Characteristics and Outcomes of Patients Who Underwent Coronary Atherectomy in Centers With and Without On-Site Cardiac Surgery

Mohamed Dafaalla, Msc[a], Muhammad Rashid, PhD[a], Saadiq Moledina, Msc[a], Tim Kinnaird, PhD[b], Peter Ludman, MD[c], Nick Curzen, PhD[d], Sarah Zaman, PhD[e,f], James Nolan, MD[a], and Mamas A. Mamas, DPhil[a,g,*]

We aimed to describe the clinical characteristics and outcomes of patients who underwent atherectomy at the time of percutaneous coronary intervention in centers with on-site surgical centers (SCs) versus nonsurgical centers (NSCs). Patients treated with coronary atherectomy between January 1, 2006, to December 31, 2019, from the British Cardiovascular Society Intervention (BCIS) registry were included. Primary outcomes were in-hospital all-cause mortality and major adverse cardiovascular and cerebrovascular events. A total of 20,833 patients were treated with coronary atherectomy, of which 7,983 (38%) were performed at NSC. The proportion of coronary atherectomies performed in NSC increased from 12.5% in 2006 to 42% in 2019. Compared with patients treated at SC, patients treated in NSC were older (mean age 75.1 ± SD years vs 74.2 ± SD, p <0.001), but had comparable prevalence of hypertension (NSC 73.9% vs SC 72.8%, p = 0.085), diabetes mellitus (NSC 32.2% vs SC 31.6%, p = 0.43) and renal disease (NSC 6.0% vs SC 6.0%, p = 0.99). Intracoronary imaging was used more often in NSC than SC (22.3% vs 19.4%, p <0.001). After adjustment, the odds of in-hospital mortality (odds ratios [OR] 0.76, 95% confidence intervals [CI] 0.50 to 1.16), major adverse cardiovascular and cerebrovascular events (OR 0.80, 95% CI 0.53 to 1.21), emergency coronary artery bypass graft (OR 0.49, 95% CI 0.15 to 1.57), major bleeding (OR 0.67, 95% CI 0.36 to 1.24) and coronary perforation (OR 1.07, 95% CI 0.97 to 1.43) in NSC were comparable with SC. In conclusion, coronary atherectomy in hospitals with off-site surgical cover has become more frequent, with no association with poorer outcomes, compared with hospitals with on-site surgical cover. **(Am J Cardiol 2023;204:242−248)**

Keywords: atherectomy, nonsurgical centers, outcomes

Around 1 in 5 patients who underwent percutaneous coronary intervention (PCI) have moderate to severe calcific coronary disease which is associated with higher rates of procedural complications and higher stent failure.[1−3] The incidence of severe calcific coronary disease has increased because of the aging population and the increasing prevalence of cardiometabolic risk factors such as diabetes mellitus and chronic kidney disease.[4] Concomitantly, the use of atherectomy has increased steadily in the last decade because of the higher incidence of severe calcific coronary lesions and the increasing recognition of the importance of calcium modification strategies.[5,6] The use of atherectomy is associated with an increased risk of coronary perforation, slow flow, and about twice the risk of transient vessel occlusion.[7,8] Randomized control trials and observational data suggest that the risk of severe complications that require urgent coronary artery bypass graft (CABG) during rotational atherectomy ranges from 0.2% to 0.8%.[9] However, there are no guidelines to mandate onsite cardiac surgery backup while performing complex PCI procedures. Currently, the use of atherectomy is not confined to centers with on-site cardiac surgery support, with previous data reporting that around 20% of atherectomies are undertaken in hospitals without on-site cardiac surgery cover.[10] The impact of onsite cardiac surgery on the clinical outcomes in all-comers PCI has been thoroughly investigated. However, there is limited large-scale, multi-site, real-world data describing the safety of atherectomy in centers without on-site cardiac surgery. This study aims to describe the impact of the availability of on-site cardiac surgery cover on clinical outcomes.

[a]Keele Cardiovascular Research Group, Centre for Prognosis Research, Institute for Primary Care and Health Sciences, Keele University, Keele, United Kingdom; [b]University Hospital of Wales, Cardiff, United Kingdom; [c]University Hospitals Birmingham NHS Foundation Trust, Birmingham, United Kingdom; [d]Coronary Research Group, University Hospital Southampton NHS Trust and Faculty of Medicine, University of Southampton, Southampton, United Kingdom; [e]Department of Cardiology, Westmead Hospital, Sydney, Australia; [f]Westmead Applied Research Centre, University of Sydney, Australia; and [g]Department of Medicine, Thomas Jefferson University, Philadelphia, Pennsylvania. Manuscript received January 27, 2023; revised manuscript received and accepted July 13, 2023.

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*Corresponding author: Tel: 01782 715444.

E-mail address: mamasmamas1@yahoo.co.uk (M.A. Mamas).

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Methods

In this retrospective cohort study, the British Cardiovascular Society Intervention (BCIS) registry was used, with all patients aged >18 years who underwent PCI with atherectomy between January 1, 2006, to December 31, 2019 included. The BCIS PCI registry collects data on clinical characteristics, angiographic profile, procedural pharmacology, and in-hospital outcomes of almost all patients (>95%) who underwent PCI in England and Wales.[11] Data are used for audit, research, and public reporting purposes, without formal patient consent under Section 251 of National Health Services Act 2006.[12,13] This study did not require institutional ethical approval as the data was analyzed without identifiable information.

Patients with missing information about important study demographics such as age, in-hospital death, and availability of on-site cardiac surgery coverage were excluded from the study. Study patients were grouped into surgical centers (SCs) and nonsurgical centers (NSCs) based on the presence or absence of on-site cardiothoracic surgical support, respectively.

The primary outcomes were in-hospital major adverse cardiovascular and cerebrovascular events (MACCEs; composite of death, acute stroke/transient ischemic attack, and reinfarction) and all-cause mortality. The secondary outcomes were emergency CABG, coronary perforation, and major bleeding (defined as gastrointestinal bleed, intracerebral bleed, retroperitoneal hematoma, blood or platelet transfusion, or an arterial access site complication requiring surgery.).[12] We also undertook a sensitivity analysis on patients who underwent PCI after excluding primary PCI patients.

We reported continuous variables as mean values with SD for the normally distributed variables and reported the mean for the skewed variables. Categorical variables are summarized as percentages and analyzed using the chi-square test. We used the multiple imputations with chained equations algorithm to input the missing data. The missing data were assumed to be missing at random, and 10 imputed datasets were generated, and the subsequent analyses were performed on the imputed dataset.[13−15] We performed multilevel logistic regression models with random effect to adjust for variation between the centers and assessed the association between surgical cover status and in-hospital adverse outcomes, namely MACCE and in-hospital mortality. Variables adjusted for in the models included age, gender, race, clinical syndrome, previous acute myocardial infarction, previous PCI, previous CABG, diabetes mellitus, chronic renal disease, family history of ischemic heart disease, left ventricular function, hypercholesterolemia, peripheral vascular disease, previous cerebrovascular accident, hypertension, smoking status, cardiogenic shock, circulatory support by intra-aortic balloon pump, vascular access, stent length, use of fractional flow reserve, intravascular imaging (intravascular ultrasound) or optical coherence tomography, warfarin and use of glycoprotein IIb/IIIa inhibitor. We reported the outcomes as odds ratios (ORs) with corresponding 95% confidence intervals (CIs). All statistical analyses were performed using Stata 16 MP (College Station, Texas).

Results

The analytical cohort of this study composed 20,833 patients who underwent atherectomy (721 [3.5%] directional atherectomy and 20,046 [96.5%] rotational atherectomy) during the study period, of which 7,983 (38%) were performed in NSC. The overall frequency of atherectomy increased steadily from 2006 (SC 335 cases [87%], NSC 48 cases [13%]) to 2019 (SC 1,213 cases [58%], NSC 867 cases [42%]) as shown in Figure 1. This constitutes around 0.9% of all-comers PCI in 2006 compared with 2.0% in 2019. The proportion of coronary atherectomies in NSC increased from 12.5% in 2006 to 42% in 2019 (Figure 1). The incremental increase in use of atherectomy was predominantly in elective PCI and non−ST-elevation myocardial infarction in both SC and NSC. In contrast, the use of atherectomy in patients with ST-elevation myocardial infarction remained relatively stable, as shown in Figures 2 and 3.

Table 1 lists the demographic and clinical characteristics of atherectomy patients according to the availability of on-site cardiac surgery cover. Patients in the NSC group were older (median age 75.1 vs 74.2 years, p <0.001), less likely to be women (26.2% vs 27.4%, p <0.001) and more likely to be of Black and minority ethnicity (15.8% vs 9.3%, p <0.001), compared with patients treated in SC. Patients treated in NSC were less likely to have cardiogenic shock (NSC 1.5% vs SC 2.1%, p <0.001) or out-of-hospital cardiac arrest (NSC 0.8% vs SC 1.3%, p <0.001). The prevalence of cardiovascular co-morbidities such as hypertension (NSC 73.9% vs SC 72.8%, p = 0.085), diabetes mellitus (NSC 32.2% vs SC 31.6%, p = 0.43), renal disease (NSC 6.0% vs SC 6.0%, p = 0.99) and hypercholesterolemia (NSC 66.4% vs SC 65.7%, p = 0.29) was similar between the 2 groups.

Table 2 lists the angiographic profile of patients who had atherectomy. Radial access was used less frequently in SC than NSC (49.4% vs 61.3%, p <0.001). The number of stents used and lesions treated was higher in the NSC cohort. The stent length in the NSC was longer than in the SC (mean stent length in the NSC 39.3 vs SC 33.3 mm, p <0.001). Left main stem lesions (NSC 40.9% vs SC 43.6%, p <0.001) and chronic total occlusions (CTOs) (NSC 9.7% vs 8.8%, p = 0.05) were common in both groups. The average stent diameter was similar (3.6 mm) for both groups. Intracoronary imaging was more common in NSC than SC (22.3% vs 19.4%, p <0.001). Supplementary figure 1 and 2 show the volume of PCIs performed in centres with onsite and off-site surgical cover.

The crude rate of procedural complications including major bleeding (SC 0.9% vs NSC 0.5%, p = 0.001), coronary perforation (SC 3.1% vs NSC 3.6%, p = 0.06), and emergency CABG (NSC 0.1% vs SC 0.1%, p = 0.092) was low in both groups. The crude in-hospital mortality (NSC 1% vs SC 2.0%, p <0.001) and MACCE (NSC 1.4% vs SC 2.1%, p <0.001) were greater in the SC cohort. After adjusting for patient and procedural variables, atherectomy performed in NSC versus SC had no significant difference in odds of in-hospital mortality (OR 0.76, 95% CI 0.50 to 1.16) or MACCE (OR 0.80, 95% CI 0.53 to 1.21). The odds of emergency CABG (OR 0.49, 95% CI 0.15 to 1.57), major bleeding (OR 0.67, 95% CI 0.36 to 1.24), or coronary perforation (OR 1.07, 95% CI 0.79 to 1.43) were not

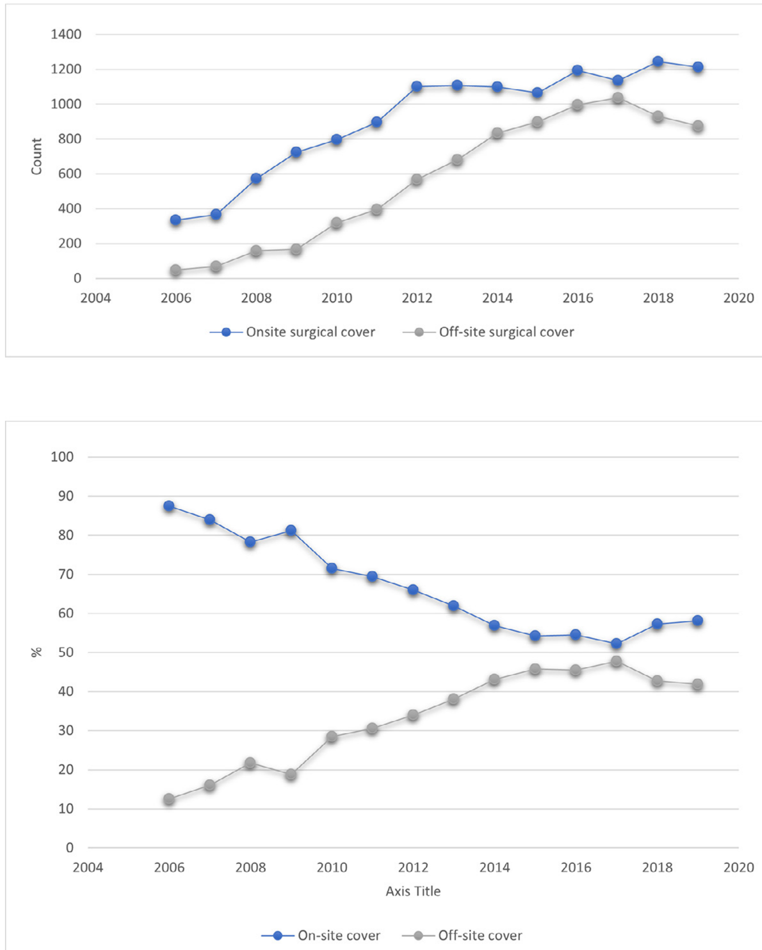

Figure 1. Atherectomy PCI in centers with on-site and off-site surgical cover. A: Number of atherectomy PCI in centers with on-site and off-site surgical cover. B: Proportion of atherectomy PCI in centers with on-site and off-site surgical cover.

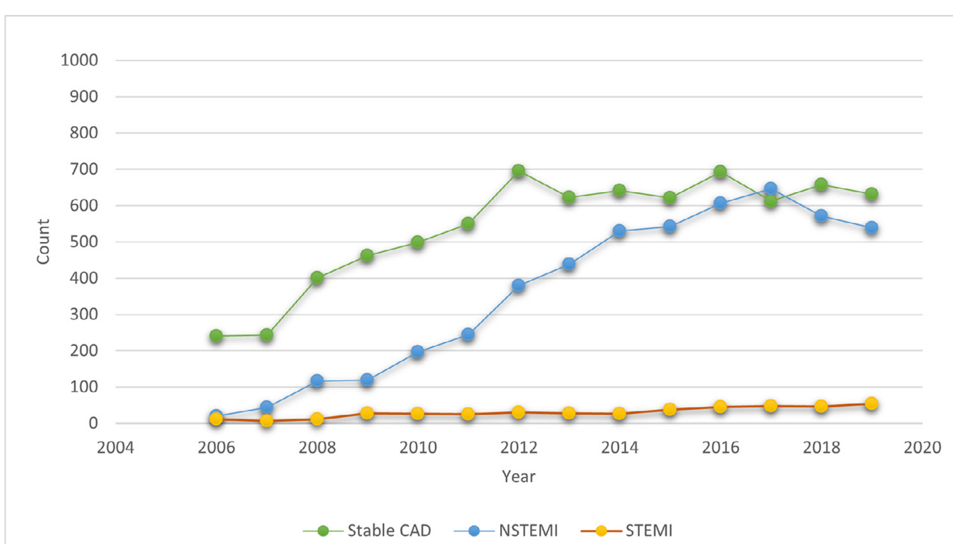

Figure 2. Use of atherectomy PCI by clinical diagnosis centers with on-site surgical cover. CAD = coronary artery disease; NSTEMI = non−ST-elevation myocardial infarction; STEMI = ST-elevation myocardial infarction.

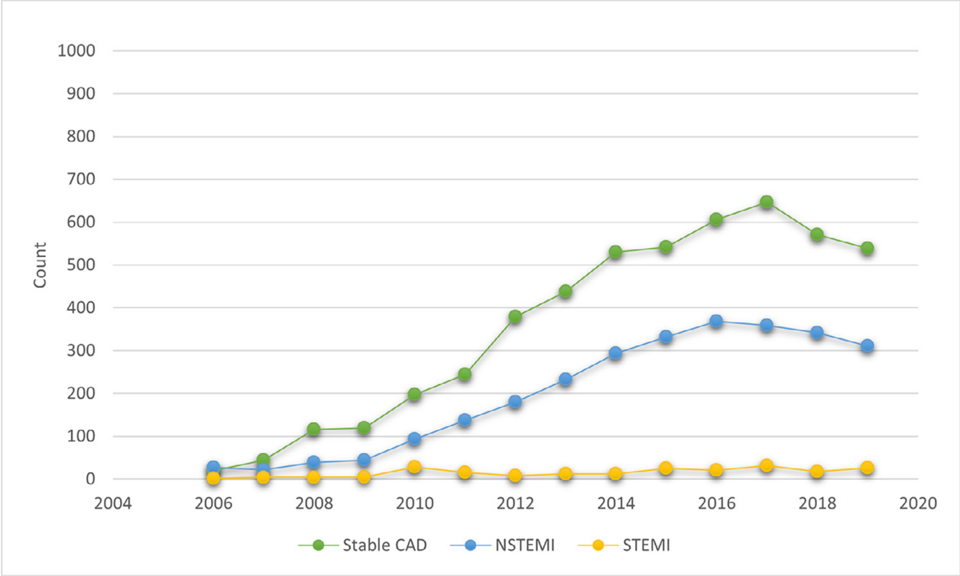

Figure 3. Use of atherectomy PCI by clinical diagnosis centers with off-site surgical cover. CAD = coronary artery disease; NSTEMI = non−ST-elevation myocardial infarction; STEMI = ST-elevation myocardial infarction.

Table 1
Baseline characteristics and angiographic profile of patients who received atherectomy in centers with on-site surgical cover versus off-site surgical centers

	On-site surgical cover (SC)	Off-site surgical cover (NSC)	p-value
N	12850	7983	
Age (years), median (IQR)	74.2 (67.2, 80.6)	75.1 (68.5, 81.0)	<0.001
Female	3517 (27.4%)	2094 (26.2%)	<0.001
Ethnicity			
White	8907 (90.7%)	4736 (84.2%)	<0.001
BAME	915 (9.3%)	891 (15.8%)	
BMI, median (IQR)	27.5 (24.4, 31.0)	27.7 (24.7, 31.1)	0.009
Indication			
Elective PCI	7570 (58.9%)	4992 (62.5%)	<0.001
ACS/NSTEMI	4857 (37.8%)	2779 (34.8%)	
STEMI	419 (3.3%)	209 (2.6%)	
Out of hospital cardiac arrest	67 (1.3%)	34 (0.8%)	0.019
Cardiogenic shock	209 (2.1%)	90 (1.5%)	0.020
Previous PCI (%)	4158 (32.8%)	2869 (36.5%)	<0.001
Previous MI (%)	5117 (40.8%)	3349 (43.0%)	0.002
Prior CABG (%)	1959 (15.4%)	1200 (15.2%)	0.79
Diabetes (%)	3961 (31.6%)	2528 (32.2%)	0.43
Hypertension (%)	8977 (72.8%)	5654 (73.9%)	0.085
Hypercholesterolemia (%)	8098 (65.7%)	5080 (66.4%)	0.29
Peripheral vascular disease (%)	1326 (10.8%)	935 (12.2%)	0.001
Previous stroke (%)	885 (7.2%)	663 (8.7%)	<0.001
Family history of heart disease (%)	4821 (42.1%)	3137 (44.5%)	0.001
Renal disease (%)	741 (6.0%)	462 (6.0%)	0.99
Smoking			
Non-smoker	4806 (41.3%)	2793 (38.6%)	<0.001
Current smoker	1025 (8.8%)	592 (8.2%)	
Ex-smoker	5794 (49.8%)	3858 (53.3%)	
Left Ventricular Ejection Fraction			
Good (LVEF >=50%)	4949 (63.0%)	3552 (64.7%)	0.009
Fair (LVEF 30%-49%)	2079 (26.5%)	1452 (26.4%)	
Poor (LVEF <= 29%)	823 (10.5%)	490 (8.9%)	
GPIIb/IIIa inhibitor	1021 (8.7%)	497 (6.6%)	<0.001
Prasugrel	156 (1.3%)	74 (1.0%)	0.039
Clopidogrel	8639 (74.5%)	5940 (80.9%)	<0.001
Ticagrelor	1286 (11.1%)	936 (12.7%)	<0.001
Warfarin	245 (2.1%)	141 (1.9%)	0.36

Table 2
Angiographic profile and crude clinical outcomes

	On-site surgical cover (SC)	Off-site surgical cover (NSC)	p-value
N	12850	7983	
Radial access	6,279 (49.4%)	4,828 (61.3%)	<0.001
IABP use	291 (2.3%)	136 (1.8%)	0.006
LMS disease	4,777 (43.6%)	2,874(40.9%)	<0.001
Target vessels for PCI:			
Proximal LAD	3,992 (31.1%)	2,589(32.4%)	0.04
Other segments of LAD	3,975 (30.9%)	2,368 (29.6%)	0.05
RCA	5,861 (45.6%)	3,550(44.5)	0.10
Left circumflex artery	4,084 (31.8%)	2,403 (30.1%)	0.01
Graft PCI	790 (6.2%)	527 (6.6%)	0.19
CTO	891 (8.8%)	607 (9.7%)	0.05
Number of drug-eluting stents			<0.001
zero	1326 (12.7%)	585 (9.1%)	
one	3328 (31.8%)	1896 (29.6%)	
two	3307 (31.6%)	2146 (33.5%)	
three or more	2515 (24.0%)	1784 (27.8%)	
Pressure Wire	736 (6.4%)	448 (6.3%)	0.84
Intravascular ultrasound or OCT	2220 (19.4%)	1572 (22.3%)	<0.001
Stent Length, mean (SD)	33.3 (18.3)	39.3 (21.6)	<0.001
Stent Diameter, mean (SD)	3.6 (0.6)	3.6 (0.6)	1.00
TIMI 3 flow post PCI	5420 (94.6%)	9638 (95.7%)	<0.001
Bleeding complications	110 (0.9%)	37 (0.5%)	0.73
Emergency CABG	16 (0.1%)	4 (0.1%)	0.092
Coronary perforation	396 (3.1%)	284 (3.6%)	0.06
In-hospital MACCE	265 (2.1%)	109 (1.4%)	<0.001
In-hospital mortality	251 (2.0%)	101 (1.3%)	<0.001

CTO = chronic total occlusion; IABP = intra-aortic balloon pump; LAD = left anterior descending artery; LMS = left main stem; RCA = right coronary artery.

significantly different between patients treated in NSC, compared with SC (Table 3).

We undertook a sensitivity analysis excluding primary PCI cases. The risk of in-hospital mortality (OR 0.78, 95% CI 0.51 to 1.20), MACCE (OR 0.83, 95% CI 0.45 to 1.26), emergency CABG (OR 0.49, 95% CI 0.15 to 1.57), major bleeding (OR 0.63, 95% CI 0.34 to 1.21), and coronary perforation (OR 1.05, 95% CI 0.78 to 1.41) was not significantly different between atherectomy performed in NSC versus SC as listed in Table 3.

Table 3
Adjusted odds of in-hospital outcomes

Outcomes	Reference	Odds Ratio (95% CI)
All atherectomy PCI:		
In-hospital mortality	On-site surgical cover	0.76 (0.50-1.16)
In-hospital MACCE	On-site surgical cover	0.80 (0.53-1.21)
Emergency CABG	On-site surgical cover	0.49 (0.15-1.57)
Major bleeding	On-site surgical cover	0.67 (0.36-1.24)
Coronary perforation	On-site surgical cover	1.07 (0.79-1.43)
Nonprimary PCI:		
In-hospital mortality	On-site surgical cover	0.78 (0.51-1.20)
In-hospital MACCE	On-site surgical cover	0.83 (0.45-1.26)
Emergency CABG	On-site surgical cover	0.49 (0.15-1.57)
Major bleeding	On-site surgical cover	0.63 (0.34-1.21)
Coronary perforation	On-site surgical cover	1.05 (0.78-1.41)

Variables adjusted for surgical cover, age, gender, ethnicity, BMI, indication (stable CAD, ACS/NSTEMI, STEMI), cardiogenic shock, previous MI, previous PCI, previous CABG, DM, renal disease, FH of IHD, hypertension, hypercholesterolemia, peripheral vascular disease, stroke, smoking, EF, GPIIb/IIIa: Glycoprotein IIb/3a inhibitor, warfarin, stent length, intravascular ultrasound/OCT, IABP use, TIMI flow after PCI, and femoral access.

Discussion

This nationwide study has shown that coronary atherectomy increased by more than threefold in the last decade, especially in centers without on-site cardiac surgery cover. The prevalence of cardiovascular co-morbidities of patients who had atherectomy at centers with and without on-site surgery was comparable, and the rate of emergency CABG and coronary perforation was low in both center types. Importantly, this study showed no difference in the odds of in-hospital death, MACCE, coronary perforation, or emergency CABG, in patients treated with atherectomy in centers with and without on-site cardiac surgery.

The establishment of PCI services in hospitals in the United Kingdom without on-site cardiac surgery cover began 2 decades ago as part of the nationwide expansion of PCI services. The initial studies demonstrated that absence of on-site surgical cover was associated with higher in-hospital MACCE and mortality, particularly in nonprimary PCI.[16,17] However, these studies were limited by the small sample size. Randomized controlled trials have not observed excess adverse events in PCI performed in centers without surgical cover.[18,19] Concurrently, innovations in PCI techniques have led to a decrease in PCI-related complications and need for emergency surgery. Current data suggest that clinical outcomes and complications of all-comer PCI at centers without on-site cardiac surgery coverage do not differ from those with on-site cover.[20,21] Therefore, the guidelines of the American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions recommend that primary PCI (class IIa) and elective and nonprimary acute coronary syndrome cases (class IIb) can be performed in centers without onsite surgical cover.[22] Although current evidence suggests that simple nonemergent PCI in centers without surgical cover is safe, there is limited evidence about the safety of complex PCI subgroups, such as CTO and atherectomy.[22−27] Before the present study, data were limited in regards to outcomes of coronary atherectomy without onsite cardiac surgery, with the evidence base driven by studies of small sample sizes or registries that included a limited number of centers.[24−26] For example, a recent study from the Queensland Cardiac Outcomes Registry (QCOR) (n = 53, 3 centers) showed that atherectomy complications were comparable between centers with and without cardiac surgical cover, and most of these complications were treated percutaneously without cardiothoracic referral.[25] In our study, we analyzed more than 20,000 patients treated with atherectomy across the United Kingdom and found consistent results to past work, with no difference in clinical outcomes in atherectomy performed in centers with and without onsite surgery.

There has been an increased uptake of calcium modification techniques like atherectomy in the last decade.[28] Our data showed that despite the overall low use of atherectomy in PCI, atherectomy has increased steadily by more than threefold, particularly in centers without onsite cardiac surgery cover. This increase is consistent with recent reports from Europe and the United States.[6,28] Although the use of atherectomy increased, the rate of postprocedure complications decreased. Consistent with our study, data from the National Cardiovascular Data Registry CathPCI registry show that there has been a steady decrease in MACCE after atherectomy, reaching an overall rate of 1.4%.[28] Technological advances in rotational atherectomy have helped reduce the rate of postprocedural complications, with operators being able to use smaller burr devices and avoid excessive deceleration speeds. The increased adoption of intracoronary imaging and operator experience are also important factors behind the low complication rate of PCI in cases where rotational atherectomy is used in contemporary practice. It is also worth noting that a much higher percentage of cases in recent years when these technologic advances were more frequently used comes from centers with off-site surgical cover which could have minimized the difference in procedural complications.

Our study showed similar use of atherectomy in complex and left main stem (LMS) disease, in centers with and without surgical backup. Moreover, patients from centers without on-site surgical cover had more complex coronary disease as the average coronary lesion length and number of stents deployed were higher in centers without surgical backup. Reassuringly, the rate of adverse outcomes remained low in centers without cardiac surgery, despite treatment of complex disease. Consistent with previous studies, the incidence of complications requiring surgical intervention was very low which likely minimized any benefit of on-site cardiac surgery. Our data also showed that PCI operators in hospitals with off-site surgical cover were more likely to use intravascular ultrasound and optical coherence tomography than hospitals with on-site surgical cover. Intravascular imaging is known to improve PCI outcomes, especially in complex lesions, where it can aid accurate assessment of disease burden, lesion preparation and stent size.[4] Utilization of intracoronary imaging has been found to be a significant predictor of lower mortality rates after atherectomy.[5]

Although our study supports the recent evidence of atherectomy safety in centers with off-site surgical cover, it is important to take into consideration the impact of the PCI operator volume. Previous studies showed that the risk of major adverse events increases significantly after atherectomy if the operator performs <4 cases/year and around 55% of operators are below this threshold.[29] Therefore, decisions related to performance of atherectomy PCI in centers without onsite surgical cover should consider the operator volume as well.

There are several limitations to take into consideration when interpreting the results of this study. First, the study does not report on outcome measures beyond the index hospital admission. Second, in-hospital outcomes in the BCIS database are self-reported in many centers, and the bulk of data input is performed immediately after the PCI procedure. The mechanism of data input of events occurring later during the index admission varies from center to center. Third, details of patients who were initially admitted to a centers without surgical cover and then transferred to a surgical center were not available. Fourth, the BCIS dataset does not capture information around the severity of calcification, burr size used, or number of burrs utilized and the presence of unmeasured confounders cannot be adjusted for. The results of this study should be interpreted with caution in patients with CTO and LMS because the incidence of CTO was <10% of the total cohort, and whereas the prevalence of LMS was in the order of 40%, anatomical subsets requiring mechanical circulatory support were relatively uncommon and so our data may not apply to those groups of patients. Lastly, the centers performing atherectomy in the BCIS dataset are large and our findings may not be generalizable to healthcare systems where hospital/operator volumes are low.

To conclude, there has been an increase in the use of atherectomy regardless of the availability of on-site cardiac surgery coverage. We report that the risk of in-hospital mortality and MACCE in hospitals without surgical cover is comparable with hospitals with surgical cover. Decisions around atherectomy should be taken in the context of operator/center experience in using this technology rather than the presence of on-site surgical cover.

Declaration of Competing Interest

The authors have no competing interests to declare.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2023.07.073.

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