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Outcomes according to timely or delayed primary percutaneous coronary intervention or fibrinolysis in a national registry of patients with ST-segment elevation myocardial infarction

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ABSTRACT

Background Time to reperfusion is a predictor of long-term outcomes in ST-segment elevation myocardial infarction (STEMI). Timely primary percutaneous coronary intervention (PCI) is the preferred strategy recommended by guidelines. Fibrinolysis is recommended in patients in whom timely primary PCI is not feasible, though concerns persist about underutilisation of this approach. We examined long-term survival outcomes in STEMI patients according to treatment strategy received in a national STEMI registry in Ireland.

Methods This was an observational, nationwide, population-based study. We identified all STEMI cases from January 2013 to March 2018. After exclusion of patients with missing data, we divided patients into three groups as per reperfusion strategy—fibrinolysis, delayed primary PCI (>120 min of diagnosis) and timely primary PCI (<120 min of diagnosis)—and analysed mortality through to 3 years follow-up. A multivariate Cox proportional hazards model was used, with a propensity score matching analysis performed as a sensitivity analysis.

Results Of the 4156 patients included in this analysis, 202 (4.9%) were treated with fibrinolysis, 1075 (25.8%) were treated with delayed primary PCI and 2879 (69.3%) were treated with timely primary PCI. At follow-up, delayed primary PCI was associated with an increased risk of mortality through to 3 years in comparison to fibrinolysis ($HR_{adjusted}$, 1.36; 95% CI 1.02 to 1.83, p=0.04). Timely primary PCI was associated with a comparable risk of mortality through to 3 years in comparison to fibrinolysis ($HR_{adjusted}$, 1.10; 95% CI 0.81 to 1.49, p=0.53).

Conclusions A sizeable proportion of STEMI patients continue to receive treatment with delayed primary PCI. This is associated with an increased risk of mortality through 3 years in comparison to fibrinolysis.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Many patients suffering ST-segment elevation myocardial infarction continue to be treated with primary percutaneous coronary intervention (PCI) beyond the clinical practice guideline recommended time window of 120 min from diagnosis. Previous observational studies have demonstrated better long-term survival associated with thrombolysis than with delayed primary PCI.

WHAT THIS STUDY ADDS

⇒ We found that delayed primary PCI was associated with a greater long-term mortality than fibrinolysis.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ While quality improvement projects should seek to reduce delay times to primary PCI, greater consideration should be given to fibrinolysis in patients for whom timely primary PCI is unlikely.

INTRODUCTION

For patients presenting with acute ST-segment elevation myocardial infarction (STEMI) and symptoms of ischaemia of ≤12 hour duration, reperfusion therapy is recommended.[1] Primary percutaneous coronary intervention (PCI) is recommended over fibrinolysis if the anticipated time from diagnosis to PCI is <120 min[1]. Fibrinolysis (followed by immediate transfer to a primary PCI centre as part of a pharmacoinvasive strategy) is recommended when timely primary PCI cannot be performed.[1]

Longer delays from clinical presentation to revascularisation in STEMI have been associated with an increased risk of mortality.[2 3] Unfortunately, a significant proportion of STEMI patients undergoing primary PCI continue to receive treatment beyond the guideline time window of 120

min.[4–6] This may partly suggest a tendency for treating physicians to persist with a primary PCI strategy, even when it is not possible for this to be performed in a timely manner.[7] This is concerning because previous observational analysis has suggested that treatment with fibrinolysis may be associated with lower mortality in comparison to treatment with delayed primary PCI.[4 8]

Therefore, we carried out a retrospective observational analysis of the Irish national acute coronary syndrome (ACS) database, comparing long-term survival outcomes in STEMI patients who were treated with timely primary PCI, delayed primary PCI or fibrinolysis.

METHODS

Population

This was an observational, national, population-based study. We started by identifying every recorded case of STEMI in Ireland from the start of January 2013 until the end of March 2018. Data were collected from the nine hospitals providing primary PCI in Ireland. As one centre did not routinely record time delays to treatment or report to the national database during the time period studied, cases from this centre were excluded from the analysis. The omitted centre treated 372 of 7601 STEMI cases in the overall data set (4.9%). Exclusion of these cases resulted in 7229 cases (95.1% of total STEMIs recorded nationally) eventually being included and analysed. Patients were also excluded if their PCI was deferred to later during their admission (n=537) or if they received other therapeutic strategies (n=621) (figure 1). Patients were also excluded from the analysis if data regarding survival status (n=31) or for any of the covariates (n=1884) were missing.

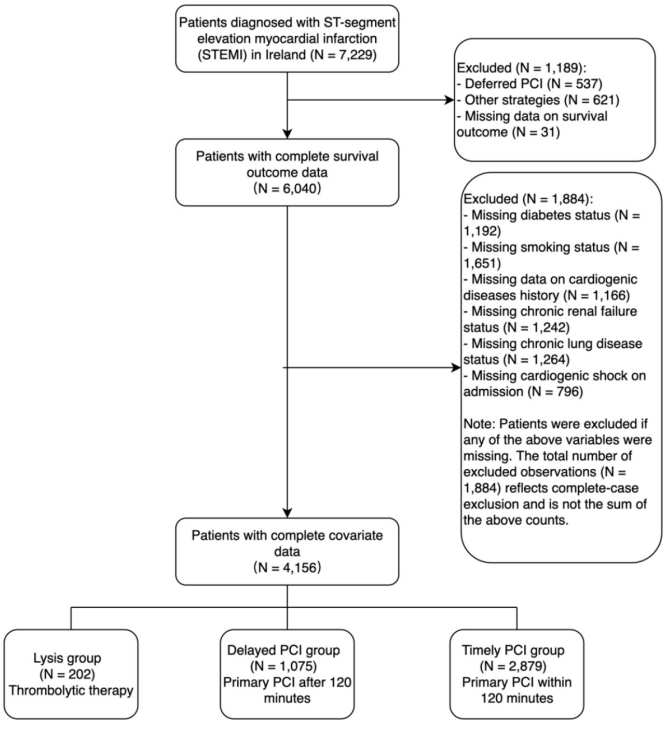


Figure 1 Study flow diagram.

Irish ACS registry

A national registry was developed as part of a national ACS programme in 2012. This records every case of STEMI, either through primary PCI pathway activation or retrospective inclusion in cases with a very late presentation. 'False alarm' or alternative diagnosis system activations are also recorded, but these were not included in our analysis. Data are recorded in each hospital that provides primary PCI and are submitted to a national audit group. Baseline patient characteristics (demographics, risk factors, medical history), as well as time delays to treatment, treatment modality employed and discharge therapies (antiplatelet/ beta blocker/renin-angiotensin-aldosterone system inhibitor/statin prescription, smoking cessation, enrolment in cardiac rehabilitation, etc) are collected prospectively for each patient. Data are collected and collated on a continuous basis from each centre. Data regarding fibrinolytic agent or dose were not recorded.

Follow-up data

Centralised data were processed in the Cardiovascular Research Institute and Royal College of Surgeons in Ireland, both in Dublin. In cases of ambiguity regarding diagnosis or time delay, electronic health records were consulted for clarification. Cases wherein accurate diagnoses or time delays could not be determined were excluded from the analysis. All-cause mortality was determined through both hospital electronic health records and referencing the Central Statistics Office national death register. Patients from outside the state, or for whom we could not ascertain follow-up data, were also excluded from the analysis.

Outcomes

The primary outcome was all-cause mortality through to 3 years follow-up. The outcome variable was defined as time from hospital admission to death, censored at 3 years (1095 days) for surviving patients.

Statistical methods

Continuous data were presented as means±SD, with differences between the three treatment groups assessed using analysis of variance tests. Categorical variables were presented as percentages and compared with X^2 tests.

For all analyses, we ran two comparisons, the first comparing fibrinolysis with delayed primary PCI, the second comparing fibrinolysis with timely primary PCI. For the analyses, we first ran unadjusted analysis on two samples (all those for whom we had survival data (this being reported in online supplemental Appendix 1) and only those for whom we had complete data about the covariates. Then we ran an adjusted analysis on the latter sample, conditional on the covariates.

Covariates were age group (<50, 50–59, 60–69, 70–79, 80+), female sex, diabetes, current smoking, history of

Table 1 Baseline characteristics of patients according to treatment group (n=4156)

Variable	Lysis (n=202; 4.9%)	Delayed PCI (n=1075; 25.9%)	Timely PCI (n=2879; 69.2%)	P value
Deaths	30 (14.9%)	187 (17.4%)	415 (14.4%)	0.067
Age (years)	62.5±12.4	62.2±12.8	61.5±12.2	0.19
Age groups				0.272
<50	27 (13.4%)	163 (15.2%)	463 (16.1%)	
50–59	52 (25.7%)	305 (28.4%)	855 (29.7%)	
60–69	65 (32.2%)	287 (26.7%)	889 (30.9%)	
70–79	40 (19.8%)	210 (19.5%)	521 (18.1%)	
80+	18 (8.9%)	110 (10.2%)	231 (8.0%)	
Female	48 (23.8%)	248 (23.1%)	602 (20.9%)	0.254
Diabetes	34 (16.8%)	170 (15.8%)	380 (13.2%)	0.055
Current smoking	88 (43.6%)	469 (43.6%)	1216 (42.2%)	0.708
History of ASCVD	34 (16.8%)	191 (17.8%)	493 (17.1%)	0.88
CKD	6 (3.0%)	36 (3.4%)	56 (1.9%)	0.03
Lung disease	16 (7.9%)	99 (9.2%)	201 (7.0%)	0.062
Cardiogenic shock	4 (2.0%)	26 (2.4%)	97 (3.4%)	0.2

Data are presented as mean±SD or number (percentage).
P values calculated using X^2 test for categorical variables and analysis of variance for continuous variables.
ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; PCI, percutaneous coronary intervention.

chronic kidney disease, history of lung disease, cardiogenic shock and history of atherosclerotic cardiovascular disease. This latter variable took a value of 1 if the patient had any prior history of myocardial infarction, cerebrovascular disease, coronary artery bypass grafting or PCI. We also controlled for year of admission.

The Kaplan-Meier method was used to assess the survival between treatment groups with multivariate Cox proportional hazards models (specified in online supplemental Appendix 2) used to evaluate timely or delayed primary PCI compared with fibrinolysis as an independent predictor of outcome. Results are presented as unadjusted and adjusted hazard ratios with 95% CIs.

Sensitivity analysis

As a sensitivity analysis (reported in online supplemental Appendix 3), we built two cohorts of patients using propensity score matching (PSM), with three to one matching of fibrinolysis to delayed primary PCI patients and to timely primary PCI patients, using the same set of covariates as included in the Cox regression for matching. Only patients within the common support region and successfully matched using 3:1 nearest-neighbour matching (calliper=0.1, logit model) were included in the PSM analyses.

Subgroup analysis

We also conducted subgroup analyses (reported in online supplemental Appendix 4) to assess potential effect modification by age, sex and diabetes status, following the approach taken by Danchin *et al*.[4]

RESULTS

Study population

In the final analysis, we included 4156 patients with complete data; 202 were treated with fibrinolysis, 1075 were treated with delayed primary PCI and 2879 were treated with timely primary PCI. The study flow is demonstrated in figure 1. Baseline characteristics for the three treatment groups are presented in table 1. There was a consistent decline in use of fibrinolysis from 7.5% of cases in 2013 to 2.6% in 2018. There was a decline in patients receiving delayed primary PCI from 26% in 2013 to 23% in 2018, with an increase in patients receiving timely primary PCI from 66.5% in 2013 to 74.4% in 2018. Further data is available in the online supplemental Appendix 5.

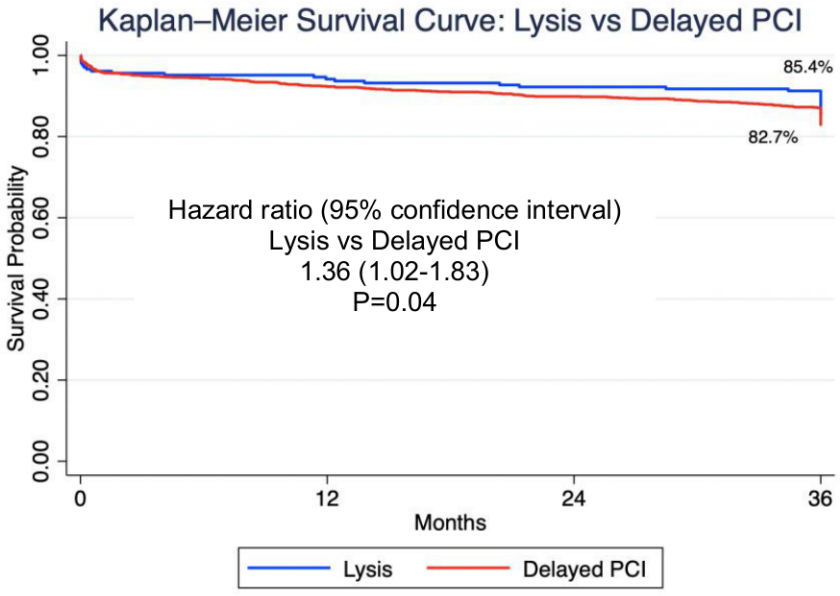
Outcomes

Mortality

Through to 3 years follow-up, mortality occurred in 30 of 202 patients (14.9%) in the fibrinolysis group, 187 of 1075 patients (17.4%) in the delayed primary PCI group and 415 of 2879 patients (14.4%) in the timely primary PCI group.

Unadjusted analysis

On unadjusted survival analysis for those patients with complete covariate data, delayed primary PCI was associated with a comparable risk of mortality through to 3 years in comparison to fibrinolysis ($HR_{unadjusted}$ 1.2; 95% CI 0.81 to 1.76, p=0.36). Timely primary PCI was associated with a comparable risk of mortality through to 3 years in



Number at risk				
Months	0	12	24	36
Lysis	202	191	187	184
Delayed PCI	1075	993	966	933

Figure 2 Three-year survival probabilities among STEMI patients treated with fibrinolysis versus delayed primary PCI. PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

comparison to fibrinolysis ($HR_{unadjusted}$ 0.97; 95% CI 0.67 to 1.4, p=0.88).

Adjusted analysis

On adjusted survival analysis using a multivariate Cox proportional hazards model, delayed primary PCI was associated with an increased risk of mortality through to 3 years in comparison to fibrinolysis ($HR_{adjusted}$ 1.36; 95% CI 1.02 to 1.83, p=0.04). This is demonstrated in figure 2 and table 2. Timely primary PCI was associated with a comparable risk of mortality through to 3 years in comparison to fibrinolysis ($HR_{adjusted}$ 1.10; 95% CI 0.81 to 1.49, p=0.53) (figure 3, table 2).

Sensitivity analyses

As outlined in the methods, we also conducted a PSM analysis as a sensitivity analysis. The results were consistent with the Cox multivariate analysis and are provided in the online supplemental Appendix 3.

DISCUSSION

The main findings of this study are as follows:

1. A large proportion (~1 in 4) of STEMI patients received delayed primary PCI.
2. A relatively small proportion (~1 in 20) of STEMI patients were treated with fibrinolysis.
3. Fibrinolysis was associated with improved 3-year survival in comparison to delayed primary PCI, and comparable 3-year survival to timely primary PCI.

As we have entered the primary PCI era, one concern raised has been that the increased focus on providing primary PCI to as many patients as possible has reduced the focus on the key aspect of STEMI care: timely reperfusion of the infarct-related artery.[7] This may partly have occurred as a result of the false dichotomisation that can occur when two treatments are compared head-to-head, and one is judged to be superior.[9] While timely primary PCI remains the default approach recommended by the guidelines (Class I recommendation), fibrinolysis also has a Class I recommendation when timely primary PCI cannot be performed.[1] The results of our analysis, with a small proportion of patients receiving fibrinolysis and a large proportion receiving delayed primary PCI, suggest that physicians are tending to favour a primary PCI strategy in comparison to a fibrinolysis strategy, even when timely primary PCI is not feasible. Even more concerningly, our results indicate that delayed primary PCI is associated with an increased risk of mortality in comparison to fibrinolysis, suggesting that patients are being harmed with this approach. Although prehospital fibrinolysis has been administered by primary practitioners working in remote regions of Ireland in the past, this is now seldom done.[10 11] This might represent a potential opportunity for future improvement.

Previous observational studies conducted in other settings have raised similar concerns. An analysis of the French FAST-MI registry also reported that patients treated with delayed primary PCI had increased mortality

Table 2 Cox proportional hazards regression comparing 3-year mortality in STEMI patients treated with fibrinolysis versus primary PCI (pPCI) (delayed or timely)

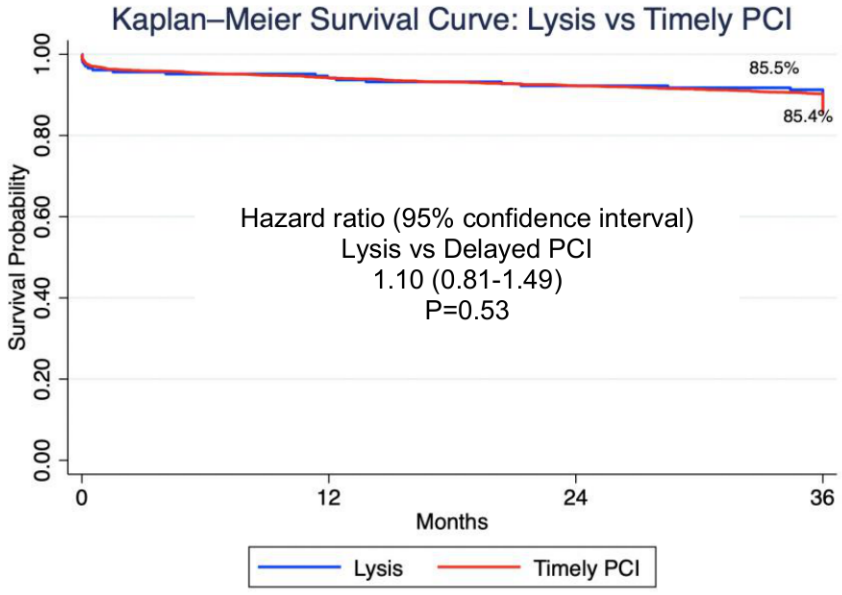
	Lysis vs delayed pPCI		Lysis vs timely pPCI	
Variable	**HR (95% CI)**	**P value**	**HR (95% CI)**	**P value**
Treatment	1.36 (1.02 to 1.83)	**0.039**	1.10 (0.81 to 1.49)	0.534
Age groups				
50–59	1.56 (0.96 to 2.53)	0.071	1.45 (1.02 to 2.05)	**0.037**
60–69	3.20 (1.68 to 6.11)	**<0.001**	2.42 (1.56 to 3.75)	**<0.001**
70–79	8.79 (4.16 to 18.6)	**<0.001**	5.55 (3.70 to 8.32)	**<0.001**
80+	22.2 (11.5 to 43.2)	**<0.001**	12.7 (8.75 to 18.5)	**<0.001**
Female	0.92 (0.59 to 1.44)	0.707	1.11 (0.92 to 1.33)	0.27
Diabetes status	1.38 (1.21 to 1.58)	**<0.001**	1.40 (1.08 to 1.80)	**0.01**
Current smoking	1.55 (1.14 to 2.11)	**0.006**	1.03 (0.71 to 1.50)	0.86
Medical card indicator (GMS)	1.13 (0.66 to 1.94)	0.647	1.36 (1.01 to 1.83)	**0.045**
ASCVD	1.26 (1.06 to 1.58)	**0.046**	1.39 (1.13 to 1.71)	**0.002**
Previous CKD	1.51 (0.93 to 2.45)	0.093	1.22 (0.70 to 2.13)	0.484
Previous lung disease	1.66 (1.29 to 2.14)	**<0.001**	1.96 (1.65 to 2.33)	**<0.001**
Cardiogenic shock at admission	3.27 (2.17 to 4.92)	**<0.001**	6.45 (4.49 to 9.28)	**<0.001**
Year of admission				
2014	0.45 (0.31 to 0.66)	**<0.001**	0.97 (0.52 to 1.83)	0.93
2015	0.44 (0.31 to 0.63)	**<0.001**	0.95 (0.56 to 1.62)	0.86
2016	0.35 (0.20 to 0.60)	**<0.001**	0.61 (0.37 to 1.00)	0.052
2017	0.25 (0.12 to 0.51)	**<0.001**	0.60 (0.31 to 1.17)	0.137
2018	0.10 (0.02 to 0.66)	**0.016**	0.69 (0.25 to 1.46)	0.267
Model Information				
Number of observations	1277		3881	
Number of failures	217		445	
Wald chi2(8)	1915.48		183.13	
Prob>X^2	**0.000**		**0.000**	

Cox proportional hazards regression was used to estimate adjusted HRs for all-cause mortality. The outcome was defined as mortality within 3 years, with censoring at 1095 days. Robust standard errors were clustered by hospital to account for within correlation. Bold values indicate statistical significance (p <0.05).
ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; GMS, General Medical Services (lower income patients); HR, hazard ratio; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

through to 5 years follow-up in comparison to patients treated with fibrinolysis.[4] An Australian study, comparing outcomes across three time periods with different treatment strategies for STEMI, also reported that patients treated with late primary PCI had increased mortality rates in comparison to those treated with fibrinolysis.[8] Alongside our results, these studies all suggest that physicians should follow the current European and American guidelines which recommend treating patients in whom timely primary PCI is not feasible with fibrinolysis.[1 12]

It should be acknowledged that as emergency ACS networks have developed and matured, increasing the proportion of patients treated with primary PCI, rates of fibrinolysis have fallen. It has been reported that in France, the proportion of patients treated with fibrinolysis has fallen from 30% of STEMI cases in 2005 to 16% of cases in 2010.[13] Similar data have been reported in the USA, with a decrease from 10.1% in 2009 to 5.0% in 2014.[14] The international GRACE registry reported a reduction in the use of fibrinolysis in STEMI from 40% in 1999 to 16% in 2006.[15] One unanticipated side effect of this progress with respect to primary PCI may be that physicians are now less comfortable with the pharmaco-invasive approach for STEMI, and this may partly explain the findings observed in our study.

Other factors should be considered when examining the provision of timely reperfusion. It is recognised that timely revascularisation is often more challenging for patients who present to a non-primary PCI capable hospital and require inter-hospital transfer.[16] Randomised controlled trials conducted in the primary PCI era have shown similar efficacy for resolution of coronary



Number at risk				
Months	0	12	24	36
Lysis	202	191	187	184
Timely PCI	2879	2716	2660	2602

Figure 3 Three-year survival probabilities among STEMI patients treated with fibrinolysis vs timely primary PCI. PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

ischaemia with fibrinolysis or primary PCI, in patients who could not be treated with primary PCI within 1 hour of diagnosis, although rates of intracranial bleeding were higher in the fibrinolysis group.[17 18] Regular auditing of revascularisation times should be employed by STEMI networks. This may be useful to identify centres where patients regularly experience delays to reperfusion. Local quality improvement initiatives may then be employed to try to identify specific issues locally and to increase the proportion of patients receiving timely reperfusion.

Limitations

A key limitation of this study is the retrospective, observational design. Due to the observational nature of this analysis, no direct causality can be determined. In order to explore the impact of revascularisation strategies on long-term mortality, we performed an adjusted analysis and a PSM. While the results of these analyses were consistent, we acknowledge that there may have been differences between the groups with respect to unmeasured confounders. No quantitative data were available on enzyme rise or left ventricular function. It should also be acknowledged that a large proportion of patients excluded due to incomplete data.

CONCLUSIONS

A sizeable proportion of STEMI patients continue to receive treatment with delayed primary PCI rather than fibrinolysis. Delayed primary PCI is associated with an increased risk of mortality through to 3 years in comparison to fibrinolysis. These results support current guideline recommendations for a pharmacoinvasive strategy when timely primary PCI within 120 mins is not feasible. Quality improvement initiatives within STEMI networks should focus on increasing the proportion of patients receiving timely reperfusion, whether through primary PCI or fibrinolysis. Addressing the issue of relative underutilisation of fibrinolytic therapy might be done by audit, training, better standard operating procedures and realistic time agreements across networks.

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analysis, writing - original draft, review and editing. JJC: writing – review and editing. RA: data collection and analysis. AM: data collection. GB data collection. PK: data collection. JC: data collection. TK: data collection. CMcC: data collection. GA: data collection. AP: data collection. MK: data collection, writing – draft, review and editing. RAB: methodology, administration, data analysis, writing – review and editing.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involved human participants and was approved by the Royal College of Surgeons of Ireland Research Ethics Committee, as well as the ethics committees in each primary PCI centre from which data were sourced (approval number: REC202001004). Research ethics committee approval was obtained from RCSI, the primary research university. A consent declaration was obtained from the Health Research Consent Declaration Committee (HRCDC) to access limited identifying patient data (approval number: 20-001-AF1). The HRCDC reports to the Irish Minister for Health. This was a retrospective registry-based study involving thousands of patients. All patient data were anonymised as soon as feasible. It was not feasible to obtain consent from each patient (many of whom were dead). Public information advertising was conducted to inform patients of the project, and patient interest representatives were consulted.

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