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Characteristics and Outcomes of Unsuccessful

Percutaneous Coronary Intervention

Short title: Outcomes after unsuccessful PCI

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Abstract

Objectives: To examine predictors and outcomes of unsuccessful percutaneous coronary intervention (PCI) cases in a contemporary Australian registry cohort.

Background: With improvements in techniques and pharmacotherapy in PCI, more complex lesions in older patients are now being attempted. In the context of PCI performance assessment, there are limited data regarding the characteristics and outcomes of unsuccessful PCI.

Method: We prospectively collected data on patients undergoing single-lesion PCI between 2013 and 2017 who were enrolled in the multi-centre Victorian Cardiac Outcomes Registry. Procedures were divided into 2 groups by whether or not PCI was deemed successful at the end of the procedure using a pre-specified definition.

Results: There were 34,383 single-lesion PCI performed, of which 18,644 (54.2%) were for acute coronary syndromes. Of the study cohort, 2,080 patients (6.0%) had an unsuccessful PCI – these patients were older, more likely to have previous stroke, PCI, severe left ventricular dysfunction and chronic kidney disease (all $p < 0.001$). The procedure was also more likely to be performed for stable angina ($p < 0.001$). Chronic total occlusion PCI made up 31% of unsuccessful PCI cases. Unsuccessful PCI was itself associated with higher in-hospital and 30-day mortality and MACE (all $p < 0.001$). 4.9% of unsuccessful PCIs led to unplanned in-hospital bypass surgery (compared to 0.2% in successful PCIs, $p < 0.001$).

Conclusion: Our study highlights that even in contemporary PCI practice, more than 1 in 20 PCI attempts are unsuccessful. Lack of procedural success has a strong influence on patient outcomes. Monitoring rates of unsuccessful cases is an important quality assurance tool.

Introduction

Percutaneous coronary intervention (PCI) is a well-established treatment modality used for the management of patients with both stable and unstable coronary artery disease. Since its introduction 40 years ago, advances in PCI techniques, technology and adjuvant medical therapy have resulted in a substantial improvement in procedural success rates^{1, 2}. However, a small but significant group of patients worldwide continue to have unsuccessful PCI procedures worldwide, but the incidence and clinical outcomes of these patients remain under-reported.

There is growing interest in using routinely collected healthcare data through clinical quality registries (CQRs) to measure and report procedural outcomes to healthcare regulators and consumers^{3, 4, 5}. Traditionally, in-hospital or 30-day mortality rates have been the most commonly utilised outcome measures by CQRs. However, with advances in PCI technology and gains in operator experience, short-term mortality after PCI has fortunately become uncommon in the contemporary era⁶. Furthermore, it has been shown that the majority of in-hospital deaths after PCI are mostly or wholly unpreventable, whilst only a minority are directly related to the PCI procedure^{7, 8}. Rates of unsuccessful PCI may therefore represent a better quality metric for PCI operators but one that remains under-utilised at present. Furthermore, it is important for operators to know the potential clinical implications of PCI failure in an unselected real-world cohort of patients undergoing PCI. In this study, we therefore sought to examine the incidence, predictors and short-term outcomes of unsuccessful PCI in a large multi-centre Australian PCI registry.

Methods

This was a retrospective cohort study of consecutive adult patients undergoing PCI between 1 January 2013 and 31 December 2017 inclusive, enrolled prospectively in the Victorian

Cardiac Outcomes Registry (VCOR). Patients were only included in the primary analysis if they had PCI to a single coronary lesion. Patients were then dichotomised according to whether the PCI procedure was deemed successful or unsuccessful by the PCI operator at the end of the procedure using a pre-specified definition, and compared for baseline and procedural characteristics, as well as in-hospital and 30-day clinical outcomes. A successful PCI of the treated lesion was defined as <50% residual stenosis for lesions in which a stent was not able to be deployed in the lesion (i.e. balloon angioplasty alone), or <20% residual stenosis for stented lesions. A secondary analysis was also conducted including cases in which multiple lesions were treated in a single PCI procedure. In such cases, the procedure was classified as unsuccessful if PCI to any one treated lesion was unsuccessful.

The primary endpoint in this study was the rate of major adverse cardiovascular events (MACE) within 30 days of PCI, defined as a composite of death, myocardial infarction (MI) and target vessel revascularisation (TVR) (definitions shown in Supplementary Table 1). Secondary endpoints included in-hospital and 30-day mortality and major adverse cardiovascular events (MACE), MI, stroke and major bleeding (Bleeding Academic Research Consortium (BARC) type 3 bleeding and above).

The Victorian Cardiac Outcomes Registry (VCOR) was established in 2013 to collect prospective patient-level data on consecutive adult patients undergoing PCI in both public (government-funded) and private hospitals in Victoria, Australia, and has previously been described in detail⁹. Briefly, demographic, clinical, procedural and in-hospital outcome data are prospectively recorded on case-report forms using standardized definitions for all fields. All 13 public and 17 private hospitals that perform PCI in the state of Victoria participate and contribute data to the registry. The same operators work across both public and private hospitals and there is no difference in availability of equipment. However, private hospitals tend to perform a greater proportion of PCI cases for non-acute coronary syndrome indications compared to public hospitals¹⁰. The primary ethics approval has been granted by the ethics

committee at The Alfred Hospital (approval number 47/12), and also approved by each participating hospital, including the use of opt-out consent.

Continuous variables are expressed as mean \pm standard deviation and were compared using the independent t-test or Mann-Whitney U test, as appropriate. Categorical data are expressed as numbers and percentages and were compared using Pearson's Chi-square test. Multivariable logistic regression analysis was performed to determine the independent predictors of unsuccessful PCI¹¹. In this model, 22 clinically relevant variables were considered. Those with a p value of <0.1 on univariate analysis that were not co-linear were entered into a stepwise backward selection modelling process for multivariable assessment. In addition, multivariable logistic regression analysis was also performed to determine whether unsuccessful PCI was an independent predictor of 30-day MACE. Complete case analysis was performed for purposes of multivariable modelling (i.e. patients with missing values were excluded). The proportion of missing values was $<1\%$ for all variables.

All statistical analyses were performed using Stata 15.1 software (StataCorp LP, College Station, Texas, USA). P values of <0.05 were considered to be statistically significant.

Results

The study cohort included 34,383 patients of whom 2,080 patients (6.0%) had an unsuccessful PCI procedure. The rate of unsuccessful PCI ranged between 0% and 10.8% when analysed by PCI hospital (Supplementary Figure 1) and was higher in private hospitals compared to public hospitals (7.2% vs. 5.4%¹ $p<0.001$).

Table 1 shows the baseline characteristics of the 2 groups. Patients in the unsuccessful PCI group were slightly older (67.5 ± 11.8 years vs. 65.5 ± 12.0 years; $p<0.001$), more likely to have a history of stroke (5.2% vs. 3.7%; $p<0.001$), previous PCI (36.3% vs. 31.5%;

p<0.001) and previous coronary artery bypass graft surgery (11.6% vs. 7.5%; p<0.001). They were also more likely to have severe left ventricular dysfunction (7.7% vs. 4.4%; p<0.001) and stage 4-5 chronic kidney disease (3.7% vs. 2.5%; p<0.001).

Procedural characteristics of the two groups are compared in Table 2. Over 50% of unsuccessful PCI procedures were performed for stable angina (Table 2). PCI to chronic total occlusion (CTO) lesions accounted for 30.2% of all unsuccessful PCI procedures compared to 2.2% of successful PCI procedures (p<0.001). The proportion of patients who had presented with cardiogenic shock or post out-of-hospital cardiac arrest (OHCA) was also higher in the unsuccessful PCI group (5.2% vs. 2.5%; p<0.001). Comparing indications for PCI, the rate of unsuccessful PCI was highest for patients with stable angina (7.3%), followed by STEMI (5.2%) and NSTEMI (4.9%). On discharge, patients with an unsuccessful PCI were less likely to receive antiplatelet agents including aspirin (p<0.001).

A comparison of in-hospital and 30-day clinical outcomes between the 2 groups is shown in Table 3. Patients in the unsuccessful PCI group were more likely to experience new renal impairment, myocardial infarction, stroke, unplanned PCI or CABG, major non-CABG related bleeding and death following the PCI procedure and during the index hospital stay (all p<0.001). The rates of 30-day unplanned revascularisation (6.4% vs. 1.1%), mortality (7.0% vs. 1.8%), and MACE (14.1% vs. 3.5%) were also all significantly higher in the unsuccessful PCI group (all p<0.001). On multivariable logistic regression analysis, unsuccessful PCI was a strong independent predictor of 30-day MACE (OR 3.44, 95% CI 2.75 – 4.30; p<0.001) (Table 4). The 3 other strongest independent predictors of 30-day MACE were presentation with cardiogenic shock/post-OHCA (OR 9.56, 95% CI 7.77 – 11.75; p<0.001), LV ejection fraction <35% (OR 3.70, 95% CI 3.01 – 4.56; p<0.001) and presentation with ST-elevation myocardial infarction (OR 2.78, 95% CI 2.27 – 3.40; p<0.001). Other independent predictors of 30-day MACE were estimated glomerular filtration rate of ≤ 60 ml/min/1.73m², high lesion complexity, history of peripheral vascular disease and previous PCI (all p<0.05).

In a secondary analysis of all PCI cases including those involving multi-lesion PCI, both in-hospital and 30-day mortality and MACE continued to be significantly higher in the unsuccessful PCI group, compared to the successful PCI group (all $p < 0.001$) (Supplementary Table 2). Other in-hospital complications such as stroke, unplanned PCI and CABG as well as major non-CABG related bleeding were all again higher in the unsuccessful PCI group (all $p < 0.001$). On multivariable logistic regression analysis, unsuccessful PCI was again found to be a strong independent predictor of 30-day MACE (OR 3.23, 95% CI 2.68 – 3.90; $p < 0.001$) (Supplementary Table 3).

Discussion

Since the introduction of coronary angioplasty through to the current generation of drug-eluting stents, PCI techniques and technology have both undergone substantial development. This has resulted in significant improvement in short- and long-term outcomes in patients undergoing PCI. However, indications for PCI have also broadened and more complex patients as well as lesions are now attempted to be treated percutaneously^{12, 13}. Consequently, PCI procedures are not always successful even in the current era with the availability of advanced PCI equipment. In this retrospective multi-centre registry study including 34,383 patients undergoing single lesion PCI, the rate of unsuccessful PCI was 6.0%. Unsuccessful PCI was more likely to occur in patients with previous percutaneous or surgical revascularisation procedures, as well as in those with severely impaired renal function and left ventricular systolic function. Importantly, unsuccessful PCI was demonstrated not to be a benign event with unsuccessful PCI being shown to be strongly independently associated with 30-day MACE.

In the published literature, there is a concerning paucity of data on both the incidence and outcomes of unsuccessful PCI in all-comers undergoing PCI in the contemporary era. The

rates of unsuccessful PCI reported in the present study are lower than rates reported by Mattichak *et al*, who reported an 8.2% rate of unsuccessful PCI among cases done from 1993 to 2003 at a single PCI centre, however, this included a period where conventional balloon angioplasty was the default PCI strategy¹⁴. Reassuringly, our PCI failure rates fall within the range reported by other large PCI registries around the world in the contemporary era of 3.5% to 7.8%^{15, 16, 17, 18}. However, comparison between various registries is challenging due to differing definitions of successful PCI used by individual registries. In particular, unlike in VCOR, many registries define PCI success as a binary variable that is based solely on operator judgement on PCI success or failure without specific metrics, such as residual stenosis, being provided for what entails a successful or unsuccessful PCI.¹⁸ This may explain some of the differences seen in results between the registries. Among patients undergoing PCI for STEMI, the PCI failure rate reported in the present study (5.2%) is comparable to a contemporary study by Levi *et al* who reported a PCI failure rate of 5.4%¹⁹. The reasons for the reduction in PCI failure rates over time is likely to be multifactorial. Previous studies have suggested that the cause of unsuccessful PCI in the vast majority of cases is suboptimal lumen enlargement (due to elastic recoil or inability to cross the lesion) or no reflow.¹⁴ Improvement in PCI technology including guidewire and stent design, increased use of intravascular imaging as well as greater availability of more potent antiplatelet agents such as prasugrel, ticagrelor and glycoprotein IIb/IIIa inhibitors is likely to have contributed to the improvement in PCI success rates over time^{20, 21, 22, 23, 24}.

An important finding from this study is that PCI failure is not a benign event and is associated with a worse short-term prognosis even when adjusted for other patient and procedural factors. Patients who have an unsuccessful PCI have a higher likelihood of in-hospital and 30-day mortality and morbidity including myocardial infarction, stroke, unplanned revascularisation and cardiac readmissions. While previous studies have demonstrated the adverse impact of unsuccessful PCI on prognosis in patient with STEMI and NSTEMI, this has been less well-described among patients undergoing PCI for stable angina, particularly

for non-CTO lesions¹⁹. In our study however, nearly 70% of unsuccessful PCI cases occurred for non-CTO lesions. In view of the recent findings of the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) trial demonstrating equipoise between an invasive versus conservative strategy in patients with stable angina, as well as the hazard demonstrated in our study from unsuccessful PCI, perhaps greater consideration on the indication for PCI particularly in patients with stable angina needs to be given before an attempt at PCI is undertaken, especially if lesion complexity is high²⁵.

There is an increasing push from healthcare policymakers and funders worldwide to measure real-world procedural safety and outcomes, especially as there are often key differences from results seen in large randomised controlled trials that underpin clinical practice and guidelines^{4, 26, 27, 28}. For example, in the Norwegian Coronary Stent Trial (NORSTENT) comparing outcomes of PCI with bare-metal stents with contemporary drug-eluting stents, the rate of PCI failure based on angiographic assessment of individual vessel segments was 2.2%, which is much lower than PCI failure rates measured in registry-based studies including ours.²⁰ CQRs such as VCOR provide an ideal vehicle for the collection and analysis of real-world procedural data and are increasingly being used by healthcare regulators for the purposes of monitoring quality and safety of clinical practice²⁸. For CQRs in the area of interventional cardiology, PCI failure rates are therefore likely to become a reportable key quality metric, particularly given its potentially significant impact on patient prognosis. However, few registries appear to report PCI failure rates either in the form of peer-reviewed publications or publicly available annual registry reports. While the lack of a universal definition of PCI failure may limit the ability to compare unsuccessful PCI rates between registries and countries, we think that unsuccessful PCI rates still represent an important quality indicator for comparison and benchmarking of hospitals and operators within individual countries or multi-centre registries, and more widespread reporting of this metric is warranted, especially given the large variation in unsuccessful PCI rates between different PCI centres that we have observed in this study. However, for future regulatory use, similar to post-PCI mortality, a risk-

adjusted rate of unsuccessful PCI should ideally be used to account for lesion and patient complexity²⁹. This will ensure that operators taking on high-risk patients such as those who are a surgical turn-down, are not disincentivised from attempting to treat patients who may have no other revascularisation options other than high-risk PCI.

Limitations

Our study has several limitations that must be acknowledged. The primary limitation is related to the observational nature of the study and its attendant biases, namely that not all potentially confounding variables were recorded or could be adjusted for. This includes the presence or absence of bystander disease at the time of PCI, which could have had an impact on clinical outcomes. Furthermore, the mechanism of PCI failure such as inability to cross the lesion, failure of stent delivery or residual stenosis despite stent deployment was not recorded in the registry thereby limiting interpretation of the data. PCI failure was also self-reported by PCI operators and therefore, in the absence of core-laboratory angiographic review of all cases, failure rates may have been under-reported.

Conclusion

Despite improvements in PCI technology, PCI failure continues to occur in at least 1 in 20 cases and identifies a high-risk patient subset in whom it is associated with a poor prognosis. The highest rate of PCI failure in our study was seen in patients undergoing PCI for stable angina who may be considered to be lower-risk patients and therefore warrants further study. Unsuccessful PCI rates may be seen as a key quality indicator for PCI centres and individual operators. Clinical quality registries therefore have an important role in reporting a metric such as this, particularly in the current era of data-driven healthcare regulation and safety monitoring.

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The authors have no conflicts of interest to declare.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Supplementary Figure Legend

Supplementary Figure 1: Variation in unsuccessful PCI rate by hospital

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