality rate for all types of surgery was less than 1% which is comparable to the reported mortality in the literature 0 – 6.5% [20-23]. Reported recurrence rates in the literature vary from 3- 33% [23-26] depending on the type of surgical repair and length of follow up. Our overall reoperation rate was approximately 12% for both elective and emergency cases.

There are several limitations to this study. The study used the HES database which contains administrative data reliant on the accuracy of clinical coding. A recent systematic review shows coding accuracy is improving and following the introduction of payment by results in 2002 the accuracy of coding for primary diagnoses has improved from 73.8% (IQR: 59.3-92.1%) to 96.0% (IQR: 89.3-96.3)[27]. It has been suggested that researchers should consider the context of conclusions that are drawn from HES data. If findings are of a general nature, then even a relatively high coding error rate at some, or all, hospitals will not detract markedly from the overall conclusions, particularly if significant deviation can be shown[28, 29]. Thus, studies based on HES data may actually be appropriate for dealing with research questions such as those posed in this study although less good at identifying variations in care between individual trusts or clinicians[29]. Notably, we were unable to distinguish between patients with external and internal prolapse. There is no HES diagnostic code for internal prolapse and thus a minority of the cohort would be expected to represent patients with obstructed defection syndrome and high grade internal prolapse. Some specific procedure codes may point to such patients in the current cohort e.g. Per-anal resection of rectum using staples (H412) but only 201 patients (<1% cohort) underwent this procedure. Others, e.g. laparoscopic mesh fixation, have been applied to internal and external prolapse [30, 31] but it was not possible in the current cohort to determine how many patients had internal prolapse (hindered further by there being no code for anterior fixation with mesh). We elected to avoid any attempt to dissect data on this basis (hence we describe 'rectal prolapse' rather than 'external rectal prolapse' throughout). Another limitation of this study was the use of reoperation rate rather than actual recurrence rate. Thus, some patients who had a recurrence, but declined (or were unfit) for further repair, will not have been included in the analysis. This indicates that recurrence rates might be higher than the figures provided by these data. Finally, we acknowledge the time expiration on the data presented (only up to 2012). While sometimes it is normal for HES data to be presented several years after initial entry[32, 33], our data are now 7 years old. We do however feel that these still have value in understanding trends in surgical strategy, lack of subspecialisation / centralisation to at least this point in time. It provides surrogate outcomes on much larger numbers of patients than for instance widely cited single centre cohort studies and an under-recruited trial from the same time period[4].

In summary, this population-based cohort study demonstrates an increasing trend in both numbers of admissions and operations for rectal prolapse over the studied decade. Despite there being little or no evidence of service centralisation, there has been a significant change to laparoscopic fixation during this period and this operation appears safe with acceptable reoperation rates.

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