Medical Devices - Clinical Outcomes

PMD1
CLINICAL PERFORMANCE AND COST ANALYSIS OF DIFFERENT PERIPHERAL INTRAVENOUS CATHETERS WITH THE IMPLEMENTATION OF VOLUME-BASED PROCUREMENT IN CHINA

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Objectives: China introduced "Volume-based Procurement (VoBP)" for medical products to contain healthcare costs recently. This study aims to understand the clinical and economic impacts associated with the utilization of different PIVCs resulting from the implementation of VoBP. ***Methods:*** Semi-structured interviews were conducted with qualifying nurses in Nanjing and Linyi, the pilot cities implementing VoBP for PIVCs. Nurses who used a leading multinational company's (MNC's) PIVCs before VoBP and changed to China local brands after VoBP were included. A conceptual framework was developed to systematically organize defined concepts (PIVC placement, complications, product issues, and training). A saturation grid was created to ensure sufficient sample size. Additionally, a cost model from healthcare system perspective was developed to evaluate the corresponding total costs considering the amount of PIVC use, product defects, complication managements, and nursing labor costs. ***Results:*** A total of 27 nurses from 16 clinical settings in Nanjing and Linyi were included. All domains listed in conceptual framework were mentioned in the first 15 interviews, indicating that saturation was achieved. After the change from MNC's PIVCs to local brands, PIVCs used per patient increased from 2.0 to 3.5 and the average indwelling time decreased from 3.7 days to 2.1 days. Compared with MNC's PIVCs, those from local brands were associated with a 0.9-minute increase in PIVC insertion time and a 9% relative decrease in first stick success rate. Increased complication, poor PIVC quality and reduced product training after PIVC change were also mentioned. Taking 100 inpatients as an example, the total costs increased by CNY1,573.3 (from CNY7,765.4 to CNY9,338.7) after PIVC product change. ***Conclusions:*** PIVC product change following the implementation of VoBP may result in unexpected clinical performance issues and increased total costs. Therefore, establishing quality evaluation criteria, incorporating comprehensive economic assessment, and strengthening product monitoring mechanism are recommended for VoBP policy optimization on medical consumables.

PMD2
LAPAROSCOPIC RADIOFREQUENCY ABLATION VS LAPAROSCOPIC MYOMECTOMY IN THE TREATMENT OF SYMPTOMATIC UTERINE LEIOMYOMAS: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

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Objectives: This meta-analysis reviews the evidence from randomized controlled trials (RCTs) which compare laparoscopic radiofrequency ablation (LAP-RFA) and laparoscopic myomectomy (LM), two uterine sparing procedures for managing symptomatic uterine leiomyomas (UL). ***Methods:*** A comprehensive search was performed on PubMed, EMBASE®, and Cochrane Library through October 2020. The inclusion criteria were RCTs comparing LAP-RFA with LM in women with UL. RCTs comparing LAP-RFA with other treatments were excluded. Outcomes of interest were changes in quality of life (QOL) measures such as EQ-5D, uterine fibroid symptom QOL (UFSQOL), health-related QOL (HRQOL) and clinical endpoints such as mean operative blood loss (MOBL), length of hospital stay (LOS), and mean number of fibroids excised. Fixed-effects (FE) and random-effects (RE) models were used to quantify pooled effectiveness of LAP-RFA vs LM. Mean difference (MD), 95% CI, p-value were computed for clinical endpoints using R software (2020). ***Results:*** A total of 579 citations were found and after removing the duplicates, 495 title and abstracts were screened for eligibility. Four studies were eligible for qualitative review and 2 studies (LUSTOR Germany, and TRUST Canada) reporting the results of 96 total patients (47 Lap-RFA, 49 LM), met the inclusion criteria. Improvement in QOL endpoints were similar for Lap-RFA and LM (EQ-5D: p=0.8750, UFSQOL: p=0.7019, HRQOL: p=0.6220). LAP-RFA reduced MOBL compared to LM with statistical significance (FE: MD=-43.93 ml (95% CI: -61.42, -26.45, p<0.001); RE: MD=-44.64 ml (95% CI: -66.21, -23.08; p<0.001)). Moreover, LAP-RFA also reduced the LOS postoperatively compared to LM (FE: MD=-9.47 hours (95% CI: -13.13, -5.81, p<0.001); RE: MD=-11.44 hours (95% CI: -27.80, 4.93; p>0.1707)). Overall, LAP-RFA treated more fibroids than LM but the results were not statistically significant (RE: MD=0.72 (95% CI: -0.17, 1.61; p>0.114). ***Conclusions:*** LAP-RFA was associated with shorter LOS, lower MOBL and similar QOL outcomes compared to LM.

PMD3
THE CURRENT BURDEN OF CATARACT SURGERY AND OUTCOMES OF IMAGE-GUIDED SYSTEMS: A TARGETED LITERATURE REVIEW

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Objectives: To conduct a targeted literature review evaluating the current burden of traditional cataract surgery (with manual marking) and the outcomes associated with digital image-guided systems (DIGS). ***Methods:*** A targeted review of the literature was undertaken using MEDLINE. The review targeted: 1) publications quantifying the burden of traditional cataract surgery (with manual marking) for Toric IOL implantation, and 2) publications evaluating the outcomes of cataract surgery with DIGS. ***Results:*** There were seven studies included in this study, six prospective studies and one meta-analysis. Transcription errors, manual marking inaccuracies, and variabilities from incision size and implantation location were the biggest drivers of burden of traditional cataract surgeries. Transcription errors included incorrect measurement transcription, errors in handwritten results, and illegible writing. Measurement inaccuracies were found to be attributable to movement by the patient, marking pens, and experience of the marker. Additionally, difficulties in accounting for cyclotorsion when making corneal incision and aligning the IOL were observed. Use of DIGS was found to be safe, as or more effective, and more efficient alternative to manual marking. Of the five head-to-head prospective studies, three studies observed significant improvement in accuracy, IOL alignment, and/or visual quality (Strehl Ratio and Modulation Transfer Function). The DIGS significantly reduced Toric IOL misalignment, post-operative astigmatism, and difference vector compared to manual marking in the meta-analysis. ***Conclusions:*** This review found a significant burden associated with traditional cataract surgery, and DIGSs to be safe and effective, while also providing surgeons and practices with increased efficiency.

PMD4
PATIENT-SPECIFIC FACTORS IMPACTING THE REDUCTION IN PAIN OR PAIN MEDICATION UTILIZATION AFTER TREATMENT WITH INTRA-ARTICULAR HYALURONIC ACID IN KNEE OSTEOARTHRITIS: A RETROSPECTIVE COHORT STUDY

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Objectives: Studies have demonstrated that intra-articular hyaluronic acid (IAHA) treatment reduces pain and pain medication use (steroids, non-steroidal anti-inflammatory drugs [NSAIDs] and opioids/narcotics) among patients with knee osteoarthritis (KOA). This study evaluated patient-specific factors that may impact the reduction in pain and pain medication utilization after treatment of KOA with IAHA. ***Methods:*** This retrospective cohort study utilized Optum PanTher Electronic Health Records from 2007 to 2018. Patients >21 years of age were selected if they had a diagnosis of KOA and received IAHA treatment. Outcome was reduced response to IAHA, defined as less than a 15% reduction or any increase in: 1) pain score, 2) NSAIDs, 3) corticosteroids and 4) opioids - between the 6-month pre- and 6-month post-IAHA-treatment periods. Four different multivariable logistic regressions were constructed to assess the impact of various patient-specific factors on each outcome. In addition, Random Forest machine learning models (MLM) were built to understand each factor's importance. ***Results:*** A total of 194,900 patients met inclusion criteria. Of these, data was available for analysis of 42,173 patients for pain scores, 3,587 for NSAIDS, 14,440 for corticosteroids, and 2,530 for opioids. The pain score model showed (Odds Ratio, 95% Confidence Interval): renal disease (5.1, 1.1-23.2), rheumatoid arthritis (1.1, 1.1-1.2), and back pain (1.1, 1.1-1.2) as significantly associated with reduced response to IAHA. The pain medication models showed OA of multiple joints for NSAIDS (1.2, 1.1-1.4) and corticosteroids (1.2, 1.1-1.3), and neurological disorders (2.0, 1.2-3.2) for opioids, were significantly associated with reduced response to IAHA. MLM confirmed the feature importance of the patient-specific factors identified. ***Conclusions:*** Certain patient-specific factors impact the reduction in pain or pain medication utilization after treatment with IAHA. None maintained significance across all models, which may signify other outcomes achieved a response. Results may help providers better manage patient expectations after IAHA treatment of KOA.

Medical Devices - Economic Evaluation

PMD5
DESIGNING A COMPLEX INTERVENTION USING EARLY MODEL-BASED COST-EFFECTIVENESS ANALYSIS: A CASE STUDY OF AN ARTIFICIAL INTELLIGENCE-BASED ALGORITHM TO IDENTIFY VERTEBRAL FRAGILITY FRACTURES

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Objectives: Understand if, and how, using an artificial intelligence-based algorithm (AI) to identify vertebral fragility fractures (VFFs) from routine computed tomography scans (CT) should be used to maximise added value to patients. ***Methods:*** A de-novo decision-analytic model (lifetime horizon; NHS-England perspective) linking a bespoke decision-tree with a published discrete-event

simulation (DES) was conceptualised and developed for a cohort of 400,000 individuals aged 70 years. The intervention (ASPIRE™) used AI to identify VFFs from existing CT with referral (to Fracture Liaison Service (FLS) or general practitioner) to start a bisphosphonate. The comparator was the current practice of radiologists identifying VFFs from CT and referral to start a bisphosphonate. Technical validation was completed using TECH-VER criteria. Model input parameters were identified from published literature and structured expert elicitation. For ASPIRE™ and current practice the base-case analysis reported: number of VFFs identified; costs (£; 2014); quality-adjusted-life-years (QALYs). Uncertainty was quantified using one-way, two-way, scenario, threshold and probabilistic sensitivity analyses. ***Results:*** ASPIRE™ identified 47,029 additional VFFs, costing an additional £8,681,804 (95% confidence interval (CI): £8,606,882 to £8,756,726) generating 139 (CI: 137 to 140) QALYs. The incremental cost-effectiveness ratio was £185 per additional VFF identified. All QALY gains (0.00035 per person) were derived from starting a bisphosphonate (the DES component). Threshold analysis showed increasing QALY gains to 0.00108 resulted in £20,000 per QALY gained. Key drivers of cost-effectiveness were: specificity; ASPIRE™ unit cost; radiologists' time averted by ASPIRE™ and FLS cost. There was substantial uncertainty in the limited evidence available. ***Conclusions:*** Indicative cost-effectiveness analysis shows the importance of embedding ASPIRE™ into a complex intervention directing people to effective bone management strategies (fall prevention, exercise and nutrition programmes) in addition to bisphosphonates and have data to show radiologists' time averted. Importantly, decision-makers must be sufficiently certain in the model-estimated QALY gains from bisphosphonates to understand the potential value of ASPIRE™.

PMD6
PROCEDURE COST-COMPARISON ANALYSIS OF LIQUID EMBOLIC SYSTEM TECHNIQUES USING EVOH AND N-BCA IN THE EMBOLIZATION OF BRAIN ARTERIOVENOUS MALFORMATIONS

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Objectives: To reduce bleeding risk during surgery, brain arteriovenous malformations (bAVMs) may be treated with liquid embolic systems (LES) such as the n-BCA (n-butyl cyanoacrylate) LES and the EVOH [(ethylene vinyl alcohol) copolymer dissolved in DMSO (dimethyl sulfoxide)] LES. To determine the procedure cost of embolization, technique and ancillary devices should be considered including specialized microcatheters developed to reduce complications. A cost-comparison analysis from a US healthcare-cost perspective was conducted to assess procedure costs using n-BCA or EVOH LES techniques. ***Methods:*** The analysis assumed a total of 4mL of liquid embolic was needed to treat 2 pedicles of a bAVM using four techniques. For the n-BCA technique, a 3:1 solution (3mL ethiodized oil/1ml n-BCA); 4mL total, 2mL of solution with 1 PROWLER10 microcatheter were used per pedicle. In the EVOH "Plug-and-Push" technique, 1 unit EVOH34, 2 units EVOH18 and 1 MARATHON microcatheter were used per pedicle. In the EVOH "Detachable-Tip" technique, 2 units EVOH18 and 1 APOLLO ONYX LES delivery microcatheter were used per pedicle. In the EVOH "Balloon-Assisted" technique, 2 units EVOH18 and 1 SCEPTER -XC balloon catheter were used per pedicle. Average selling price was used for devices. ***Results:*** The Plug-and-Push technique had the highest total device cost ($16,998; $15,616 for EVOH, $1,382 for microcatheters). Followed by the Detachable-Tip technique ($14,524; $10,536 for EVOH, $3,988 for microcatheters) and Balloon-Assisted technique ($13,592; $10,536 for EVOH, $3,056 for balloon microcatheters). The least costly was the n-BCA technique $5,834 ($3,942 for n-BCA, $1,892 for microcatheters). Total device costs were 2.3 to 2.9-times higher with EVOH LES techniques compared with n-BCA owing to the need for additional units of EVOH and ancillary devices. ***Conclusions:*** This analysis illustrates that ancillary devices and number of LES kits impact procedure costs. The cost-sparing n-BCA technique for bAVM embolization may result in cost savings for US hospitals.

PMD7
BUDGET IMPACT ANALYSIS OF TRANSCUTANEOUS AFFERENT PATTERNED STIMULATION THERAPY FOR THE TREATMENT OF ESSENTIAL TREMOR IN THE UNITED STATES

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INTRODUCTION: Essential tremor (ET) is a chronic, progressive, and disabling neurological disease, managed with poorly tolerated, partially effective pharmacological treatments and, in some patients, costly surgical or non-reversible ablative procedures. Transcutaneous afferent patterned stimulation (TAPS), delivered by a novel personalized medical device, provides non-invasive, on-demand stimulation of the same key brain networks as the most effective surgery, deep brain stimulation, and has an extensive clinical program demonstrating its efficacy and safety in the treatment of ET. ***Objectives:*** With TAPS device costs concentrated at treatment initiation, an economic analysis was conducted to assess the near-term budget impact of its introduction for the treatment of ET. ***Methods:*** A cost minimization model was developed to calculate the 3-year impact of introducing TAPS therapy for a healthcare plan cohort of 1,000,000 people. Prevalence of ET, as well as costs and incidence of surgical and non-reversible ablative procedures, were gathered from published literature. Acquisition costs and proportion of patients receiving pharmacological treatment options were sourced from Redbook and 24-month data from Truven databases. The economic impact of introducing TAPS was calculated based on an alternative scenario where 3% of patients from each treatment received TAPS therapy. ***Results:*** Within the plan population, 2,992 patients were estimated to receive ET treatment. Introduction of TAPS therapy would have a 3-year budget impact of $62,126 (+0.25% compared with current costs; +$130,233 in the first year and approximately -$34,050 in subsequent years), or $20.56 per treated patient and $0.002 PMPM. ***Conclusions:*** Introduction of TAPS therapy for the treatment of ET had a modest budget impact in the near-term based on acquisition costs alone. TAPS therapy offers an additional, clinically meaningful option for the treatment of ET that is likely to be cost neutral or cost saving when pharmacological adverse event costs or surgical and procedure complication costs are considered.

PMD8
COST-EFFECTIVENESS MODEL OF SUTURELESS AORTIC VALVE IN AORTIC VALVE REPLACEMENT - AN ADAPTATION TO THE BRAZILIAN PUBLIC HEALTHCARE SETTING

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Objectives: To develop a core cost-effectiveness model for the assessment of sutureless aortic valve (SuAV) in comparison to conventional vale replacement (cAVR), and transcatheter aortic valve implantation (TAVI) applying it in the Brazilian setting. ***Methods:*** The model simultaneously analyzes short-term (30 days perioperative) and long-term outcomes (overall, hospitalization-free days and on-dialysis survival). All patients enter the model during the perioperative state which uses discrete simulation modelling techniques (10,000 simulations) and survivors continue to the lifetime Markov part of the model to track long-term outcomes. Overall survival (OS) can be estimated directly from long-term follow up OS studies (base case utilizing data from *Muneretto et al 2015*), or indirectly through an intervention impact on paravalvular leakage (proxy of OS). Analysis was conducted from healthcare payer perspective, and direct costs estimates sourced from clinical practice in Brazil. Utilities have been estimated according to the different quality of life estimates for different heart failure NYHA classes, as heart failure is a direct consequence of ineffective AVR intervention. Both, costs and utilities were annually discounted at rate of 3%. ***Results:*** Based on local Brazilian costing data, SuAV replacement results in cost savings ($-8,047) followed by incremental effectiveness (1.001QALY) compared to TAVI, and should be regarded as a pharmacoeconomically dominant intervention. In comparison with cAVR, the SuAV remains more costly, however results in additional health gains. Respectively for these comparisons, the incremental cost-effectiveness ratio of the SuAV is $8,225/QALY, and $13,079/QALY, which is lower than the informal cost-effectiveness threshold for Brazil ($26,762/QALY). ***Conclusions:*** A novel modelling approach was used to estimate the cost-effectiveness associated with the SuAV. Direct OS estimation sourced from long-term clinical studies was applied through common parametric distributions fits. Base case cost-effectiveness results Brazilian healthcare setting indicate pharmacoeconomic dominance of the SuAV in comparison to TAVI, and acceptable cost-effectiveness versus cAVR.

PMD9
COST-EFFECTIVENESS OF AN ANTIBACTERIAL ENVELOPE FOR CARDIAC ELECTRONIC IMPLANTABLE DEVICES IN HIGH-RISK PATIENTS IN THE PUBLIC SECTOR IN MEXICO

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Objectives: Use of an absorbable antibacterial envelope reduces cardiac implantable electronic device (CIED) infection in patients undergoing implantation, revision, replacement or upgrade. The risk of infection during these procedures is estimated from 1-4% and increases for patients with high-risk factors. We evaluated the cost-effectiveness of the antibacterial envelope in Mexican public institutes in high-risk patients. ***Methods:*** A decision tree model was used to compare costs and outcomes of the antibacterial envelope used