**Temporal changes in radial access use, associates and outcomes in patients undergoing PCI using rotational atherectomy between 2007 and 2014: results from the British Cardiovascular Intervention Society national database**

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**Abstract**

**Aims:** Access site choice for cases requiring rotational atherectomy (PCI-ROTA) is poorly defined. Using the British Cardiovascular Intervention Society PCI database, temporal changes and contemporary associates/outcomes of access site choice for PCI-ROTA were studied. **Methods and Results:** Data were analysed from 11,444 PCI-ROTA procedures performed in England and Wales between 2007 and 2014. Multivariate logistic regression was used to identify predictors of access site choice and its association with outcomes. **Results:** For PCI-ROTA, radial access increased from 19.6% in 2007 to 58.6% in 2014. Adoption of radial access was slower in females, those with prior CABG, and in patients with chronic occlusive (CTO) or left main disease. In 2013/14, the strongest predictors of femoral artery use were age (OR 1.02, [1.005-1.036], p=0.008), CTO intervention (OR 1.95, [1.209-3.314], p=0.006), and history of previous CABG (OR 1.68, [1.124-2.515], p=0.010). Radial access was associated with reductions in overall length of stay, and increased rates of same-day discharge. Procedural success rates were similar although femoral access use was associated with increased access site complications (2.4 vs. 0.1%, p<0.001). After adjustment for baseline differences, arterial complications (OR 15.6, p<0.001), transfusion (OR 12.5, p=0.023) and major bleeding OR 6.0, p<0.001) remained more common with FA use. Adjusted mortality and MACE rates were similar in both groups.**Conclusions:** In contemporary practice, radial access for PCI-ROTA results in similar procedural success when compared to femoral access but is associated with shorter length of stay, and lower rates of vascular complication, major bleeding and transfusion.

**Condensed abstract**

Using the BCIS PCI database, temporal changes in access site choice and outcomes for PCI-ROTA were assessed. In 11,444 patients undergoing PCI-ROTA, radial artery access increased from 19.6% in 2007 to 58.6% in 2014. The strongest predictors of femoral artery use were age, CTO intervention, and history of previous CABG. Radial artery access was associated with shorter hospital stays. Arterial complications, transfusion and major bleeding were more common with femoral artery use. Adjusted mortality and MACE rates were similar in both groups.

**Abbreviations**

BCIS - British Cardiovascular Intervention Society

CABG – Coronary artery bypass surgery

CCS- Canadian Cardiovascular Society

CTO - Chronic total occlusion

MI - Myocardial infarction

NICOR - The National Institute of Cardiovascular Outcomes Research

NYHA – New York Heart Association

OR - Odds ratio

PCI - Percutaneous coronary intervention

ROTA- rotational atherectomy

**Introduction**

Radial arterial access is increasingly used for percutaneous coronary intervention (PCI) worldwide (1-2). Many factors have driven this change in practice over the last decade including a reduction in major bleeding, transfusion and access site complications, an improvement in patient experience, a reduction in length of stay, and a reduction in mortality in certain sub-groups (3-4). Although there remains a significant variation in radial rates by country, centre and operator, many default radial centers now perform over 90% of procedures using radial access (5-6).

Access site choice is defined by a number of factors including physician practice and preference, patient variables, coronary anatomy, radial occlusion, upper arm vascular anatomy, and arterial spasm (7).However, certain complex case sub-groups may still be undertaken using femoral arterial access particularly where larger lumen catheters or dual arterial access is required (8). Rotational atherectomy is one such sub-group in which the need for large lumen catheters particularly for larger burr sizes might be influential in defining access site. The use of temporary venous pacing during rotational atherectomy procedures in certain centres may also influence access choice with operators electing to use the femoral site for both arterial and venous access (9).

Although national trends and outcomes are well defined for unselected PCI procedures, there are few data for the sub-group of complex patients undergoing rotational atherectomy. Therefore, the aim of the present study was to use the British Cardiovascular Intervention Society (BCIS) National PCI Audit data for 2007 to 2014, to explore temporal changes in national arterial access site practice in patients undergoing percutaneous coronary intervention including rotational atherectomy (PCI-ROTA).

**Methods**

*Study design, setting and participants*

We analysed national data from all patients undergoing percutaneous coronary intervention with rotational atherectomy (PCI-ROTA) in England and Wales between January 2007 and December 2014. Only rotational atherectomy cases were included in the analysis with no other mechanical atherectomy devices available used in the United Kingdom. Participants with missing information on access site or use of rotational atherectomy were excluded.

*Setting, data source, and study size*

Data on PCI practice in the United Kingdom were obtained from the British Cardiovascular Intervention Society (BCIS) dataset which records 113 clinical, procedural and outcomes variables with approximately 80,000 new records added each year. The accuracy of and quality of the BCIS dataset has previously been ascertained (10). The participants of the database are tracked by linkage with life status information held by the Office of National Statistics (ONS) using the patients' NHS number.

Study definitions

Using the BCIS dataset, patients were categorised into either radial or femoral access during PCI-ROTA. The dataset records access site as either radial, brachial or femoral as well as left or right side used. Cases where brachial access, multiple arterial access or where the access site was not specified were excluded from the analysis. Study definitions were used as in the BCIS-NICOR database. We excluded any cases where more than one access site was used. To ensure operators first access site choice was recorded and categorised. The atherectomy balloons recorded in the BCIS registry are Scoreflex, Angioscupt and Flextome. The penetration catheters recorded in the BCIS registry are Tornus and Gopher. An access site complication is defined as either a false aneurysm, haemorrhage (without haematoma), haemorrhage with delayed discharge, retroperitoneal haematoma, arterial dissection, or any access site complication requiring surgical repair. In-hospital major bleeding was defined as either gastrointestinal bleed, intra-cerebral bleed, retroperitoneal haematoma, blood or platelet transfusion, or an arterial access site complication requiring surgery. Major adverse cardiac events (MACE) were defined as a combination death, stroke, or myocardial infarction (or re-infarction, depending on indication) after PCI.

*Data analyses*

All study years (2007-2014) are presented initially to study temporal changes in access site during PCI-ROTA. We first investigated if there was a trend over time in use of rotablation in patients with femoral or radial access separately. This was done using a linear regression model and testing for the slope of the regression line. We then investigated if the trend over time for different patient sub-groups was similar according to whether the patient was treated using radial or femoral access by fitting a linear regression model with time, access type and an interaction term between time and access type.

For the purposes of examining the predictors of access site for PCI-RA, analysis was restricted to the final two years of data (2013 and 2014) to encompass more contemporary interventional practice and when changes in access choice rates were minimal. For these years, we examined the baseline characteristics of participants by access site. We tested for associations between each categorical variable and access site using a Chi-squared test, and for continuous variables we used one-way analysis of variance. We then performed an analysis of the predictors of access site in 2013-2014 using multivariate logistic regression to investigate the influence of baseline and procedural characteristics variables that have the potential for being included in the linear component of a proportional hazard model. Covariates included in the model were age, gender, NYA class, previous MI, previous CABG, previous PCI, diabetes, weight, hypertension, renal disease, BMI, LV function, number disease vessels, operator grade, left main PCI, CTO attempted, and procedural imaging use. To correct for missing values, we first imputed missing data on baseline covariates using multiple imputations with chained equations to adjust for missing data (11). We then ran a stepwise forward selection with a proportional hazard model with p<0.02 as entry criteria.

The outcomes of interest were immediate coronary complications, arterial access site complications, length of stay, and clinical outcomes (including in-hospital death, bleeding and MACE, 30-day mortality, and 1-year mortality) for which we initially calculated the crude rates by access site. For length of stay, we investigated if the trend over time in length of stay was similar between radial and femoral access by fitting a linear regression model with time, access type and an interaction term between time and access type. Individual logistic regressions were done on the imputed data set for each of the MACE events according to the access site to quantify the independent association between access site and outcomes. In order to take into account baseline characteristics that might influence outcomes, we performed a propensity score analysis using the inverse probability of treatment weights (12). Covariates included in this analysis were age, gender, ACS presentation, NYHA class, previous MI, previous CABG, previous PCI, diabetes, hypertension, peripheral vascular disease, cerebrovascular disease, renal disease, BMI, left main disease and presence of a CTO. A time to event analysis was performed using Kaplan-Meier curves, log-rank tests and Cox proportional hazard model to estimate the corresponding hazard ratio for mortality.

**Results**

*Temporal changes in access site for PCI-ROTA between 2007 and 2014*

A total of 11,444 patients were treated with PCI-ROTA and included in the analysis between 2007 and 2014. Crude numbers of PCI-ROTA and percentage of PCI-ROTA performed as part of all PCI procedures increased significantly during the study period (Figure 1, left panel). The frequency of radial artery use increased significantly over time with 19.6% of procedures performed radially in 2007 compared with 58.6% in 2014 (Figure 1 right panel, p<0.001 for trend). Although radial access use in most patient sub-groups increased in a similar fashion to the whole cohort, adoption of radial access was less rapid in female patients, those with renal failure, NHYA 3 or 4 and/or a prior history of CABG, and in patients undergoing PCI-ROTA for chronic occlusive or left main disease (Figure 2).

*Baseline demographics and procedural details by access site for PCI-ROTA in 2013 and 2014*

In 2013 and 2014, 4,302 patients underwent PCI-ROTA. Patients who were treated via femoral access were older, more likely to be women, and reported a greater degree of comorbidity including diabetes, hypertension, previous MI, LV dysfunction and renal disease. Patients treated using femoral access were also more likely to have had previous revascularisation with PCI or CABG (Table1). Patients treated via femoral access also had more complex coronary artery disease with more left main stenosis (24.4 vs. 18.5%, p<0.001), chronic occlusive disease (24.2 vs. 21.7, p=0.047) and number of vessels diseased (1.73±0.97 vs. 1.68±0.91, p=0.046) (Table 1). Femoral access appeared to be associated with more complex PCI, with CTO or left main intervention, and atherectomy balloons all more frequently used in comparison to radial access (Table 2). As demonstrated in Table 3, using multivariate analysis the strongest predictors of femoral artery use for PCI-ROTA were age per year (OR 1.02, [1.005-1.0036], p=0.008), CTO intervention (OR 1.95, [1.209-3.314], p=0.006), and history of previous CABG (OR 1.68, [1.124-2.515], p=0.010). The temporal changes in factors associated with femoral artery access are plotted in Supplementary Table 1. Significant temporal increases in patient age, CTO-PCI and left main PCI were observed and in light of this, the significant temporal increases in radial artery access are all the more compelling.

*Length of stay by access site for PCI-ROTA*

In 2013 and 2014, radial access was associated with significant adjusted mean and median decreased length of stay for the whole cohort (Table 4). In the elective sub-group, same-day discharge was significantly more likely in the radial cohort (31.6% of vs. 21.5%, p<0.001). Furthermore, when analysing 2007-2014 data, there was a highly significant temporal increase in the annualised rates of day-case elective PCI-ROTA in the radial cohort, although there was no statistical difference between the two cohorts with respect to the rate of change (Figure 3). However, radial same-day discharge rates were consistently higher than femoral access rates for every study year. For the ACS cohort, differences in same day discharge rates between access sites were not significant. However, there was a significant increase in the number of patients with a length of stay 1-2 days in the radial cohort compared to the femoral cohort. Even if same day discharge cases were excluded to adjustment for inherent biases, mean LOS for radial access remained significantly shorter in elective (1.6±3.3 vs. 1.9±3.9 days, p<0.001) and ACS (2.8±4.8 vs. 3.8±5.0 days, p<0.001) PCI-ROTA cases than femoral cases. The relative difference in the percentage of patients undergoing rotational atherectomy within each category of number of days of admission compared by access site is displayed in Figure 4.

*Clinical outcomes by access site for PCI-ROTA in 2013 and 2014*

Immediate procedural success was similar between femoral and radial access for PCI-ROTA (number of successful lesions 1.61±0.87 vs. 1.58±0.86, p=0.149, Table 5). Coronary complications including perforation and dissection were also similar between the two access sites (5.7 vs. 5.4% for all complications, p=0.677). However, femoral access was strongly associated with increases in all access site complications (2.4 vs. 0.1%, p<0.001), access site haemorrhage (1.3 vs. 0.0%, p<0.001, and access site surgical repair (0.7 vs. 0%, p<0.001). Crude unadjusted clinical end-points including transfusion (1.2 vs. 0.2%, p<0.001), in-hospital major bleeding (2.4 vs. 0.4%, p<0.001), in-hospital death (2.3 vs. 1.4%, p=0.023), in-hospital MACE (4.9 vs. 2.1, p<0.001), and 30-day mortality (3.3 vs. 2.2%, p=0.043) were more likely in patients having PCI-ROTA using femoral access (Table 5). After adjustment for baseline differences, arterial complications (OR 15.6, [3.30-76.92], p<0.001), transfusion (OR 12.5, [1.32-35.67], p=0.023) and major bleeding OR 6.0, [2.11-16.9], p<0.001) remained more common with femoral access use. (Table 6). There were trends for increased in-hospital and 12-month mortality associated with femoral access that did not reach statistical significance. The adjusted Kaplan Meier curves for 12-month survival by access site are displayed in Figure 5.

**Discussion**

In the United Kingdom, as in many countries, radial artery access for angiography and PCI has risen steadily year on year. Despite the major change in overall practice, several sub-groups of procedures such as PCI for chronic occlusive disease continue to be undertaken more often from the femoral artery (8).In the current study, although radial access is now the predominant access site for PCI-ROTA, over 40% of cases still utilise femoral access. This contrasts sharply with the most recent British Cardiovascular Intervention Society (BCIS) National Angioplasty Audit in which for the same year, 75.3% of all PCI procedures in the United Kingdom were performed using the radial artery (13).However, as is demonstrated in this study, radial access rates continue to increase for rotational atherectomy implying that in future years, the radial artery utilisation rate might approach that of less complex procedures. It is noteworthy that the rate of radial access adoption for rotational atherectomy was less rapid in certain important sub-groups such as female sex, patients with previous CABG, and in PCI for chronic occlusive or left main disease. In contemporary practice as a result of this differential in the rate of change, it was these factors along with increased patient age that were predictive of femoral artery access for rotational atherectomy. These data also demonstrate the “radial paradox” i.e. that patients such as the elderly and female who have most to benefit from radial access for complex PCI are less likely to have their procedure performed using this access site (14). The lower rates of vascular access complications and bleeding observed in the whole population in this study are likely to be amplified in these high-risk groups, and these data should encourage operator to further expand radial access use in sub-groups with most to gain.

The relationship between procedural complexity and access site choice for rotational atherectomy has been observed in other cohorts. For example, in a previous study of BCIS data focusing on CTO-PCI, femoral artery use was the predominant access site choice representing 57% of cases even in contemporary practice (8). Similarly, in patients with previous CABG, recent data indicates the predominant of femoral artery access, whether or not rotational atherectomy was utilised (unpublished data). The current data are consistent with previous studies of access site and rotational atherectomy although these published data are on a much smaller scale and limited to single centre series (15-18). The results of these studies have largely demonstrated similar procedural success rates, fluoroscopy times and contrast doses between radial and femoral access for rotational atherectomy. However, as maximal study sizes have all been less than 200 cases, they are underpowered to demonstrate differences in patient outcomes. Therefore, the current study is the first to present data on a national scale, include temporal trends, and report sufficient patient outcomes to allow robust data on patient outcomes to be presented.

In considering the predictors of access choice for rotational atherectomy, the association between femoral access and a history of CABG may reflect the technical challenges of guide manipulation for graft PCI, operator confidence in the ability to achieve adequate catheter support, radial artery harvesting, bilateral mammary artery use, a propensity for CTO disease and unfamiliarity with left radial artery use. Additionally, in a previous study of access site for CTO, we demonstrated that use of enabling technologies/techniques such as trapping balloons necessitating larger caliber guide catheters and significantly increased the likelihood of femoral artery access (8).Therefore, the need for larger sheath size is a likely explanation for the similar association observed between CTO-PCI and femoral access in the current analysis of rotational atherectomy.

A limitation of the current data is that the BCIS registry also does not record sheath size or burr size and therefore it is not possible to construct models such as propensity scores or regression to account for these factors. As 1.25 and 1.5mm burrs will fit down a 6F sheath, the influence of burr size on access site may be relatively modest. Additionally, several emerging technologies and techniques have facilitated more predictable use of larger guide catheters and therefore further ameliorate the influence of burr size required on access site choice in contemporary rotational atherectomy practice. For example, a series of patients treated using a 7F hydrophilic thin-walled sheath for complex coronary interventions reported high rates of procedural success (19). Additionally, dedicated sheathless guide-catheters may also allow increased utilisation of radial artery access with high success rates reported for a 7.5F system (20). Other emerging techniques such as balloon tracking to facilitate standard guide catheter use but without the use of sheath might also support increased use of radial access for rotational atherectomy (21-22). Finally, it remains uncertain whether use of burrs of large size necessitating anything other than 6Fr guide catheters are required in routine PCI practice.

The results of the current analysis suggest that there are several major benefits of radial artery access over femoral artery access for rotational atherectomy. Although acute coronary complications were similar between the femoral and radial cohorts, there was a significant increase in access site complications in the femoral cohort. This was associated with significant increases in transfusion, major bleeding and a trend for increased in-hospital mortality. Previous data from our group and others has confirmed the significant negative impact of vascular complications, bleeding and transfusion on patient morbidity and mortality (23-29).These adverse outcomes may in part contribute to the longer length of stay seen in the femoral cohort. However, the more rapid ambulation after a radial procedure compared to a femoral procedure is likely to be the main reason for these observations (30-31).As is demonstrated by this study, practice in the UK has evolved across all cohorts to encourage same-day discharge for elective PCI, and early mobilization and discharge for ACS-PCI. However, for every year in this study of rotational atherectomy PCI, radial access was associated with increased rates of same-day discharge and shorter length of stay when compared to the femoral cohort. The importance of this should not be underestimated in part because it enhances patient experience but also because of potential cost savings. The financial implications of even modest changes in access site have been estimated to lead to potential annual savings in the United States of $300 million (32).

*Limitations*
As with any database, the robustness of the conclusions are directly related to the quality of data entered. Although there are high levels of case ascertainment and field completion within the database, the accuracy of field completion for individual centers cannot be validated. Additionally, although the BCIS dataset records 113 variables it does not record screening times, procedural times or contrast volumes. Therefore, we are unable to provide data on differences in these end-points with respect to access site. Because of the observational nature of this study, any conclusions may be influenced by unmeasured confounders such as comorbidity and frailty.

*Conclusions*

In contemporary practice, radial access for PCI-ROTA results in similar procedural success when compared to femoral access but is associated with shorter length of stay, and lower rates of vascular complication, major bleeding and transfusion.

**Impact on daily practice**

Access site choice for PCI is a vital part of procedure planning and completion and although many operators have moved to routine radial access, patients undergoing rotational atherectomy present several challenges to the use of the radial route. In the current study, we demonstrate that although, the radial artery has become more frequent in recent years, a significant minority of rotablation procedures (>40%) are still undertaken trans-femorally. Use of the femoral artery was associated with more access site complications and longer lengths of stay and therefore with increased patient morbidity and procedural costs.

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**Conflicts of interest**

There are no conflicts of interest relevant to this work to report on behalf of any authors.

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**Figure Legends**

**Figure 1** Left panel: Crude numbers of rotational atherectomy procedures and percentage of total PCI performed in the United Kingdom between 2007 and 2014 (p<0.001 for trend for both); Right panel: Temporal change in access site choice PCI-ROTA procedures 2007-2014 (p<0.001 for trends).

**Figure 2** Temporal changes in radial access use for rotational atherectomy between 2007 and 2014 plotted by various study sub-groups associated with access site choice for rotablation (p values are for comparison between the trends).

**Figure 3** Temporal change in the percentage of elective rotational atherectomy cases performed on a day-case basis plotted by access site between 2007 and 2014 (p values for individual trends <0.001, p value for comparison between the trends= 0.171).

**Figure 4:** Relative difference in the percentage of patients undergoing rotational atherectomy within each category of number of days of admission compared by access site

**Figure 5** Adjusted Kaplan-Meier curve of 12-month cumulative mortality for patients undergoing PCI-ROTA in 2013 and 2014 plotted by access site, p-value=0.111.