**In-hospital outcomes of ad-hoc vs. planned PCI for unprotected left-main disease: an analysis of 8,574 cases from British Cardiovascular Intervention Society database 2006-2018**

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**Brief title:** Temporal trend in uLMS-PCI

**Dislosures:** NC received unrestricted research grants from Boston Scientific, Haemonetics, Heartflow, Beckmann Coulter; speaker fees or consultancy fees from Haemonetics, Abbot Vascular, Heartflow, and Boston Scientific; and travel sponsorship from Biosensors, Abbot, Edwards, Lilly/D-S, St Jude Medical, and Medtronic.

**Financial Support:** None

**Word count:** 4363

**Keywords:** Left main artery, percutaneous coronary intervention, national database, ad-hoc PCI

**Abstract**

**Background:** Although data suggests ad-hoc PCI results in similar patient outcomes compared to planned PCI in non-selected patients, data for ad-hoc unprotected left main stem PCI (uLMS-PCI) are lacking.

**Aim:** To determine if in-hospitals outcomes of uLMS-PCI vary by ad-hoc versus planned basis.

**Methods:** Data were analysed from all patients undergoing uLMS-PCI in the United Kingdom 2006-2018, and patients grouped into uLMS-PCI undertaken on an ad-hoc or a planned basis. Patients who presented with ST-segment elevation, cardiogenic shock, or with an emergency PCI indication were excluded.

**Results:** In total, 8,574 uLMS-PCI procedures were undertaken with 2,837 (33.1%) of procedures performed on an ad-hoc basis. There was a lower likelihood of intervention for stable angina (28.8% vs. 53.8%, p<0.001) and a higher rate of potent P2Y12 inhibitor use (16.4% vs. 12.1%, p<0.001) in the ad-hoc PCI group compared to the planned PCI group. Patients undergoing uLMS-PCI on an ad-hoc basis tended to undergo less complex procedures. Acute procedural complications including slow flow (OR 1.70, 95% CI 1.01-2.86), coronary dissection (OR 1.41, 95% CI 1.12-1.77) and shock induction (OR 2.80, 95% CI 1.64-4.78) were more likely in the ad-hoc PCI group. In-hospital death (OR 1.65, 95% CI 1.19-2.27) and in-hospital MACCE (OR 1.50, 95% CI 1.13-1.98) occurred more frequently in the ad-hoc group. In sensitivity analyses, these observations did not differ when several sub-groups were separately examined

**Conclusions:** Ad-hoc PCI for uLMS disease is associated with adverse outcomes compared to planned PCI. These data should inform uLMS-PCI procedural planning.

**Condensed abstract**

Data were analysed from all patients undergoing uLMS-PCI in the United Kingdom 2006-2018, and patients grouped into uLMS-PCI undertaken on an ad-hoc or a planned basis. Patients undergoing uLMS-PCI on an ad-hoc basis tended to undergo less complex procedures. Acute procedural complications including slow flow, coronary dissection, and shock induction were more likely in the ad-hoc PCI group compared to the planned PCI group. In-hospital death and in-hospital MACCE occurred more frequently in the ad-hoc group compared to the planned group. In sensitivity analyses, these observations did not differ when several sub-groups were separately examined.

**Impact on Daily Practice**

Given the association of adverse in-hospital outcomes with ad-hoc uLMS-PCI, these data suggest that cases requiring uLMS-PCI, which by definition is a complex PCI, should be deferred and planned prior to returning for PCI. This planning ensures that sufficient time exists to complete all aspects of the procedure, ensuring that all interventional tools required (such as rotational atherectomy and imaging) are available, and perhaps most importantly, that the operator expertise to deal with procedural challenges of uLMS-PCI (such as bifurcation and calcium) is available.

**List of abbreviations**

ACS – acute coronary syndrome

BCIS - British Cardiovascular Intervention Society

CABG – coronary artery bypass surgery

CVA – cerebrovascular disease

DES – drug-eluting stent

IVUS - intravascular ultrasound

LAD – left anterior descending

LMS - left main stem

LV – left ventricle

MACCE - major adverse cardiac or cerebrovascular events

MI – myocardial infarction

NYHA – New York Heart Association

PVD – peripheral vascular disease

PCI - percutaneous coronary intervention

uLMS-PCI – unprotected left main stem percutaneous intervention

**Introduction**

Percutaneous coronary intervention (PCI) can be undertaken immediately following on from diagnostic catheterisation (ad-hoc PCI) or at a later date after diagnostic catheterisation (staged PCI).1 Ad-hoc PCI is increasingly popular as it increases catheterisation laboratory efficiency, improves cost effectiveness, potentially reduces overall radiation and contrast dose, and is popular with patients.2,3 The majority of data confirm equivalent outcomes in ad hoc versus planned PCI although data in more contemporary practice is limited. There is also little data on the outcomes of ad-hoc PCI versus planned PCI in more complex sub-groups of PCI.

PCI is increasingly considered as a revascularisation strategy in certain anatomical and patient subsets of unprotected left main stem (uLMS) disease and is supported by the European Society of Cardiology 2018 Guidelines on myocardial revascularization and the AHA/ACC guidelines.4,5 However, given the clinical equipoise in many patients with uLMS-PCI, the guidelines generally recommend that unless patients have an emergency indication for PCI (for example cardiogenic shock, haemodynamic instability or ST elevation myocardial infarction (MI)), patients with uLMS disease should be discussed in a Multidisciplinary Team (MDT) setting.

There are no data comparing patient outcomes following uLMS-PCI between procedures undertaken on an ad-hoc basis versus a planned basis. We therefore analysed the British Cardiovascular Intervention Society National PCI Audit dataset, comparing patient outcomes with uLMS disease categorised by ad-hoc versus planned PCI.

**Methods**

*Study design and participants*

We analysed data from all patients undergoing PCI for unprotected left main stem disease (uLMS-PCI) in the United Kingdom between January 1st 2006 and March 31st 2018. Patients were divided into two groups depending on whether uLMS-PCI was undertaken on an ad-hoc or a planned basis. Ad-hoc is defined in the BCIS dataset as diagnostic angiography proceeding to PCI in the same session.6 Angiography and PCI on separate days was defined as staged PCI. Patients who presented with ST-segment elevation, cardiogenic shock, or with an emergency indication for PCI were excluded. Thus, only patients without an immediate clinical need for uLMS-PCI were included in the analysis to minimise confounding. Patients were also excluded if the ad-hoc field was blank.

*Study setting and sources of data*

Data on PCI practice were obtained from the British Cardiovascular Intervention Society National PCI Audit dataset which records over 120 clinical, procedural and outcomes variables for every PCI performed in the UK, and thus approximately 100,000 new records are currently recorded each year. Entry of all PCI procedures by UK interventional operators is mandated as part of their professional revalidation. The accuracy and quality of the BCIS dataset has previously been described.7,8 The study was approved by the BCIS data extraction group and by Healthcare Quality Improvement Partnership (HQIP) research ethics groups.

*Study definitions*

Study definitions were used as in the BCIS National PCI Audit dataset.6 Pre- or post-PCI disease severity was defined as vessels with a stenosis ≥70% in the case of the LAD, circumflex or right coronary arteries, or ≥50% in the case of the left main artery. Chronic kidney disease was defined as chronic dialysis, history of renal transplant or a creatinine >200umol/l. The clinical outcomes of interest were in-hospital mortality, in-hospital MACCE (defined as a composite of death, peri-procedural CVA or peri-procedural MI), in-hospital bleeding (defined as either gastrointestinal bleeding, intra-cerebral bleeding, retroperitoneal haematoma, blood or platelet transfusion, access site haemorrhage, or an arterial access site complication requiring surgery), and an acute coronary procedural complication (defined as a composite of no/slow flow, coronary perforation, coronary dissection, shock induction, emergency CABG and major side-branch loss). Peri-procedural MI is defined in the BCIS dataset as “a rise of more than 3 times the 99th percentile of the upper reference limit of a troponin biomarker.

*Data analyses*

Statistical analysis was performed using the R coding environment (Open Source, v3.6.2). Multiple imputations were carried out using the *mice* package to reduce the potential bias from missing data, assuming missingness completely at random mechanisms. We used chained equations to impute the data for all variables with missing information and generated 5 datasets to be used in the analyses (Supplementary Table 1). We examined the baseline and procedural characteristics of participants by ad-hoc status. We explored crude baseline comorbidities using a Chi-squared test for categorical variables and the Wilcoxon-Mann-Whitney test for continuous variables. A multiple logistic regression model was developed to identify the association of in-hospital MACE or in-hospital mortality with ad-hoc status in all comer PCI and the subgroup of LMS-PCI. The co-variates included in the model were age >80 years, gender, acute coronary syndrome (ACS) status, previous myocardial infarction (MI), previous coronary artery bypass grafting (CABG), previous PCI, diabetes, ejection fraction (EF) <30%, 3-vessel PCI, chronic total occlusion PCI, rotational atherectomy, mechanical left ventricular (LV) support, hypertension, stroke, peripheral vascular disease (PVD), valvular heart disease and history of renal disease. Next, we focused on the association of ad-hoc status in LMS-PCI. We first examined the association of baseline co-variates with ad-hoc status in a multiple logistic regression model. This included age >80 years, gender, ACS status, previous MI, previous PCI, diabetes, EF <30%, number of diseased vessels, 3-vessel PCI, GPIIBIIA inhibitor use, rotational atherectomy, mechanical LV support, hypertension, peripheral vascular disease, valvular heart disease, history of renal disease and femoral access. To examine the influence of ad-hoc status on LMS-PCI outcomes, we built on and included the previously described baseline model to investigate the independent odds of periprocedural MI, emergency PCI, transfusion, tamponade, stroke, GI bleed, acute kidney injury, vascular complications, major bleed, length of stay, slow flow, side-branch loss, dissection, perforation, shock induction, any complication, in-hospital death and In-hospital MACE. Finally, a subgroup sensitivity analysis of in-hospital MACE was carried out for high-risk groups, defined as 3-vessel PCI (3V-PCI), ACS, EF<30, female gender, and mechanical LV support use using similar methodology to above, accounting for interaction between these variables and in-hospital MACE.

**Results**

*uLMS-PCI crude numbers and trends in the United Kingdom 2006-2018*

Between January 1st 2006 and March 31st 2018, 8,574 uLMS-PCI procedures were undertaken in the United Kingdom. Of this, a total of 2,837 (33.1%) procedures were undertaken on an ad-hoc basis. However, over the study period, ad-hoc PCI increased significantly from 25.8% in 2006 to 42.8% (p<0.001 for trend, Figure 1 left panel). This change was driven mainly by an increase in ad-hoc intervention within the stable angina sub-group (Figure 1 right panel, p<0.001 for trend). The predictors of intervening on an ad-hoc basis are presented in Figure 2. An ACS presentation was strongly predictive of ad-hoc intervention (OR 2.18, 95% confidence interval 2.54-3.11). Conversely, rotational atherectomy (OR 0.64, 95% confidence interval 0.55-0.74). three vessel PCI (OR 0.88, 95% confidence interval 0.80-0.98). and femoral access (OR 0.70, 95% confidence interval 0.63-0.77) were associated with a lower likelihood of ad-hoc intervention.

*Patient and procedural characteristics by ad-hoc status*

The baseline characteristics by ad-hoc status are presented in Table 1. The two cohorts were similar although there was an excess of Q-wave on the ECG (12.4% vs. 10.6%, p=0.019), a lower likelihood of intervention for stable angina (28.8% vs. 53.8%, p<0.001) and a higher rate of potent P2Y12 inhibitor use (16.4% vs. 12.1%, p<0.001) in the ad-hoc PCI group compared to the planned PCI group.

The procedural characteristics by ad-hoc status are presented in Table 2. Patients undergoing uLMS-PCI on an ad-hoc basis tended to undergo less complex procedures that those on a planned basis. For example, in the ad-hoc PCI group, the number of vessels treated, the number of lesions treated, the number of CTOs treated, the use of microcatheters and rotational atherectomy were significantly less than in the planned PCI group. In contrast, radial access and glycoprotein inhibitor were more likely to be used in the ad-hoc PCI group compared to the planned PCI group. Off-site surgical cover and a trainee first operator were more likely in the ad-hoc PCI group.

*Outcomes by ad-hoc status*

The crude unadjusted outcomes by ad-hoc status for unprotected left main stem PCI performed in England and Wales in 2006-2018 are presented in Table 3 and illustrate a higher rate of procedural complications and adverse clinical outcomes in the ad-hoc group. Ad-hoc PCI was also associated with higher rates of residual disease. Length of stay was similar between the two groups. Adjusted mortality and MACCE for the uLMS-PCI vs all PCI are presented in Figure 3 and illustrate similar outcomes by ad-hoc status for all PCI but excess mortality and MACCE when uLMS-PCI was undertaken on an ad-hoc vs. planned basis within the uLMS-PCI group. Multivariate adjusted in-hospital data for all clinical outcomes by ad-hoc vs planned uLMS-PCI are presented in Figure 4. Acute procedural complications including slow flow (OR 1.70, 95% confidence interval 1.01-2.86), coronary dissection (OR 1.41, 95% confidence interval 1.12-1.77) and shock induction (OR 2.80, 95% confidence interval 1.64-4.78) were more likely in the ad-hoc PCI group compared to the planned PCI group. In-hospital death (OR 1.65, 95% confidence interval 1.19-2.27) and in-hospital MACCE (OR 1.50, 95% confidence interval 1.13-1.98) occurred more frequently when uLMS-PCI was undertaken on an ad-hoc basis compared to a planned basis. In sensitivity analyses, the observed excess in-hospital MACCE associated with ad-hoc PCI within several important sub-groups including 3-vessel PCI, acute coronary syndrome presentation, ejection fraction <30%, patient sex and use of mechanical LV support did not differ significantly from the overall main study population findings (Figure 5).

**Discussion**

**S**tudies of ad-hoc PCI initially demonstrated a temporal increase in ad-hoc rates.9,10 In more recent years, rates of ad-hoc PCI may have declined, an observation particularly seen in CTO-PCI.11,12 Proceeding to PCI immediately following on from diagnostic angiography has potential benefits including time efficient use of catheterisation laboratory capacity, a reduction in the cumulative contrast and radiation dose of separate procedures, and an improved patient experience.2,3,13 Previous studies of ad-hoc PCI vs planned PCI are relatively non-contemporary and have only been undertaken in unselected PCI. In a study of 46,565 New York State patients who underwent PCI between 2003 and 2005, although there was no difference in risk-adjusted in-hospital mortality between groups, the ad hoc PCI patients had significantly lower 36-month mortality (adjusted hazard ratio [HR]: 0.76, 95% CI: 0.69 to 0.85, p < 0.0001) than the planned group.9 Using New York State PCI Registry data, Feldman et reported the outcome of 47,020 patients undergoing PCI from 2000 to 2001.14 Similar rates of death, major adverse cardiac events and renal failure were observed for ad hoc and planned PCI. Similarly, using data from 68,528 PCIs for stable angina taken from the National Cardiovascular Data Registry, procedural mortality, cerebrovascular events, and renal failure were similar between groups.15 A number of other studies found largely similar findings, with no observable difference in clinical outcomes between ad-hoc and planned PCI.16-18 As a result of these data, most guidelines support the use of ad-hoc PCI when deemed reasonable.1,4

However, significant uncertainty exists as to the appropriateness of ad hoc PCI for more complex cohorts of coronary disease. Of relevance, previous studies have suggested that up to 30% of USA patients undergoing ad-hoc PCI may be candidates for CABG.19 No data exists for example where extensive calcification exists and calcium modification is required, or in subsets of patients with other markers of complex disease such as chronic total occlusion PCI, severe LV dysfunction or last remaining vessel PCI. Therefore, guidelines typically recommend that ad-hoc PCI for complex multivessel or unprotected left main disease should be reserved for specific circumstances such as haemodynamic instability or significant comorbidity precluding surgical options. Potential risks of ad-hoc PCI in complex cohorts of patients includes a lack of time to complete an optimal procedure, a lack of the necessary equipment or expertise, and an underappreciation of the technical challenge of the procedure itself.20,21

In light of the lack of data supporting ad-hoc PCI in uLMS disease, and the guideline support for MDT discussions when revascularisation for uLMS disease is being considered, it is perhaps surprising that ad-hoc PCI for uLMS-PCI increased year on year in the United Kingdom and represented 42.8% of all PCIs undertaken for uLMS disease in the most recent study year. Of relevance is that the study population is such (where STEMI, emergency indication and cardiogenic shock were all excluded) that there would be no clinical necessity to proceed with PCI immediately after angiography. The increasing comfort and familiarity with which interventional cardiologists approach uLMS-PCI may in part explain these trends.22,23 Notwithstanding this, the current data observes an increase in in-hospital adverse outcomes when unprotected LMS-PCI is undertaken compared to when undertaken on a planned basis. Several mechanisms may underpin these observations. Procedural planning intuitively seems important in all subsets of PCI and in particular more complex sub-sets including uLMS PCI. The current data suggests that planned uLMS-PCI procedures are more complex than ad-hoc uLMS-PCI procedures with more vessels attempted, more calcium modification used, more femoral access and more stents used. Despite this, better outcomes were observed. These observations would imply that improved in-hospital outcomes were not necessarily associated with differences in case selection, but may in part be due to improved procedural planning and execution. Planning complex PCI also ensures that sufficient time exists to complete all aspects of the procedure, ensuring that all interventional tools required (such as rotational atherectomy and imaging) are available, and perhaps most importantly, that the operator expertise to deal with procedural challenges of uLMS-PCI (such as bifurcation and calcium) is available. The importance of operator PCI volume and expertise for uLMS-PCI has been demonstrated in a previous analysis of the BCIS dataset.24

There are several major strengths of the current study. Firstly, it is the first study to examine outcomes of ad-hoc versus planned PCI in patients with uLMS-PCI disease. Secondly, the current series reports procedures from a more contemporary time frame in comparison to previous studies, which given the evolution of procedural complexity in recent years is an important consideration. Thirdly, the large study population provides sufficient statistical power to perform a robust sensitivity analysis of several important sub-groups of uLMS -PCI. Finally, we excluded patients with an emergency indication for PCI but included NSTEMI patients without these exclusions criteria. Thus, the current study of the “CHIP-indicated” population is the first analysis of ad-hoc PCI in such a population. As a NSTEMI indication represents the largest sub-group of patients undergoing PCI, exclusion of this group of ad-hoc PCI is a major limitation of previous studies.

In considering the limitations of the present study, although we attempted to correct for baseline differences over time, it remains possible that unmeasured confounders have biased the results. We used multiple imputation to account for the missing data and this method assumes statistical assumptions that are difficult to check and sometimes not met. Additionally, the BCIS database does not capture details of anatomical data such as the location of disease with the LMS, complexity of lesions such as calcification or the presence, or type of distal LMS bifurcation disease. Therefore, we cannot provide detailed data on the relationship to the pattern of disease and outcomes with respect to ad-hoc status. Similarly, whilst there are robust data regarding the type and number of stents used, there are no data provided on the exact technical approach used to treat the LMS disease. Therefore, the current analysis is unable to explore the potential of differing bifurcation strategies on outcomes by ad-hoc status. Moreover, this dataset lacks center and operator identifier fields, making it impossible to adjust for fixed effects related to center or operator volume and account for site-specific variations. Finally, due to technical issues with linkage of the national PCI database to post-discharge outcomes, we are unable to provide data on longer term MACCE rates over time. Whether the differential in-hospital outcomes between groups leads to differences in longer term patient outcomes cannot be studied.

**Conclusions**

Ad-hoc PCI for uLMS disease increased year or year and represented 42% of all uLMS-PCI procedures in the most recent study year. Ad-hoc PCI was associated with increased rates of acute procedural complications, in-hospital death and in-hospital MACCE PCI. These data should inform uLMS-PCI procedural planning.

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**Figure Legends**

**Figure 1: Temporal changes in frequency of ad-hoc uLMS-PCI in the United Kingdom 2006 to 2018.** Panel A: Percentage of all uLMS-PCI undertaken on an ad-hoc basis over time; Panel B, upper figure: percentage of all stable angina uLMS-PCI undertaken on an ad-hoc basis over time, lower figure: percentage of all acute coronary syndrome uLMS-PCI undertaken on an ad-hoc basis over time.

**Figure 2: Predictors of uLMS-PCI being undertaken on an ad-hoc basis:** Multi-variate adjusted model of the independent associated of ad-hoc uLMS-PCI in the United Kingdom 2006-2018

**Figure 3: Adjusted in-hospital outcomes for all PCI and uLMS-PCI sub-group:** Top panel: Multi-variable adjusted in-hospital MACCE (major adverse cardiac or cerebrovascular events) by ad-hoc vs. planned procedures for uLMS-PCI in the United Kingdom 2006-2018; Bottom panel: Multi-variable adjusted in-hospital mortality by ad-hoc vs. planned procedures for uLMS-PCI in the United Kingdom 2006-2018

**Figure 4: Outcomes after uLMS-PCI by ad-hoc status:** Multivariate adjusted in-hospital clinical outcomes by ad-hoc vs planned uLMS-PCI in the United Kingdom 2006-2018. MACCE: Major adverse cardiac or cerebrovascular events.

**Figure 5: Adjusted in-hospital MACCE after uLMS-PCI by sub-group:** Sensitivity analyses for outcomes within 3-vessel, ACS, ejection fraction <30%, female sex and mechanical LV support sub-groups by ad-hoc vs planned uLMS-PCI in the United Kingdom 2006-2018. MACCE: Major adverse cardiac or cerebrovascular events.