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Manuscript number: CIRCCVINT/2017/005311R1

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Radial versus Femoral Access for Rotational Atherectomy: A UK Observational Study of 8622 Patients

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Short title: Radial vs. femoral for rotational atherectomy

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Word count: 4457

ABSTRACT

Background

Rotational atherectomy (RA) is an important interventional tool for heavily calcified coronary lesions. We compared the early clinical outcomes in patients undergoing RA using radial or femoral access.

Methods and Results

We identified all patients in England and Wales who underwent RA between January 1, 2005 and March 31, 2014. 8622 RA cases (3069 radial and 5553 femoral) were included in the analysis. The study primary outcome was 30-day mortality. Propensity scores (PS) were calculated to determine the factors associated with treatment assignment to radial or femoral access. Multivariable logistic regression analysis, using the calculated PS, was performed. 30-day mortality was 2.2% in the radial and 2.3% in the femoral group (p = 0.76). Radial access was associated with equivalent 30-day mortality (adjusted odds ratio [OR], 1.06; 95% confidence interval [CI], 0.77 to 1.46; p = 0.71), procedural success (OR, 1.04; 95% CI, 0.84 to 1.29; p = 0.73), major adverse cardiac and cerebrovascular events (OR, 1.05; 95% CI, 0.80 to 1.38; p = 0.72) and net adverse clinical events (OR, 0.90; 95% CI 0.71 to 1.15; p = 0.41), but lower rates of in-hospital major bleeding (OR, 0.62; 95% CI, 0.40 to 0.98; p = 0.04) and major access site complications (OR, 0.05; 95% CI, 0.01 to 0.38; p = 0.004), compared with femoral access.

Conclusions

In this large real-world study of patients undergoing RA, radial access was associated with equivalent 30-day mortality and procedural success, but reduced major bleeding and access site complications, compared with femoral access.

INTRODUCTION

Rotational atherectomy (RA) is an important option for the percutaneous treatment of heavily calcified and undilatable coronary lesions (1,2). Historically, femoral artery access was the preferred approach for RA, due to a perceived need for large calibre guiding catheters to accommodate atherectomy burrs with the primary aim of calcium debulking. RA has since evolved into a plaque modification technique, requiring smaller burr sizes, with the aim of facilitating subsequent balloon dilation and implantation of drug-eluting stents (DES). This evolution presents the opportunity to routinely perform RA using radial artery access (3).

In a recent meta-analysis of 24 randomized trials in stable and unstable coronary syndromes, radial access for percutaneous coronary intervention (PCI) was found to reduce overall mortality and improve patient safety, compared with femoral access. There were reductions in major vascular complications and bleeding across the entire spectrum of patients with coronary artery disease (4). Radial access leads to earlier patient ambulation compared with femoral access (5) and is preferred by patients (6). However, there are no large-scale studies to support radial access as the preferred approach for RA in contemporary clinical practice. Reliable comparative data for procedural success and the risk of adverse events after RA, associated with arterial access, site are lacking. This paucity of evidence is important because radial access is increasingly being used worldwide and there has been a resurgence of interest in RA, due to the anatomical complexity of the ageing population and the effectiveness of DES to negate the limitations of RA. Patients who undergo RA have a high risk of recurrent ischemia and bleeding (7) and would benefit from strategies to improve periprocedural safety, but not at the cost of reduced efficacy. Therefore, in a large population of consecutive patients undergoing RA in the United Kingdom (UK), we compared the procedural and 30-day outcomes using radial access versus femoral access.

METHODS

Data collection

The British Cardiovascular Intervention Society (BCIS) collects data related to all PCI procedures performed in the UK. The National Institute of Cardiovascular Outcomes Research (NICOR) manages this database. The BCIS-NICOR database documents more than 100 clinical, procedural and outcome variables. These include demographic data, baseline clinical parameters, angiographic findings and procedural details. In-hospital death, major adverse cardiac and cerebrovascular events (MACCE), major bleeding and access site complications are recorded. Data is collected according to a standard set of definitions and used for national audit and quality purposes, including public reporting of results. Any research department in the UK can apply to receive anonymised data from BCIS-NICOR for the purposes of research. Mortality tracking was provided by the Medical Research Information Service, using unique patient identifiers for all persons registered with the National Health Service in England and Wales. Mortality tracking was unavailable for patients treated in Scotland or Northern Ireland, therefore all procedures from these countries were not included.

Study population

All RA procedures in England or Wales between January 1, 2005 and March 31, 2014 were included. Patients who underwent RA via the right or left radial artery, or the right or left femoral artery, were included in the radial and femoral groups, respectively. Patients who had both radial and femoral arterial access sites used during the same procedure were excluded. Further exclusions were made for missing access site or 30-day mortality data.

Clinical outcomes

The primary outcome of this study was 30-day mortality. The secondary outcomes were procedural success, in-hospital major bleeding, in-hospital major access site complications, in-hospital MACCE and net adverse clinical events (NACE). Procedural success was recorded by the local operator. Major bleeding was defined as gastrointestinal, intracranial or retroperitoneal bleeding, pericardial bleeding causing tamponade, or any bleeding requiring blood or platelet transfusion or resulting in surgery. Major access site complications were defined as false aneurysm, retroperitoneal bleeding, major arterial dissection, access site bleeding requiring blood or platelet transfusion, resulting in surgery or causing delayed discharge. MACCE was defined as a composite of 30-day mortality, in-hospital myocardial infarction, in-hospital target vessel revascularisation (TVR) or in-hospital cerebrovascular event (stroke or transient ischemic attack). NACE was a composite of MACCE or in-hospital major bleeding. Complete revascularisation was defined as zero vessels with obstructive stenosis post-PCI (left main stem ≥ 50%, or left anterior descending, circumflex or right coronary artery ≥ 75%), excluding cases with previous, unknown or missing coronary artery bypass grafting (CABG) status and residual obstructive stenosis, as BCIS does not record data for bypass graft patency.

Statistical Analysis

Data analysis was performed using Stata V14.1 (College Station, Texas). Baseline data were compared for all eligible RA cases by radial and femoral access site. Missing data were dealt with by imputation through chained equations (ICE) using the “ice” module in Stata. The degree of missing data is provided in the Supplementary Table. We used the FMI (fraction of missing data) to determine the number of imputed data sets. Baseline data were compared using χ^2 statistic for categorical variables and Kruskal-Wallis tests for continuous data. We estimated odds ratios (ORs) of study outcomes associated with access site using logistic regression models. The association between access site and outcome was first assessed with univariable logistic regression.

To allow appropriate multivariable adjustment, and to avoid the issue of overfitting, a two-step process employing propensity scores (PS) was used. First, we calculated the PS for each case, defining the dependent outcome as access site (radial or femoral). The PS was calculated, based on predefined clinically important covariables, available within the BCIS-NICOR database. The following variables were included in the PS model: age, sex, diabetes, hypertension, peripheral arterial disease, clinical presentation (stable or acute coronary syndrome [ACS]), renal disease, hypercholesterolemia, largest balloon or stent diameter, stent length, number of vessels treated, artery treated, mechanical support, family history, previous CABG, use of glycoprotein inhibitor, deprivation quintile, cardiogenic shock, previous stroke or transient ischemic attack, use of DES, impaired left ventricular (LV) function, recent fibrinolysis, heart block requiring pacing and year of procedure. The second step was to use the calculated PS as a covariable adjustment when assessing the association between radial (vs. femoral) access and the study outcomes. Both univariable and multivariable (PS-adjusted) logistic regression analyses are reported.

RESULTS

Study population

The flow of procedures in the study is shown in Figure 1. A total of 729 268 PCI procedures were recorded by BCIS-NICOR in England and Wales between January 1, 2005 and March 31, 2014, of which 9712 (1.3%) involved RA. 8622 RA procedures had utilized a single arterial access route (radial or femoral only) and were included in the analysis. There were 3069 RA procedures in the radial group and 5553 in the femoral group. There was a progressive increase in the use of radial access for RA throughout the study period (Figure 2).

Patients in the radial group were more likely to be male and treated for an ACS, and had a lower incidence of previous CABG, renal disease, impaired LV function, mechanical support and temporary pacing (Table 1). A higher rate of DES implantation was present in the radial group, reflecting the temporal shift in the use of radial access and DES use. Use of glycoprotein inhibitors and recent fibrinolysis were similar in both groups. The PS was calculated and the c-statistic was 0.68, indicating moderate to good discrimination. The Hosmer-Lemeshow test was non-significant (p = 0.32).

Relationship between access site and 30-day mortality

Crude 30-day mortality was available for all patients and was 2.25% (194/8622) in the overall RA population, 2.18% (67/3069) in patients treated using radial access and 2.29% (127/5553) in patients treated using femoral access (radial [vs. femoral] OR, 0.95; 95% confidence interval [CI], 0.71 to 1.29; p = 0.76) (Table 2 and 3). PS-adjusted logistic regression analysis was performed, accounting for differences in baseline clinical and procedural characteristics, and demonstrated no difference in 30-day mortality between radial and femoral groups (adjusted OR, 1.06; 95% CI, 0.77 to 1.46; p = 0.71) (Table 3). There was no difference in the time trend analysis of 30-day mortality, based on year of procedure (test of homogeneity [equal odds], p = 0.36).

Relationship between access site and secondary outcomes

The crude rates of all prespecified study outcomes associated with access site are shown in Table 2. Univariable and PS-adjusted ORs using radial access as a predictor of study outcomes are shown in Table 3. Procedural success was equivalent in radial and femoral groups (95.2% vs. 94.9%; p = 0.56; adjusted OR, 1.04; 95% CI, 0.84 to 1.29; p = 0.73). Radial access was associated with a lower incidence of in-hospital major bleeding, compared with femoral access (1.0% vs. 1.8%; p = 0.004). Using PS-adjusted logistic regression analysis, radial access was independently associated with a lower incidence of in-hospital major bleeding (adjusted OR, 0.62; 95% CI, 0.40 to 0.98; p = 0.04). Radial access was associated with a lower incidence of major access site complications, compared with femoral access (0.04% vs. 1.3%; p < 0.001); after PS-adjustment, radial access was independently associated with a reduction in major access site complications (adjusted OR, 0.05; 95% CI, 0.01 to 0.38; p = 0.004).

The incidence of MACCE was similar in radial and femoral groups (3.2% vs. 3.5%; p = 0.37; adjusted OR, 1.05; 95% CI, 0.80 to 1.38; p = 0.72). There was a lower incidence of NACE in the radial group (3.7% vs. 4.9%; p = 0.01); however, after PS-adjustment, we found no difference for this outcome (adjusted OR, 0.90; 95% CI, 0.71 to 1.15; p = 0.41). The incidence of 30-day mortality, in-hospital myocardial infarction or cerebrovascular event (2.9% vs. 3.4%; p = 0.22; adjusted OR, 0.99; 95% CI, 0.75 to 1.32; p = 0.97) and in-hospital TVR (0.3% vs. 0.2%; p = 0.28; adjusted OR, 1.58; 95% CI, 0.63 to 3.94; p = 0.32) were not different between radial and femoral groups, respectively. The rate of complete revascularization was lower in patients treated using radial access (63.7% vs. 66.8%; p = 0.02); however, after PS-adjustment, radial access was not an independent predictor of complete revascularization (adjusted OR 0.92, 95% CI, 0.82 to 1.04; p = 0.19).

DISCUSSION

The BCIS-NICOR database effectively includes the totality of UK experience and outcomes related to the use of RA during the past decade. This observational study is the largest real-world comparison of patients undergoing RA via the radial or femoral arterial access route. We found no difference in 30-day mortality between radial and femoral groups. The absence of early mortality benefit associated with radial access in this study may reflect the predominantly stable population treated (approximately two-thirds of procedures were for stable angina) and the very low incidence of RA performed in the primary or rescue PCI population (1.3% of cases in this study), both of which represent patient groups in whom the greatest mortality benefit with radial access has been demonstrated. However, radial access was associated with equivalent procedural success and a significantly lower incidence of in-hospital major bleeding and major access site complications, suggesting radial access was the safer approach for RA. Importantly, no drawbacks of radial access were identified, despite the historical perceived advantages of femoral access.

Whilst no differences in survival were identified in our analysis, avoidance of vascular complications and bleeding is a major safety principle in modern PCI practice. In other studies, access site bleeding has been independently associated with an increase in mortality in patients undergoing PCI (8,9). Periprocedural major bleeding increases the risk of early and late mortality (10, 11), and the adverse effect on survival is more pronounced in women, who have a higher risk of major bleeding than men (12). Preprocedural risk stratification for bleeding may prompt implementation of bleeding avoidance strategies (including radial access) that can reduce the risk of major bleeding associated with PCI (13).

RA necessitates additional technical and training considerations compared to standard PCI, perhaps reflected in the relatively cautious adoption of radial access for this procedure in the UK. However, there is now widespread understanding that the technical challenges and procedure-related complications related to the historical calcium debulking technique can be overcome in the great majority using a contemporary smaller (and usually single) burr approach (3). A 6 French guiding catheter can easily accommodate a 1.25 mm or 1.5 mm atherectomy burr and, in some cases, a 1.75 mm burr, depending on the internal catheter dimensions stated by the manufacturer and experience of the operator. Contemporary RA using burrs within this range (providing a burr-to-artery ratio of 0.5-0.6) will, in most cases, fulfil the main objective of plaque modification, by disrupting the continuity of concentric atherosclerotic calcium rings. If more extensive RA is required, 1.75 mm and 2.00 burrs can be accommodated using a 7 or 7.5 French guiding catheter, which are compatible with most radial arteries, when inserted through a thin-walled hydrophilic sheath (14) or using a sheathless approach (15). Radial access enables more patients with severe peripheral arterial disease or high bleeding risk, such as the elderly and patients presenting with ACS, to undergo RA safely and effectively. Given the safety and potential for routine early ambulation after radial procedures, day case elective RA may be feasible for some patients.

Advantages

Using the BCIS-NICOR dataset, we have been able to study 8622 complex PCI cases involving RA during the past decade. It is highly unlikely that this number of RA procedures could be studied in a prospective randomized controlled manner. Thus, in the present PCI era, the current RA study provides a unique opportunity to study the effects of important procedural factors in this complex and increasingly common lesion subset. Mortality tracking was complete for all patients, and this provided a robust and unbiased primary end-point. Although observational in nature, the positive findings of this study are consistent with the weight of evidence supporting radial access for PCI in patients with less complex lesion types.

Limitations

Our study has some limitations. Due to the retrospective observational nature of the study, differences may exist between groups which may affect the success and safety of each approach if examined in a prospective randomized manner. Hence, we cannot prove causality or exclude the possibility of residual confounding. It was not possible to assess whether both radial and femoral access were equally feasible for each individual case. In-hospital complications were recorded by individual institutions and may have been subject to under-reporting. The radial group differed from the femoral group with respect to several baseline variables, however we performed multivariable logistic regression using PS, to adjust for potential confounding.

Certain data are unavailable in the BCIS-NICOR national dataset, and cannot be added retrospectively. Anatomical features, such as degree of calcification or tortuosity, were not recorded and, if lesion complexity had been significantly different between groups, this may have influenced the relative procedural success and incidence of complications. Patient radiation exposure and procedure time were not known; however, we have previously reported no access site-dependent difference in these parameters for rotational atherectomy (16). Data for arterial sheath, guiding catheter or burr size were not recorded, although it is likely that these were smaller in the radial group (16). Smaller calibre devices may contribute to improved safety with radial access, but without reduced procedural success, when using a contemporary RA technique.

Limitations in collected data fields and missing data are inherent in studies derived from large-scale national registries. However, the large number of cases available for comparison more than mitigates these shortcomings and provides an invaluable insight into real-world practice.

CONCLUSION

We have demonstrated in a large all-comer UK population of 8622 patients undergoing RA, that radial access was associated with equivalent 30-day mortality, procedural success and MACCE, compared with femoral access. Radial access was associated with a lower risk of in-hospital major bleeding and major access site complications, thus supporting radial access as the default contemporary approach for most patients requiring RA.

SOURCES OF FUNDING

Boston Scientific provided the funding for the data extract from BCIS-NICOR, but had no input into any aspect of the study.

DISCLOSURES

Dr Oldroyd reports receiving speaker fees and research support from Boston Scientific. Dr Austin has received speaker and proctoring fees from Abbott Vascular.

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Table 1. Baseline clinical and procedural characteristics.

Variable	Radial (n = 3069)	Femoral (n = 5553)	p Value
Age, yrs.	72.5 ± 0.17	73.0 ± 0.12	0.006
Male	2299/3062 (75.1)	3893/5541 (70.3)	< 0.001
ACS	1233/3069 (40.2)	1896/5553 (34.1)	< 0.001
Diabetes	911/2994 (30.4)	1604/5309 (30.2)	0.84
Smoking history	1851/2843 (65.1)	2963/4840 (61.2)	0.001
Hypercholesterolaemia	2010/2932 (68.6)	3698/5227 (70.8)	0.04
Hypertension	2129/2937 (72.5)	3917/5227 (74.9)	0.02
Previous MI	1072/2854 (37.6)	2125/5019 (42.3)	< 0.001
Previous CABG	349/3016 (11.6)	964/5407 (17.8)	< 0.001
Impaired LV function (EF <50%)	730/2138 (34.1)	1239/3326 (37.3)	0.02
Cardiogenic shock	19/2849 (0.7)	57/5151 (1.1)	0.05
Peripheral arterial disease	369/2932 (12.6)	603/5221 (11.6)	0.17
Previous stroke or TIA	245/2931 (8.4)	373/5223 (7.1)	0.05
Renal disease	139/2923 (4.8)	418/5230 (8.0)	< 0.001
No. of vessels attempted	1.37 ± 0.01	1.34 ± 0.01	0.02
Vessel attempted -			
Left main stem	387/3055 (12.7)	914/5522 (16.6)	< 0.001
Left anterior descending artery	1752/3055 (57.3)	2879/5522 (52.1)	< 0.001
Circumflex artery	645/3055 (21.1)	1118/5522 (20.2)	0.34
Right coronary artery	1021/3055 (33.4)	1984/5522 (35.9)	0.02
Bypass graft	27/3055 (0.9)	76/5522 (1.4)	0.05
No. of lesions attempted	1.62 ± 0.02	1.61 ± 0.01	0.68
Drug-eluting stent used	2677/3046 (87.9)	4533/5471 (82.9)	< 0.001

Glycoprotein inhibitor used	378/2751 (13.7)	751/5058 (14.9)	0.18
Recent fibrinolysis	30/1268 (2.4)	40/2182 (1.8)	0.29
Mechanical support	46/2825 (1.6)	174/5209 (3.3)	< 0.001
Temporary pacing	12/2819 (0.4)	42/5169 (0.8)	0.04

Values are mean ± SD or n/denominator (%). ACS acute coronary syndrome, MI myocardial infarction, CABG coronary artery bypass grafting, LV left ventricular, EF ejection fraction, TIA transient ischemic attack.

Table 2. Access site and crude rate of study outcomes.

Outcome	Radial (n=3069)	Femoral (n=5553)	p Value
30-day mortality	67/3069 (2.2)	127/5553 (2.3)	0.76
Procedural success	2906/3052 (95.2)	5173/5449 (94.9)	0.56
In-hospital major bleeding	29/2969 (1.0)	96/5402 (1.8)	0.004
Major access site complication	1/2782 (0.04)	66/5184 (1.3)	< 0.001
MACCE	94/2969 (3.2)	191/5401 (3.5)	0.37
NACE	111/2969 (3.7)	265/5401 (4.9)	0.01

Values are n/denominator (%). MACCE major adverse cardiac and cerebrovascular events. NACE net adverse clinical events.

Table 3. Univariable and multivariable analysis using radial access (vs. femoral) as a predictor of study outcomes.

Outcome	Univariable OR (95% CI)	p Value	Multivariable OR (95% CI)	p Value
30-day mortality	0.95 (0.71-1.29)	0.76	1.06 (0.77-1.46)	0.71
Procedural success	1.05 (0.86-1.29)	0.62	1.04 (0.84-1.29)	0.73
In-hospital major bleeding	0.54 (0.36-0.82)	0.004	0.62 (0.40-0.98)	0.039
Major access site complication	0.05 (0.01-0.30)	0.001	0.05 (0.01-0.38)	0.004
MACCE	0.89 (0.69-1.14)	0.36	1.05 (0.80-1.38)	0.72
NACE	0.78 (0.63-0.97)	0.03	0.90 (0.71-1.15)	0.41

MACCE major adverse cardiac and cerebrovascular events. NACE net adverse clinical events.

Supplementary Table. Baseline characteristics and extent of missing data.

Variable	Radial (n = 3069)	Femoral (n = 5553)
Age, yrs	72.5 ± 0.17	73.0 ± 0.12
Missing	1	2
Male	2299/3062 (75.1)	3893/5541 (70.3)
Missing	7	12
ACS	1233/3069 (40.2)	1896/5553 (34.1)
Missing	0	0
Diabetes	911/2994 (30.4)	1604/5309 (30.2)
Missing	75	244
Smoking history	1851/2843 (65.1)	2963/4840 (61.2)
Missing	226	713
Hypercholesterolaemia	2010/2932 (68.6)	3698/5227 (70.8)
Missing	137	326
Hypertension	2129/2937 (72.5)	3917/5227 (74.9)
Missing	132	326
Previous MI	1072/2854 (37.6)	2125/5019 (42.3)
Missing	215	524
Previous CABG	349/3016 (11.6)	964/5407 (17.8)
Missing	53	146
Impaired LV function (EF <50%)	730/2138 (34.1)	1239/3326 (37.3)
Missing	931	2227
Cardiogenic shock	19/2849 (0.7)	57/5151 (1.1)
Missing	220	402

Peripheral arterial disease	369/2932 (12.6)	603/5221 (11.6)
Missing	137	332
Previous stroke or TIA	245/2931 (8.4)	373/5223 (7.1)
Missing	138	330
Renal disease	139/2923 (4.8)	418/5230 (8.0)
Missing	146	323
No. of vessels attempted	1.37 ± 0.01	1.34 ± 0.01
Missing	20	37
Vessels attempted -		
Left main stem	387/3055 (12.7)	914/5522 (16.6)
Missing	14	31
Left anterior descending artery	1752/3055 (57.3)	2879/5522 (52.1)
Missing	14	31
Circumflex artery	645/3055 (21.1)	1118/5522 (20.2)
Missing	14	31
Right coronary artery	1021/3055 (33.4)	1984/5522 (35.9)
Missing	14	31
Bypass graft	27/3055 (0.9)	76/5522 (1.4)
Missing	14	31
No. of lesions attempted	1.62 ± 0.02	1.61 ± 0.01
Missing	20	37
Drug-eluting stent used	2677/3046 (87.9)	4533/5471 (82.9)
Missing	23	82
Glycoprotein inhibitor used	378/2751 (13.7)	751/5058 (14.9)
Missing	318	495

Recent fibrinolysis	30/1268 (2.4)	40/2182 (1.8)
Missing	1801	3371
Mechanical support	46/2825 (1.6)	174/5209 (3.3)
Missing	244	344
Temporary pacing	12/2819 (0.4)	42/5169 (0.8)
Missing	250	384

Values are mean ± SD or n/denominator (%). ACS acute coronary syndrome, MI myocardial infarction, CABG coronary artery bypass grafting, LV left ventricular, EF ejection fraction, TIA transient ischemic attack.

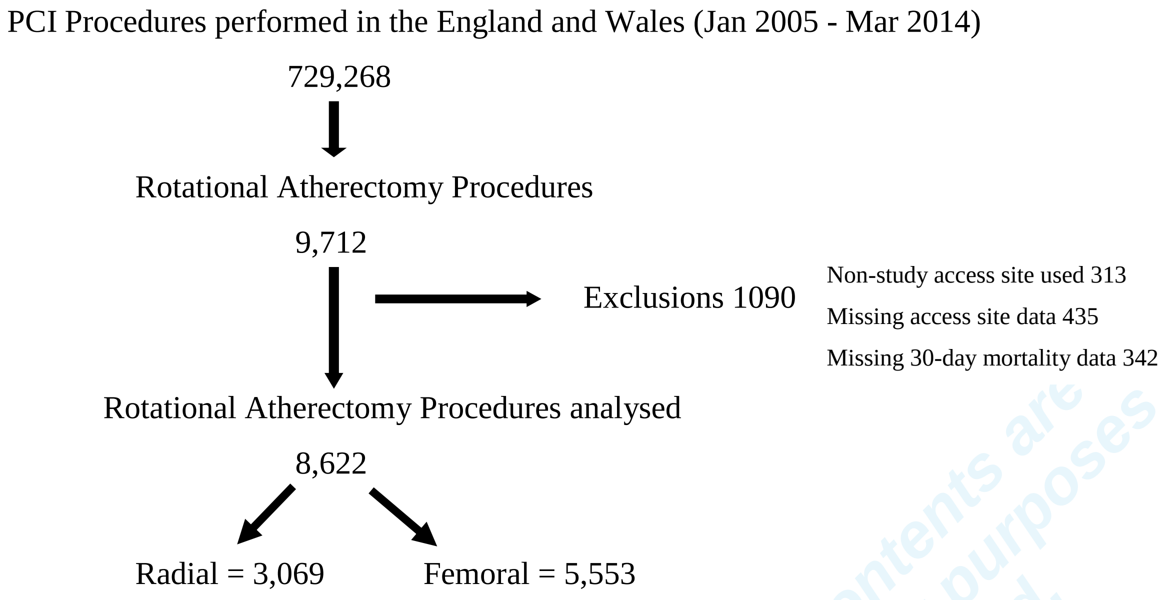

Figure 1. Flowchart of eligibility and exclusions of the BCIS-NICOR dataset.

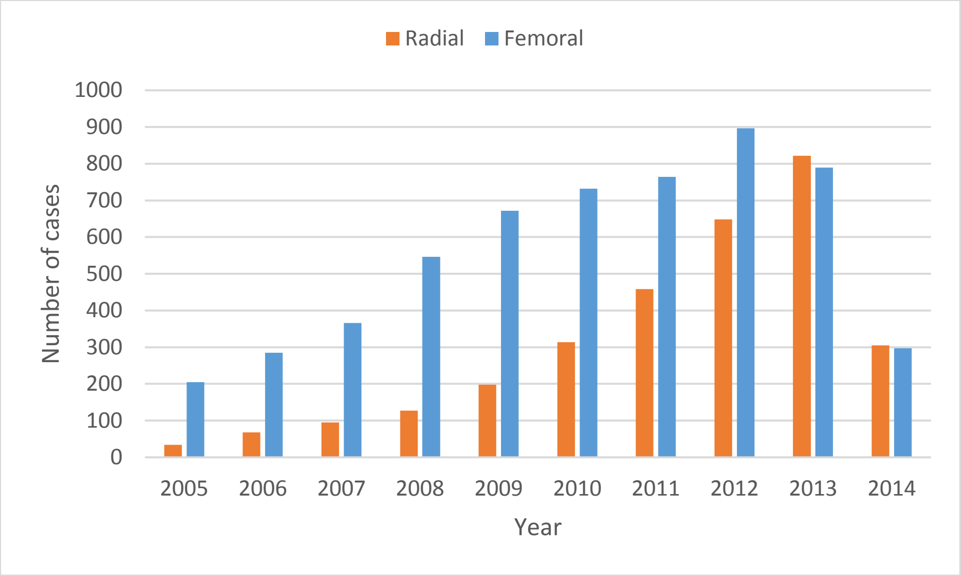

Figure 2. Year of procedure for radial and femoral cases (Jan 2005 to Mar 2014).