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Complex PCI in Patients Unable to Undergo CABG During the COVID-19 Pandemic: Insights From the UK-ReVasc Registry

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Abstract

Background: Cardiac surgery for coronary artery disease was dramatically reduced during the first wave of the COVID-19 pandemic. Many patients with disease ordinarily treated with coronary artery bypass grafting (CABG) instead underwent percutaneous coronary intervention (PCI). We sought to describe 12-month outcomes following PCI in patients who would typically have undergone CABG.

Methods: Between 1st March and 31st July 2020, patients who received revascularisation with PCI when CABG would have been the primary choice of revascularisation were enrolled in the prospective, multicentre UK-ReVasc Registry. We evaluated the following major adverse cardiovascular events at 12 months: all-cause mortality, myocardial infarction, repeat revascularisation, stroke, major bleeding, and stent thrombosis.

Results: A total of 215 patients were enrolled across 45 PCI centres in the United Kingdom. Twelve-month follow up data were obtained in 97%. There were 9 deaths (4.3%), 5 myocardial infarctions (2.4%), 12 repeat revascularisations (5.7%), 1 stroke (0.5%), 3 major bleeds (1.4%), and no cases of stent thrombosis. No difference in the primary endpoint was observed between patients who received complete versus incomplete revascularisation (residual SYNTAX score $\leq$8 vs. >8) (p=0.22).

Conclusions: In patients with patterns of coronary disease in whom CABG would have been primary therapeutic choice outside of the pandemic, PCI was associated with acceptable outcomes at 12 months of follow up. Contemporary randomised trials that compare PCI to CABG in such patient cohorts may be warranted.

Keywords: percutaneous coronary intervention, coronary artery bypass grafting; multivessel disease

INTRODUCTION

International guidelines advocate superiority of coronary artery bypass grafting (CABG) over percutaneous coronary intervention (PCI) in multivessel and left main stem disease, particularly in patients with increased anatomic complexity.[1,2] This practice is driven by clear evidence of long-term mortality benefit in those with multivessel disease,[3] and in those with left main disease and intermediate or high SYNTAX score.[4,5] Accordingly, such patients in whom surgical risk is not prohibitively high are seldom offered or treated with PCI.

During the first wave of the COVID-19 pandemic, access to CABG in the United Kingdom (UK) was severely limited.[6] Many patients who would have been treated with surgical revascularisation as the first choice instead underwent PCI. The UK-ReVasc Registry was a prospective, multicentre registry study established to appraise contemporary clinical outcomes following PCI in patients with coronary anatomy that would usually mandate CABG.

In-hospital and 30-day outcomes from the UK-ReVasc Registry have previously been reported, with in-hospital event rates comparable to those observed in a CABG control group.[7] In the present study, we sought to evaluate 12-month major adverse cardiovascular events (MACE).

METHODS

Study design

We conducted the UK-ReVasc registry, an investigator-initiated, multicentre, observational study at 45 sites across the UK. Lead investigators at University of Leicester and University Hospitals of Leicester (UHL) NHS Trust, in collaboration with the Robertson Centre for Biostatistics at University of Glasgow, designed an online remote data entry system specific for the registry. After seeking institutional regulatory advice from the UHL Clinical Audit department, the study was registered and approved as a health survey audit and, as such, formal ethical approval was not required. Data transfer agreements utilising fully anonymised patient data were established between UHL, University of Glasgow, and investigating sites as required.

Study participants

Participants were eligible for enrolment in the registry if they had a pattern of coronary artery disease (CAD) typically considered for revascularisation with CABG under normal circumstances, but instead underwent PCI due to COVID-19 pandemic enforced cancellation of cardiac surgery services. Investigators from UK PCI centres were invited to include anonymised data on consecutive patients at their respective site. The study recruitment period ran from 1st March 2020 to 31st July 2020.

Data collection

Baseline demographics, clinical presentation, and reasons for not undergoing CABG were recorded. Arterial access site, anatomical distribution of CAD, SYNTAX score[4] and residual SYNTAX Score (rSS),[8] as well as PCI procedural characteristics (i.e., use of intravascular

imaging, calcium modification, mechanical support devices) were also documented. Adjudication of coronary angiography images was undertaken by the lead investigator at each individual site. Complete revascularisation was defined as intervention on all vessels >2.25mm with at least one stenosis >50%. Participating centres were asked to enter data on PCI success (defined as Thrombosis in Myocardial Infarction [TIMI] 3 flow with <30% residual stenosis).

Outcomes

The primary outcome was a composite of all-cause mortality, myocardial infarction (MI) (defined by 4th Universal Definition of Myocardial Infarction),[9] unplanned revascularisation, and stroke. Data on hospitalisation for heart failure (typical signs, symptoms, and investigation results consistent with diagnosis),[10] stent thrombosis, and Bleeding Academic Research Consortium (BARC) 3-5 bleeding were also collected.[11]

Statistical analysis

Continuous data are expressed as mean (standard deviation) or median (range), and categorical data as counts and percentages. To compare groups, an independent samples t-test was used for continuous data and chi-squared or Fisher's exact testing for categorical data. Statistical significance was set at 0.05. Statistical analyses were performed using STATA (Version 17.0; StataCorp, College Station, TX, USA).

RESULTS

Patients

The UK-ReVasc registry enrolled 215 patients from 45 UK PCI centres. The mean age of the patients was 67 years, 34% had diabetes, 37% had LV function $\leq$ 50%, and 75% presented with non-ST elevation acute coronary syndrome (NSTE-ACS) (**Table 1**). Fifty-one percent of patients had multivessel disease (MVD) with left main stem (LMS) involvement and 45% had MVD without LMS involvement. Left anterior descending artery disease was present in 95% of cases. The mean SYNTAX score was 28.0 (SD = 10.4) and mean EUROSCORE II score 2.9% (SD = 3.9).

Procedural characteristics are displayed in **Table 2**. In the UK-Revasc registry, 93% of procedures were performed via the radial artery. Intravascular imaging (predominantly intravascular ultrasound) was used in 45% of patients and calcium modification therapy (rotational atherectomy, intravascular lithotripsy, laser atherectomy) undertaken in 24%. Mechanical support devices, both intra-aortic balloon pump, were used during 2 procedures (0.8%). Complete revascularisation was achieved in 54% of participants. PCI success was reported in 93% of procedures.

Endpoints

Twelve month follow up data was obtained in 97% of patients enrolled in the registry. The incidence of the primary endpoint in the UK-ReVasc registry patients treated with PCI was 11.0%. There were 9 deaths (4.3%), 5 myocardial infarctions (2.4%), 12 repeat revascularisations (5.7%), 1 stroke (0.5%), 3 major bleeds (1.4%), and no cases of stent thrombosis. In-hospital mortality in our UK-ReVasc registry cohort was 1.4% (3/215),

compared to an EUROSCORE II score predicted in-hospital mortality following CABG of 2.9% (Fisher's exact test, p=0.39).

Results of pre-specified subgroup analyses are provided in **Table 4**. The use of image-guided PCI in UK-ReVasc registry patients was associated with a lower incidence of the primary endpoint (9.2% vs. 14.9%, p<0.01), driven by five fewer repeat revascularisation events compared to when intravascular imaging was not utilised. No difference in outcome was observed when the UK-ReVasc registry cohort was stratified by diabetes status.

Time-to-event analysis

A time-to-event analysis that compared complete revascularisation versus incomplete revascularisation in UK-ReVasc registry patients for the incidence of the primary endpoint, as defined by residual SYNTAX score thresholds of ≤8 and >8, is displayed in **Figure 1**. At 12 months follow up, the rate of event-free survival was 88% and 93% in the complete revascularisation and incomplete revascularisation groups, respectively (p=0.22).

DISCUSSION

In this multicentre registry study that enrolled a novel cohort of higher baseline risk patients who underwent PCI instead of CABG during the COVID-19 pandemic, favourable clinical outcomes at 12 months of follow up were observed. Despite 75% acute coronary syndrome presentation and 38% experiencing reduced left ventricular ejection fraction (LVEF), our results are comparable to outcomes of lower risk patients in the PCI arms of pivotal randomised trials comparing revascularisation strategies in complex CAD (**Table 5**). The incidence of the primary endpoint (all-cause mortality/MI/repeat revascularisation/stroke) in the UK-ReVasc registry was 11.0%, with no adverse safety signals demonstrated.

Current guidelines recommend CABG over PCI for LMS and/or multivessel CAD with intermediate or high SYNTAX score.[1,2] Such guidance is largely based on historical randomised trials that recruited participants more than a decade ago. The pivotal Synergy Between PCI with Taxus and Cardiac Surgery (SYNTAX) study demonstrated superiority of CABG versus PCI with first generation paclitaxel-eluting stents in 1800 patients with MVD or LMS, principally driven by higher rates of repeat revascularisation in the PCI arm.[4] These findings were supported by the Randomised Comparison of Coronary Artery Bypass Surgery and Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Disease (BEST) study that tested second generation everolimus-eluting stents, again favouring CABG due to lower repeat revascularisations.[12] The two major randomised trials that have investigated PCI versus CABG in patients with left main stem disease report somewhat conflicting results – the Nordic-Baltic-British Left Main Revascularisation Trial (NOBLE) did not meet non-inferiority for 12-month MACE when PCI was compared to CABG ,[5] while the Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main

Revascularisation (EXCEL) trial presented data to support non-inferiority of PCI – however, EXCEL's published results have proven controversial due to the choice of the endpoint definition for MI.[13] In essence, both studies convey a similar message of excess spontaneous MI and repeat revascularisation in those patients initially treated with PCI. Longer-term follow up of SYNTAX, BEST and NOBLE have all indicated improved clinical outcomes with CABG.[3,14,15] Interestingly, in the SYNTAX Extended Survival 10-year follow up cohort, mortality was significantly higher in PCI than CABG patients with multivessel disease, but not in those with left main lesions.[3] Such results are highly pertinent to the current UK-ReVasc registry population because patients in SYNTAX evidently had to be deemed suitable for both forms of revascularisation to be considered for randomization. More recently, the FAME-3 trial compared fractional flow reserve-guided PCI to CABG in 1500 patients and did not meet non-inferiority when compared to CABG.[16] The result was driven by numerical differences in favour of CABG for all components of the primary endpoint. However, it is possible that outcomes in the FAME-3 PCI arm may have improved if intracoronary imaging was more widely employed (11.7% of FAME-3 PCI cases), since its low use in the study is perhaps not reflective of current, and certainly not best, practice in patients with complex CAD.[17]

The body of evidence thus far indicates that in patients amenable for either mode of revascularisation, CABG is most likely to provide the greatest chance of event-free survival. However, contemporary clinical outcome data reflective of current interventional cardiology practice are lacking. While surgical techniques have no doubt improved, interventional cardiologists now more commonly utilise intravascular imaging to guide and optimise PCI strategy, since this is associated with a reduction in all-cause mortality, cardiovascular death and adverse events as demonstrated by an 18,000 patient meta-analysis.[18] Furthermore,

potent anti-platelet agents and novel stent technologies have reduced the risk of stent failure and subsequent ischemic events.[19,20]

The establishment of the UK-ReVasc registry afforded a unique opportunity to observe practice and outcomes in a cohort of patients denied access to CABG because of the COVID-19 pandemic.[7] Such patients with complex CAD and of low surgical risk (EUROSCORE II = 2.9%) are rarely treated outside of randomised trials because CABG is now well established as the default mode of revascularisation in this group. The elevated risk profile of our UK-ReVasc registry cohort is highlighted when compared to data from PCI arms of pivotal randomised controlled trials, such as SYTAX, BEST, and FAME-3 (**Table 5**).[4,12,16] Our cohort is older, with more complex disease and a higher incidence of reduced LVEF and unstable presentation. These factors are associated with increased mortality risk, with reduced LVEF a well-established independent predictor of poorer prognosis, in particular.[21]

Outcomes following surgical revascularisation have improved over recent years, and in the recent FAME-3 trial, were very good indeed. The FAME-3 CABG arm MACE rate of 6.9% compares favourably to the SYNTAX trial reported 12.4% incidence for the identical composite endpoint of death, MI, stroke and repeat revascularisation.[4,16] Such significant improvements in event-free survival following CABG have been described over time, in part due to higher rates of off-pump CABG, increased use of blood cardioplegia, and improvements in guideline-directed medical therapy.[22]

While outcome from FAME-3 are not directly comparable to our UK-ReVasc registry cohort given the marked differences in baseline demographics, it does indicate that a high bar has

been set for PCI to achieve clinical equipoise in this patient group. It is notable that the markedly higher rate of repeat revascularisation required in PCI patients from prior studies was not reproduced in our UK-ReVasc patients when compared to the FAME-3 CABG cohort (UK-ReVasc: 5.7% vs. FAME-3 CABG: 3.9%). However, despite a four-fold higher rate of intravascular imaging use (44.8%) in the UK-ReVasc registry as compared to the PCI arm of FAME-3 (11.7%), similar incidence of repeat revascularisation procedures was noted (UK-ReVasc: 5.7% vs. FAME-3 PCI: 5.9%), although our patient population was of higher baseline risk and greater anatomical complexity.

Subgroup analysis of the UK-ReVasc registry patients suggests that intravascular imaging use was associated with a significant reduction (9.2% vs. 14.9%) in the incidence of the primary endpoint. This is a hypothesis-generating result but supports findings of large, randomised data sets that have concluded intravascular imaging to guide PCI strategy results in lower rates of target vessel failure and repeat revascularisation.[23]

A further sub analysis of event-free survival stratified by residual SYNTAX score demonstrated no difference between those UK-ReVasc registry patients that received residual SYNTAX score defined complete revascularisation (rSS $\leq$8) versus those who did not (rSS >8). However, this was limited by the small sample size and relatively short follow up period, as benefits from more complete revascularisation in the PCI cohort of the original SYNTAX trial were principally observed at 5 years.[24]

To address the potential flaws of prior studies that have compared CABG versus PCI in this patient population, especially in relation to systematic intracoronary imaging, calcium

modification, and other advances in contemporary revascularisation, a further randomised trial may be required to best inform contemporary practice. However, this is of course with the caveat that in these rapidly evolving fields, by the time any such a trial reports, techniques may have further advanced, limiting the contemporaneity and pertinence of the results.

This study has several limitations. First, the data collected are observational and subject to selection bias at each individual centre. The number of patients enrolled at each centre was low and may suggest such bias, however the study was undertaken during the first wave of the COVID-19 pandemic when elective coronary angiography was essentially cancelled in the UK and a 40% reduction of patients with ACS attending hospital was observed. All cases were investigator reported and not centrally adjudicated. However, all centres are familiar with systematic data collection for national British Interventional Cardiovascular Society audit purposes and should be considered accurate. Second, our registry is relatively small with few clinical events. However, a very low number of patients were lost to follow up and these data thus provide an accurate representation of contemporary UK PCI practice in complex CAD patients. Third, our secondary analyses do not take account of all potential confounding factors and should only be interpreted in that context.

Conclusion

In patients with patterns of coronary disease in whom CABG would have been primary therapeutic choice outside of the pandemic, PCI was associated with acceptable outcomes at 12 months of follow up. Contemporary randomised trials that compare PCI to CABG in such patient cohorts may be warranted.

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Table 1: Baseline demographics

	UK-ReVasc (n=215)
Mean age – year (SD)	67.4 (10.2)
Male sex – % (n)	77.2 (167/215)
Hypertension – % (n)	65.1 (140/215)
Hyperlipidaemia – % (n)	69.3 (149/215)
Diabetes – % (n)	34.4 (74/215)
Smoking status	
• Current smoker – % (n)	12.1 (26/215)
• Prior smoker – % (n)	37.7 (81/215)
Previous MI – % (n)	24.7 (53/215)
Previous PCI – % (n)	17.7 (38/215)
Previous CABG – % (n)	0.0 (0/215)
LV function $\leq$ 50% – % (n)	37.7 (79/215)
Chronic kidney disease (eGFR <60ml/min) – % (n)	14.4 (31/215)
Pulmonary disease – % (n)	10.2 (22/215)
Presentation	
• Chronic coronary syndrome – % (n)	25.1 (54/215)
• NSTE-ACS – % (n)	74.9 (161/215)
Pattern of CAD	
• Multi-vessel disease with LMS – % (n)	51.4 (108/210)
• Multi-vessel disease without LMS – % (n)	45.2 (95/210)

• LMS only – % (n)	1.4 (3/210)
• LAD only – % (n)	3.3 (7/210)
• LAD disease – % (n)	94.8 (199/210)
• Non-LMS/non-LAD – % (n)	2.4 (5/210)
SYNTAX score^ - mean (SD)	28.0 (10.4)
SYNTAX score tertiles	
• <23 - % (n)	32.9 (69/210)
• 23-32 - % (n)	35.7 (75/210)
• >32 – % (n)	31.4 (66/210)
SYNTAX II score^	
• PCI 4-year mortality – mean (SD) (%)	14.2 (13.2)
• CABG 4-year mortality – mean (SD) (%)	10.5 (10.4)
EUROSCORE II score – mean (SD)*	2.9 (3.9)

CAD: coronary artery disease; eGFR: estimated glomerular filtration rate; LAD: left anterior descending; LMS: left main stem; NSTE-ACS: non-ST elevation acute coronary syndrome; SD: standard deviation

^ = SYNTAX/SYNTAX II score data available for 210 patients

* = EUROSCORE II data available for 161 patients

Table 2: Procedural characteristics

	UK-ReVasc (n=215)
Radial access - % (n)	93.4 (225/241*)
Image-guided PCI - % (n)	44.8 (108/241)
• IVUS - % (n)	41.9 (101/241)
• OCT - %	2.9 (7/241)
Calcium modification - % (n)	24.1 (58/241)
• Rotational atherectomy - % (n)	13.7 (33/241)
• Intravascular lithotripsy - % (n)	10.0 (24/241)
• Laser atherectomy - % (n)	0.4 (1/241)
CTO PCI performed - % (n)	13.8 (31/225)
Mechanical circulatory support device used - % (n)	0.8 (2/241)
Complete revascularisation at 12 months - % (n)	54.4 (117/215)
Residual SYNTAX score in patients with incomplete revascularisation - mean (SD)	11.9 (8.6)
PCI success - % (n)	93.4 (225/241)

CTO = chronic total occlusion; IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention; OCT = optical coherence tomography
*Total number of procedures (n=241), 26 patients underwent >1 procedure

Table 3: Twelve-month outcomes

Endpoint	**UK-ReVasc (n=209)**
Primary endpoint	11.0% (23/209)
All-cause mortality	4.3% (9/209)
MI	2.4% (5/209)
Repeat revascularisation	5.7% (12/209)
Stroke	0.5% (1/209)
Cardiovascular death	1.4% (3/209)
Admission for heart failure	1.4% (3/209)
BARC 3-5 bleeding	1.4% (3/209)
Stent thrombosis	0.0% (0/209)

BARC: Bleeding Academic Research Consortium; MI: myocardial infarction
Primary endpoint is composite of all-cause mortality, myocardial infarction, repeat revascularisation and stroke

Table 4: UK-ReVasc registry subgroup analyses for the primary endpoint

	Event rate	P value
PCI with intravascular imaging	9.2% (9/98)	<0.01
PCI without intravascular imaging	14.9% (15/101)	
Diabetes	10.8% (8/74)	0.92
No diabetes	10.4% (14/135)	

PCI: percutaneous coronary intervention
Primary endpoint is composite of all-cause mortality, myocardial infarction, repeat revascularisation and stroke

Table 5: Comparison of PCI arms from pivotal randomised controlled trials and the UK-ReVasc registry

Baseline demographics							12-month MACE			
Study	**Date**	**n**	**Age**	**LVEF <50%**	**ACS presentation**	**Mean SYNTAX score**	**All-cause mortality**	**MI**	**Stroke**	**Repeat revascularisation**
SYNTAX	2009	1800	65.2	NA	28.9%	28.4	4.4%	4.8%	0.6%	13.5%
BEST	2015	880	64.0	NA*	42.2%	24.2	6.6%	4.8%	2.5%	11.0%
FAME-3	2022	1500	65.2	18.2%	39.7%	26.0	1.6%	5.2%	0.9%	5.9%
UK-ReVasc	2020	215	67.4	37.7%	74.9%	28.0	4.3%	2.4%	0.5%	5.7%

ACS: acute coronary syndrome; LVEF: left ventricular ejection fraction; MACE: major adverse cardiovascular events; MI: myocardial infarction; NA: not available
*mean LVEF in PCI arm = 59.1%
NOBLE and EXCEL excluded as 12-month MACE not reported

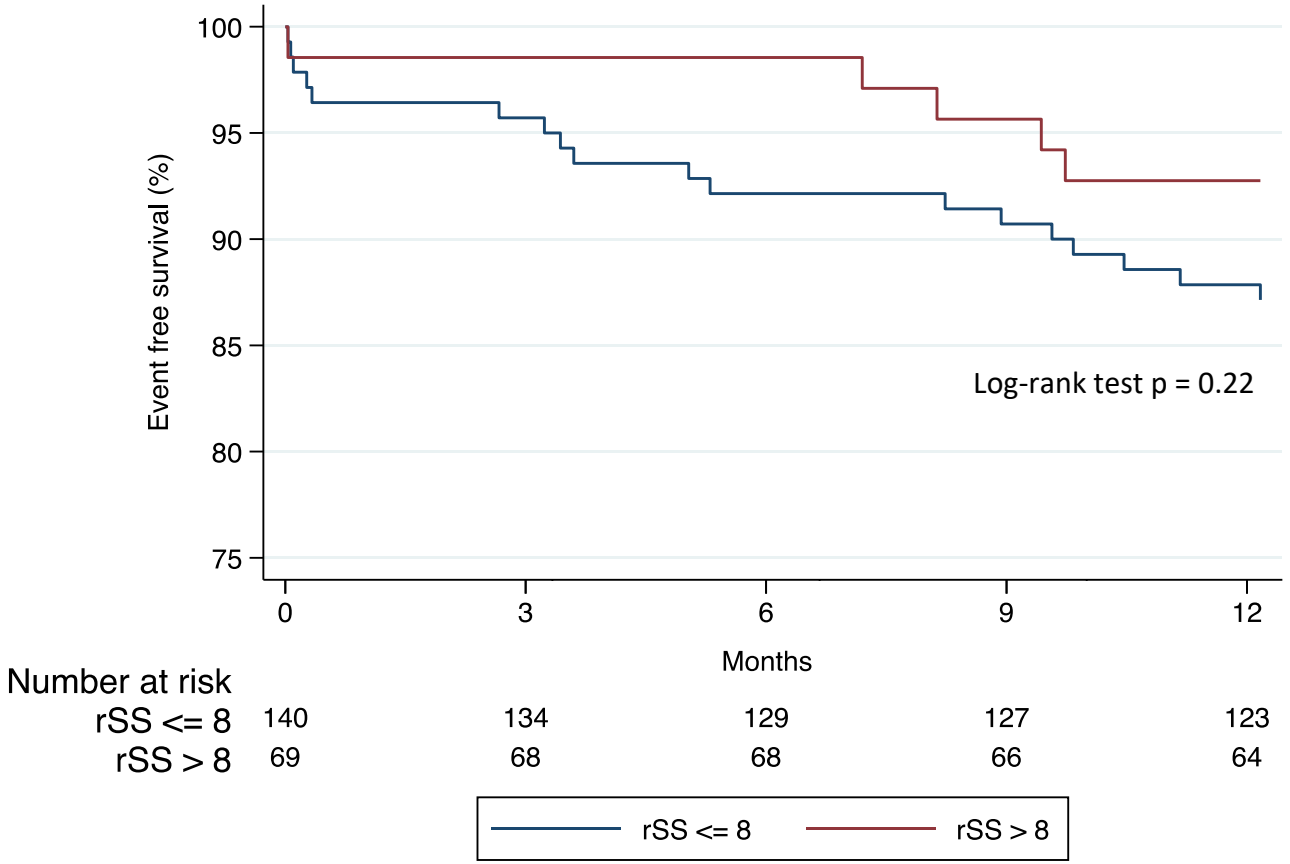

Figure 1: Time-to-event analysis comparing complete (residual SYNTAX score ≤8) versus incomplete (residual SYNTAX score >8) revascularisation for the primary endpoint in UK-ReVasc registry patients