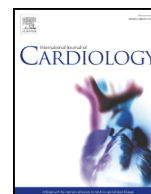




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Adoption of same day discharge following elective left main stem percutaneous coronary intervention

Paraskevi Taxiarchi^a, Evangelos Kontopantelis^a, Tim Kinnaird^b, Nick Curzen^c, Adrian Banning^d, Peter Ludman^e, Ahmad Shoaib^f, Muhammad Rashid^f, Glen P. Martin^a, Mamas A. Mamas^{a,f,*}

^a Centre for Biostatistics, Manchester Academic Health Science Centre, University of Manchester, Manchester, UK

^b University Hospital of Wales, Cardiff, UK

^c Coronary Research Group, University Hospital Southampton, Faculty of Medicine, University of Southampton, UK

^d John Radcliffe Hospital, Oxford, UK

^e Institute of Cardiovascular Sciences, University of Birmingham, Birmingham, UK

^f Keele Cardiovascular Research Group, Institute of Primary Care and Health Sciences, University of Keele and Academic Department of Cardiology, Royal Stoke Hospital, Stoke-on-Trent, UK

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ABSTRACT

Background: This study sought to investigate the safety and feasibility of same day discharge (SDD) practice and compare clinical outcomes to patients admitted for overnight stay (ON) undergoing elective left main stem (LMS) percutaneous coronary intervention (PCI). ON observation is still widely practiced in highly complex PCI as the standard of care, with no previous data comparing clinical outcomes in patients undergoing LMS PCI. **Methods:** We analysed 6452 patients undergoing elective LMS PCI between 2007 and 2014 in England and Wales. Multiple logistic regressions and the BCIS risk model were used to study association between SDD and 30 day mortality.

Results: SDD rates almost doubled from 19.9% in 2007 to 39.8% in 2014 for all LMS procedures and increased from 20.7% to 41.4% for unprotected LMS cases during the same study period. There was a significant increase in procedural complexity with higher use of rotational atherectomy, longer stents and multivessel PCI. SDD was not associated with increased 30 day mortality (OR 0.70 95%CI 0.30–1.65) in the overall LMS PCI cohort and the results were similar in unprotected LMS (OR 0.48 95%CI 0.17–1.41) and those requiring ON stay (OR 0.58 95%CI 0.25–1.34).

Conclusions: We did not find evidence that SDD is not safe or feasible in highly complex LMS PCI procedures despite increasing procedural complexity with no significant increase in 30 day mortality rates.

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1. Introduction

The adoption of same day discharge (SDD) following percutaneous coronary intervention (PCI) is increasingly common, being driven by financial pressures, a need for improved bed utilization, and patient preference for shorter length of stay. In reality, this practice varies widely among different healthcare systems and clinicians. Whilst clinical trials [1–5], observational studies [6–12] and meta-analyses [13,14] have investigated SDD for its feasibility and safety compared to overnight (ON) admission, only a few single centre studies have examined the effectiveness of SDD practice in more complex elective cases [15–18].

Abbreviations: BCIS, British Cardiovascular Intervention Society; CABG, Coronary Artery Bypass Graft; MI, Myocardial Infarction; ON, OverNight stay; OR, Odds Ratio; PCI, Percutaneous Coronary Intervention; SDD, Same Day Discharge.

* Corresponding author at: Keele Cardiovascular Research Group, Institute of Primary Care and Health Sciences, University of Keele and Academic Department of Cardiology, Royal Stoke Hospital, Stoke-on-Trent, UK.

E-mail address: doctorrashid7@gmail.com (M.A. Mamas).

Treatment of unprotected left main coronary artery disease with PCI has increased over the last decade following the favourable results of randomised clinical trials comparing PCI and coronary artery bypass grafting (CABG) [19–22], and may account for up to 5% of contemporary PCI cases [23]. Nevertheless, PCI of unprotected left main stem (LMS) carries a higher risk in part because of the large amount of myocardium at risk with, and also because the treatment often involves the use of complex bifurcation techniques, with more than 80% of lesions being distal LMS bifurcations [24]. To the best of our knowledge, none of the prior studies that examined the safety of SDD have focused on LMS PCI cases, while many excluded (unprotected) LMS PCI or cited LMS PCI as one of the reasons for ON stay [5,25–30], which was in line with the 2009 guidelines from the Society for Cardiovascular Angiography and Interventions (SCAI) [31]. In the United Kingdom, the evolution of PCI practice means that many elective PCI LMS patients are now discharged on the same day [32] despite safety having not been previously assessed in this population. The most recent guidelines for LMS PCI [33] and for SDD following PCI [34] do not discuss the

appropriateness of such practice. The last published consensus for the length of stay following elective PCI recommended that the decision on hospital admission or SDD should depend on overall patient outcome (i.e. stable Patient, successful Procedure, structured Program), rather than on individual procedural angiographic and procedural characteristics [34]. However, operators may not feel comfortable when the safety of SDD for more complex patients who have not been formally evaluated.

In this study, we aimed to investigate the temporal changes in the distribution of SDD practice in LMS PCI and unprotected LMS PCI cases in England and Wales, as well as the changing clinical characteristics and complexity of cases that were treated as SDD. We also aimed to examine which clinical and procedural characteristics were independently associated with SDD within the LMS PCI cases. Finally, we studied the independent predictors of 30 day mortality and examined the difference between the observed 30 day mortality rate to the expected calculated by the British Cardiovascular Intervention Society (BCIS) 30 day mortality risk model [35], by discharge status.

2. Methods

This retrospective study analysed data from patients that underwent elective LMS PCI from 1 January 2007 to 31 December 2014 in England and Wales. The BCIS collects data on all PCI procedures in the UK. Data input on every case is mandated by the UK Good Practice guidelines and is a specified responsibility of consultant operators as part of their revalidation by the General Medical Council. The data collection is coordinated by the National Institute of Cardiovascular Outcomes Research (NICOR) via a centralized electronic database. The BCIS-NICOR registry comprises 113 variables, including clinical variables, procedural parameters, and patient outcomes. The dataset's quality has been recently described in detail [36]. Mortality tracking was undertaken by NHS Digital linkage to Office for National Statistics mortality records, using the NHS number that provides a unique identifier for any person registered with the NHS in England and Wales. Because it is a legal requirement for all deaths in the UK to be registered, these life status data are considered robust.

2.1. Study population and variables

Our analysis included elective cases, for patients with stable angina, aged between 18 and 100 years old, and who underwent uncomplicated LMS PCI (PCI procedures that did not sustain an in-hospital complication) at an NHS centre in England and Wales. These elective cases are considered to be potentially eligible for SDD. Cases with missing discharge status, age, sex, or mortality data were excluded from the analysis. LMS PCI was defined as any PCI case, where the left main lesion was attempted (either on its own or with other lesions). Protected LMS are defined as a patient with a graft to either the left anterior descending artery or the left circumflex. Severity of LMS lesion prior the procedure is defined as stenosis >75%. Penetration catheters refer to either use of a Tornus or a Corsair catheter.

The analysis was adjusted for information of demographics, structural cardiac and procedural characteristics, medication and access site (Supplementary Table 1). Additionally, the Strategic Health Authorities (SHAs), which were organizations responsible for providing local health services, now reorganised into NHS Regions, and calendar year were considered in the analysis to explore geographic differences in practice over time.

2.2. Data analysis

In our population, 30 variables had missing values, with the highest percentage of incompleteness being 37.4% for left ventricular ejection fraction (LVEF). We used multiple imputation by chained equations (MICE) to impute missing values, creating 10 imputed datasets. Studies

over the performance of multiple imputation techniques have shown that such approaches perform well, even for variables with up to 80% missing values [37]. Each of the imputation models included all the other variables used in our analyses (Supplementary Table 1), including all considered outcomes. The imputation models were logistic regression for binary variables, multinomial for nominal variables, ordinal logistic regression for ordered factors and linear regression for continuous variables. Subsequently, the missing values were replaced by values drawn from the posterior distributions plus a random error [38,39]. Each finalized imputed dataset was evaluated for its consistency with the original through summary statistics and assessment of convergence. All subsequent analyses were performed in each imputed dataset individually, the results of which were then pooled according to Rubin's rules [40].

2.3. Statistical analysis

We used the unimputed data to produce graphs to display LMS prevalence over time (from 2007 to 2014) within the elective cohort. Similarly, we graphically displayed SDD change over time within the LMS. We also created spatial maps to depict temporal changes of SDD prevalence within the LMS cohort regionally in England and Wales. We investigated the temporal changes of all the variables that were included in the analysis within the SDD and the ON stay cohorts separately. At the same time, we fitted an appropriate regression model for each available variable (i.e. linear model for continuous, logistic for binary, multinomial logistic for nominals and ordinal logistic for ordered variables), to examine for differences in the distributional changes over time between the two cohorts.

Next, using the imputed data, we fitted a multiple logistic regression model with indication of SDD as the outcome and with all variables of interest, plus the year of the procedure, as covariates to examine the variables independent associations with SDD. For any groups of variables that resulted in multicollinearity, these variables were grouped together; Variance Inflation Factors (VIFs) were estimated to ensure there was no multicollinearity in the final model.

We also observed the changes of 30 day mortality rates for the SDD and the ON stay cohorts separately and compared them to the expected mortality values estimated via the BCIS risk model [35], a well validated model published in 2016. We manually estimated the observed and expected mortality risks in each of the imputed datasets and pooled them to the mean to obtain single estimations. We fitted a multiple logistic regression to assess whether SDD was independently associated with observed 30 day mortality after controlling for all other available variables.

Finally, as sensitivity analyses, we followed the same approach outlined above, but: a) focused on unprotected LMS only cases; and b) included complicated ON stay cases. Complication records are displayed in Supplementary Table 2; in short, these refer to patients that sustained any type of procedural, arterial or bleeding complications *peri* or *post* procedural, or presented adverse hospital outcomes.

We used the statistical software Stata version 15 and an alpha level of 5% all through the data analysis.

3. Results

Following all the exclusion criteria as presented in Fig. 1, our dataset included 6452 LMS PCI cases, of which 3594 underwent unprotected LMS PCI. In total we found records of 339 incidences of peri- or post-procedural complications (Supplementary Table 2), while 309 (4.6% of all elective LMS PCI) patients experienced at least one adverse episode. These patients were excluded from our finalized dataset and were only included within the sensitivity analysis.

We observed an increase of elective LMS PCI cases over time from 2.9% in 2007 to 5% in 2014, with unprotected LMS increasing from 2% in 2007 to 3.6% in 2014 (Fig. 2). SDD practice has increased to a similar extent within the two groups, from 19.9% in 2007 to 39.8% in 2014 for all

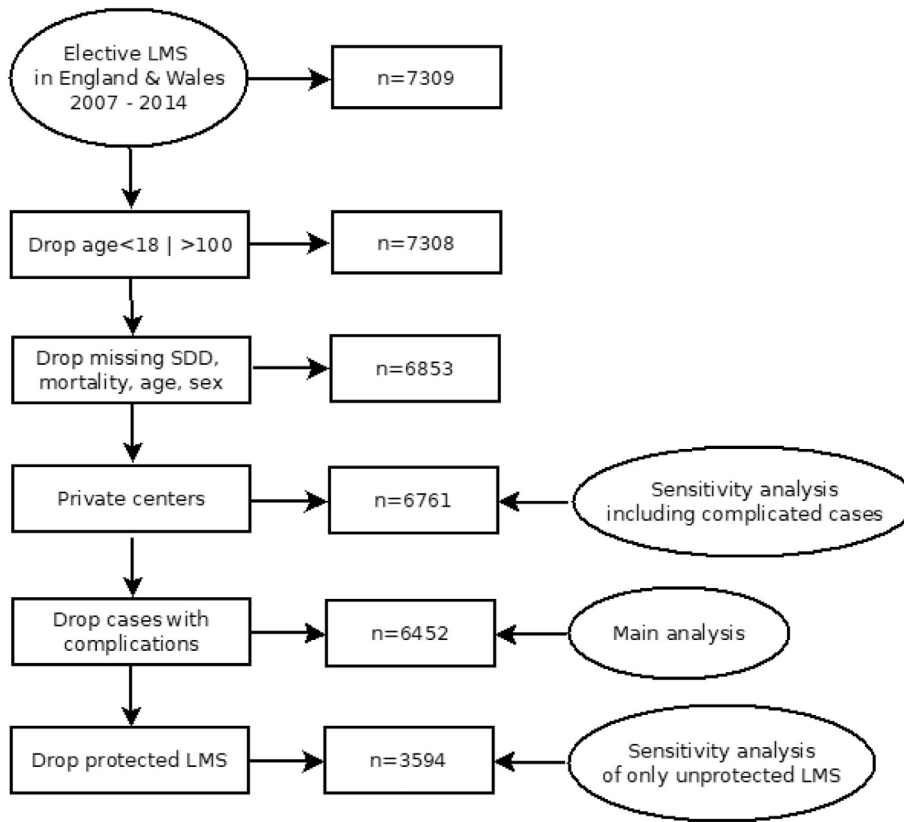


Fig. 1. Flow chart of inclusion/exclusion criteria.

the LMS cases and from 20.7% to 41.4% for unprotected LMS cases (Fig. 3). Fig. 4 and Supplementary Fig. 1 display the temporal changes and the variation of SDD practice across different regions in England and Wales for the two groups.

3.1. Clinical characteristics

Table 1 shows the temporal distributional changes of each characteristic within the SDD and ON stay cohorts, for all the LMS cases. The

prevalence of females decreased over time in the SDD cohorts, while increased for males. The average age was consistently lower in the SDD cohort but increased over time in both cohorts, from 66 years old in 2007 to 68.7 in 2014 for the SDD group and from 67.4 to 69.8 for the ON stay cases, respectively. Significant medical history and comorbidity burden were consistently lower for the SDD cases, including hypertension, peripheral vascular disease, diabetes, renal disease, poor LVEF and valvular heart disease. Over the same period, there was an upward trend of SDD patients with valvular heart disease (from 0.9% in 2007 to 5.3% in 2014), peripheral vascular disease (from 2.7% to 5.0%), previous

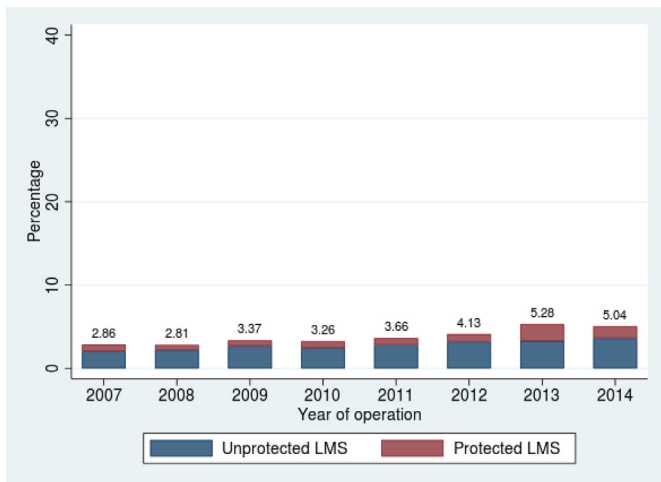


Fig. 2. Percentage of protected, unprotected, and overall left main cases observed within the elective PCI cohort. *The cumulative prevalence of protected and unprotected left main represents the overall prevalence of left main cases within the elective PCI cohort and is displayed on top of each bar.

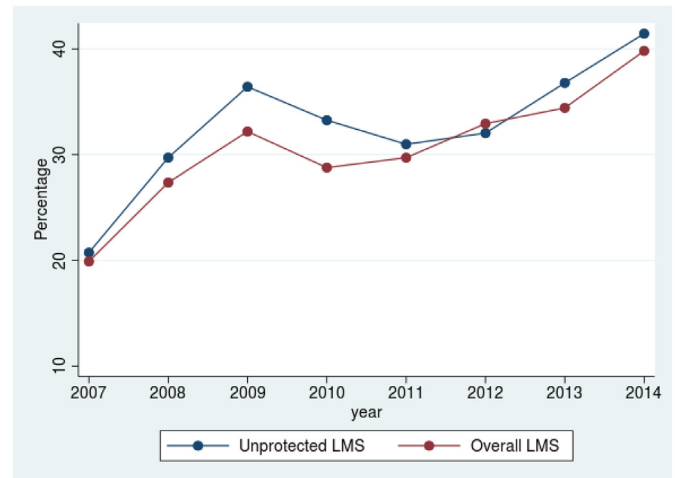


Fig. 3. Percentage of overall and unprotected left main (elective) cases that were same day discharged.

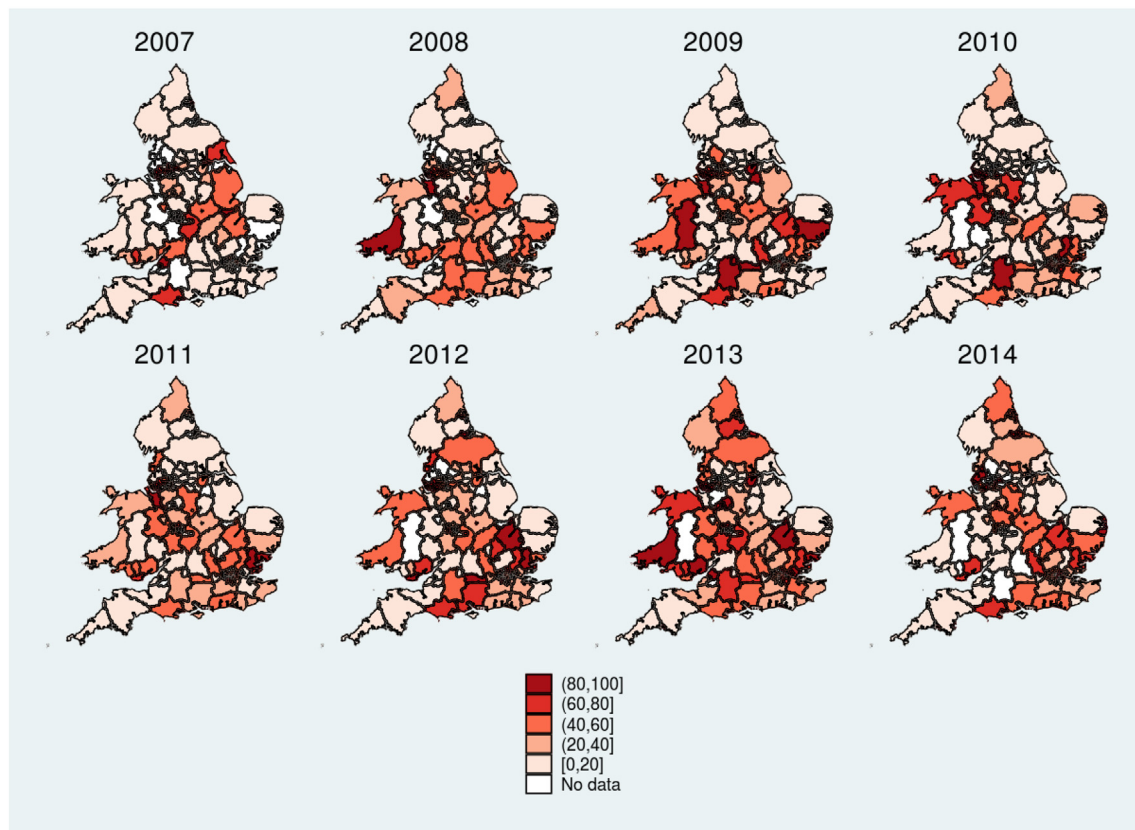


Fig. 4. Spatial maps of prevalence of SDD in the overall left main cohort over time in England and Wales. *The more red coloured a region the higher SDD practice. **The PCT's are defined based on the patient's address postcode.

stroke (from 2.7% to 5.6%), hypertension (from 52.3% to 66.8%) and severe pre-PCI LMS stenosis (from 30.5% to 48.1%). Further, the proportion of cases with poor LVEF increased from 2.4% in 2007 to 4.9% in 2014, as did diabetes from 21% in 2007 to 28% in 2014 and renal dialysis disease from 0% to 0.7%. Similar patterns were observed for the unprotected LMS cases (Supplementary Table 3) and when complicated ON cases were included (Supplementary Table 5).

3.2. Procedural characteristics

Over time, we observed significant changes in the procedural characteristics for the overall LMS cohort, particularly in the SDD group, suggesting that SDD were increasingly complex. Rotational atherectomy was increasingly used over time, from 1.1% in 2007 to 6.4% in 2014, although its use was consistently lower compared to the ON, which ranged from 7.6% to 13.8%, respectively. Intravascular imaging use also increased for both the SDD and ON stay cohorts (from 28.9% to 35.9 and from 22.6% to 37%, respectively), as did the use of longer stents (from 20.5 to 30.2 mm and from 22.2 to 29.3 mm, respectively). Multivessel PCI was increasingly attempted in the SDD cases, from 38.4% in 2007 to 61.6% in 2014, which applies for the cases that underwent LMS PCI and one or more vessels were also attempted, while use of penetration catheters increased from 0% to 1.4%. Adoption of radial access was more frequent over time in the SDD cohort (from 24.1% to 58.3%) compared to the ON stay (from 17.8% to 51%). Finally, we found that increasing numbers of patients were receiving warfarin in both cohorts (from 2% to 3.6% and from 1.3% to 3.3% for SDD and ON cases respectively), whereas the use of glycoprotein IIb/IIIa inhibitor sharply decreased, from 13.7% to 2.4% and from 28.4% to 7.1% for SDD and ON admitted cases respectively. Similar patterns were observed for the unprotected LMS cases

(Supplementary Table 4) and when complicated ON cases were included (Supplementary Table 6).

3.3. Independent factors associated with SDD

Table 3 illustrate the independent predictors of SDD within the overall LMS cohort. Older patients were significantly less likely to be discharged (OR = 0.99 per one year of age, 95% CI 0.98–0.99), as were females (OR = 0.85, 95% CI 0.74–0.98). Overall, LMS patients receiving glycoprotein IIb/IIIa inhibitor had significantly lower rates of SDD (OR = 0.24, 95% CI 0.19–0.31), as in those in whom a penetration catheter was used (OR = 0.23, 95% CI 0.12–0.45). Renal disease, use of rotational atherectomy and prior peripheral vascular disease were also independently associated with ON, with OR = 0.37 (95% CI 0.24 to 0.57), OR = 0.51 (95% CI 0.40 to 0.66), and (OR = 0.68, 95% CI 0.54–0.86) for SDD, respectively. Transradial PCI had the largest independent association with SDD, with OR = 1.76 (95% CI 1.55 to 2.00), followed by offsite surgical cover, with OR = 1.31 (95% CI 1.11 to 1.54). Finally, SDD frequency has increased significantly over time, with OR = 1.09 (95% CI 1.06 to 1.12), after case-mix adjustment.

Results of the independent associations with SDD for the unprotected LMS are displayed in Supplementary Table 7. Similar to the overall LMS cohort, older patients that underwent unprotected LMS PCI were less likely to be SDD, with OR = 0.99 per one year of age (95% CI 0.98–0.99). Glycoprotein IIb/IIIa inhibitors and use of penetration catheters were the largest independent associations with ON, with OR = 0.25 (95% CI 0.19–0.34) and OR = 0.25 (95% CI 0.10–0.62) for SDD respectively. As for overall LMS, renal disease, use of rotational atherectomy and prior peripheral vascular disease were also independently associated to ON stay within the unprotected LMS cases. SDD was

Table 1
Pre-procedural characteristics of the overall Left Main cases over time; p-value(p) tests the difference of the characteristic's distributional change over time between SDD and ON^a.

		2007	2008	2009	2010	2011	2012	2013	2014	p
Size, n	SDD	112	194	252	210	246	300	400	305	
	uncON	451	515	531	520	582	611	762	461	
Age in years, Mean (SD)	SDD	66.0 (9.9)	65.8 (9.9)	66.6 (10.5)	67.0 (9.6)	67.6 (9.5)	68.7 (10.1)	67.8 (9.9)	68.7 (10.0)	0.2
	uncON	67.4 (10.2)	68.5 (10.6)	69.7 (10.9)	68.9 (10.7)	69.5 (10.0)	70.3 (10.6)	69.2 (10.5)	69.8 (10.3)	
Gender	SDD	72.3	76.3	74.6	81.9	83.3	80.3	84.0	79.3	0.02
	uncON	80.0	79.0	77.0	73.8	76.8	76.4	79.4	78.7	
Female	SDD	27.7	23.7	25.4	18.1	16.7	19.7	16.0	20.7	
	uncON	20.0	21.0	23.0	26.2	23.2	23.6	20.6	21.3	
Ethnicity	SDD	82.6	77.7	83.9	86.7	85.9	87.7	84.3	83.6	0.13
	uncON	87.7	82.7	89.3	89.9	89.6	86.5	84.8	85.1	
Other	SDD	17.4	22.3	16.1	13.3	14.1	12.3	15.7	16.4	
	uncON	17.4	17.3	10.7	10.1	10.4	13.5	15.2	14.9	
Medical history	SDD	46.1	42.3	34.5	33.7	46.6	41.7	39.1	46.0	0.4
	uncON	46.5	45.8	43.9	41.8	44.6	41.7	47.9	45.0	
Previous CABG	SDD	58.9	47.5	41.0	40.6	42.8	44.6	51.0	47.7	0.14
	uncON	60.2	51.7	51.3	49.9	46.3	39.5	57.0	50.4	
Previous PCI	SDD	39.4	31.6	33.7	38.5	32.2	33.1	41.9	42.5	0.63
	uncON	30.0	32.5	32.4	36.0	35.9	34.0	42.0	39.8	
Hypercholesterolemia	SDD	66.7	63.7	68.5	70.5	69.1	61.3	63.6	66.1	0.13
	uncON	63.9	66.7	71.2	69.7	66.9	67.1	71.5	67.2	
Hypertension	SDD	52.3	54.9	63.3	72.9	68.3	66.3	66.4	66.8	0.19
	uncON	52.7	60.9	67.9	67.1	68.8	73.7	69.5	71.4	
Peripheral vascular disease	SDD	2.7	4.1	5.2	6.2	7.8	5.7	7.5	5.0	0.67
	uncON	8.0	6.9	10.4	9.2	9.2	10.1	9.1	11.0	
Q wave on ECG	SDD	13.8	8.4	7.2	12.4	8.6	11.7	9.7	8.2	0.02
	uncON	17.3	18.5	14.0	15.7	9.8	9.9	11.3	8.3	
Previous stroke	SDD	2.7	2.6	4.4	4.3	9.5	5.0	5.4	5.6	0.15
	uncON	4.1	5.4	6.8	4.8	5.9	5.0	4.0	6.6	
Diabetes	SDD	21.0	22.2	22.6	23.6	25.1	23.4	28.0	28.0	0.62
	uncON	21.3	29.1	25.9	21.3	27.4	24.4	29.5	30.8	
Renal disease	SDD	98.2	98.5	98.8	99.0	99.6	99.0	98.7	97.7	0.89
	uncON	98.0	94.9	95.4	96.1	96.3	96.1	95.9	95.6	
High creatinine (>200 μmol/l – no dialysis)	SDD	1.8	1.0	0.8	0.5	0.4	0.7	0.8	1.6	
	uncON	1.8	4.1	3.6	2.7	2.6	2.5	2.5	2.6	
Dialysis	SDD	0.0	0.5	0.4	0.5	0.0	0.3	0.5	0.7	
	uncON	0.2	1.0	1.0	1.2	1.0	1.3	1.6	1.7	
Smoking	SDD	64.7	57.0	50.9	53.5	53.7	49.8	53.1	53.6	0.64
	uncON	59.8	56.9	56.9	54.9	53.0	56.2	49.9	51.6	
Current smoker	SDD	9.4	8.7	8.5	9.6	10.4	10.8	9.5	8.2	
	uncON	8.7	8.0	9.1	7.6	8.9	6.5	8.2	8.5	
Never smoked	SDD	25.9	34.3	40.6	36.9	35.9	39.4	37.4	38.2	
	uncON	31.5	35.1	33.9	37.5	38.1	37.2	41.9	39.9	
LVEF	SDD	68.3	67.6	76.5	80.8	74.4	72.6	74.1	73.2	0.38
	uncON	72.0	66.2	65.3	68.6	72.6	68.7	70.6	76.2	
Moderate (LVEF 30–50%)	SDD	29.3	27.9	18.8	15.1	22.2	21.4	21.5	22.0	
	uncON	21.3	22.9	27.6	24	21.1	25.1	23.3	17.9	
Poor (LVEF <30%)	SDD	2.4	4.5	4.7	4.1	3.4	6.0	4.4	4.9	
	uncON	6.6	10.9	7.1	7.4	6.2	6.3	6.1	6.0	
Multi-vessel disease	SDD	34.9	39.3	44	52.7	55.5	55.9	51.0	51.7	0.03
	uncON	55.0	57.7	56.6	54.6	54.5	62.6	55.3	61.5	
Valvular heart disease	SDD	0.9	1.0	1.6	2.4	3.3	2.7	2.3	5.3	0.69
	uncON	1.1	1.6	3.2	4.4	4.4	5.6	4.6	5.7	
Severe LMS stenosis pre-PCI	SDD	30.5	30.1	37.0	41.6	48.5	46.5	40.9	48.1	<0.001
	uncON	54.4	51.7	59.4	57.9	58.3	59.9	43.8	52.0	

^a CABG = Coronary Artery Bypass Graft; ECG = Electrocardiogram; LVEF = Left ventricular ejection fraction; LMS = Left Main Stem; MI = Myocardial infarction; PCI= Percutaneous Coronary Intervention; SD = Standard Deviation; SDD = Same Day Discharge; uncON = uncomplicated Overnight stay.

more common in those patients in whom PCI was performed transradially PCI, OR = 1.80 (95% CI 1.51–2.14). SDD practice for the unprotected LMS also increased over calendar time, after adjustment for case-mix (OR = 1.10, 95% CI 1.05–1.14).

Supplementary Table 8 displays the results of this analysis when including the complicated ON cases, where no meaningful differences were observed compared to the main analysis. Supplementary Table 2 displays in detail the types of complications and the number of patients.

3.4. Mortality outcomes

Within the overall LMS cohort, mortality rates at 30 days post procedure were lower in the SDD cohort compared to uncomplicated ON cases, for all study years except 2008, and overall increased over time from 0% in 2007 to 0.7% in 2014 (Table 2). Supplementary Fig. 2 shows a Kaplan Meier graph of the the day of death following the procedure for SDD and ON. Out of nine 30 day mortality cases that were SDD, the time of death recorded was after three days of the procedure for eight patients and at the first day following the procedure for one patient. A slow increase was also observed in 30 day mortality for the uncomplicated ON cases, from 0.9% in 2007 to 1.1% in 2014.

Fig. 5 illustrates temporal changes of the observed 30 day mortality of the SDD, the uncomplicated ON stay and all the cases combined, as well as the expected 30 day mortality calculated via the BCIS risk prediction model, for the overall LMS cohort. The observed increase of the 30 day mortality for the SDD was in line with expected mortality, similar to that observed in the ON cases. The large variation in the observed

30 day mortality rate is due to the low numbers of deaths. Similar trends were found in the unprotected LMS and overall LMS cohort including the complicated ON cohorts, compared to the overall LMS, with increases in the observed 30 day mortality rates which were in line with what was predicted from the BCIS model (Supplementary Figs. 3 and 4).

SDD was not independently associated with 30 day mortality for the overall LMS cohort, after a case-mix adjustment, with OR = 0.72 (95% CI 0.31–1.71, P = .459) (Table 4). Results were similar for the unprotected LMS and the overall LMS including complicated ON cases, with OR = 0.48 (95% CI 0.17–1.41, P = .185) and OR = 0.58 (95% CI 0.25–1.34, P = .206), respectively (Supplementary Tables 9 and 10).

4. Discussion

This paper presents the first study to examine the adoption of SDD in patients that underwent elective left main PCI and its relationship to complexity from a healthcare system where SDD is currently the standard of care in elective PCI [32]. We show that the prevalence of SDD

Table 2

Procedural characteristics of the overall Left Main cases over time; p-value(p) tests the difference of the characteristic's distributional change over time between SDD and ON^a.

		2007	2008	2009	2010	2011	2012	2013	2014	p
Medication received										
	Warfarin	SDD 2.0	0.5	0.8	1.5	0.9	1.4	2.8	3.6	0.21
	uncON	1.3	1.7	2.4	1.4	1.8	2.2	2.6	3.3	
Bivalirudin	SDD	0.0	0.0	0.0	0.0	0.9	0.4	0.3	0.0	0.87
	uncON	2.1	0.0	0.0	0.2	1.4	1.7	1.8	0.5	
Clopidogrel	SDD	100.0	100.0	100.0	100.0	100.0	95.7	95.1	92.9	0.4
	uncON	99.7	100.0	99.5	99.3	98.5	94.7	92.9	90.0	
GP IIb/IIIa inhibitor	SDD	13.7	9.5	7.1	4.5	2.2	3.8	2.0	2.4	0.33
	uncON	28.4	25.7	21.6	15.2	12.1	13.5	8.1	7.1	
Offsite surgical cover	SDD	25.3	32.5	42.1	38.4	41.2	46.2	33.5	33.7	0.01
	uncON	14.7	24.4	24.8	33.8	31.9	31.9	26.4	33.0	
Ad hoc PCI	SDD	15.8	18.6	17.5	14.5	16.0	22.3	23.4	26.2	0.35
	uncON	15.5	20.8	23.1	23.5	28.2	24.4	27.4	23.7	
Multi-vessel attempted	SDD	38.4	47.4	66.7	71.9	68.7	68.7	57.8	61.6	<0.001
	uncON	61.0	64.3	62.9	64.2	64.9	70.0	51.6	62.5	
Stents use										
	No stents	SDD 27.4	22.9	18.0	16.6	13.4	11.7	13.6	6.5	<0.001
	uncON	7.1	5.7	5.0	6.3	8.1	5.4	6.3	4.7	
BMS only	SDD	24.2	18.4	8.3	3.6	7.1	4.2	4.3	2.1	
	uncON	20.8	17.2	17.7	11.3	10.1	8.4	3.1	2.7	
DES only	SDD	41.1	50.8	66.7	76.2	75.2	77.4	77.9	90.0	
	uncON	60.6	67.1	70.1	77.3	77.9	82.8	86.0	88.9	
Both	SDD	7.4	7.8	7.0	3.6	4.2	6.7	4.3	1.4	
	uncON	11.5	9.9	7.2	5.1	3.9	3.4	4.6	3.8	
Largest stent in mm, Mean (SD)	SDD	3.4	3.6	3.8	3.8	3.8	3.8	3.9	3.9	0.02
	uncON	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.7)	(0.7)	(0.6)	
Longest stent in mm, Mean (SD)	SDD	3.7	3.8	3.9	4.0	3.9	3.9	3.8	3.9	
	uncON	(0.6)	(0.6)	(0.7)	(0.7)	(0.6)	(0.6)	(0.7)	(0.7)	
Rotational atherectomy	SDD	20.5	26.9	29.1	28.4	25.8	28	28.1	30.2	0.02
	uncON	(13.1)	(16.0)	(19.4)	(19.2)	(18.0)	(17.0)	(18.9)	(19.5)	
Intravascular imaging	SDD	22.2	23.8	23.3	24.8	27.2	28.4	28.6	29.3	
	uncON	(11.2)	(13.4)	(14.4)	(15.7)	(18.6)	(18.2)	(18.6)	(17.9)	
Penetration catheter	SDD	1.1	1.7	4.2	4.4	3.5	6.6	6.8	6.4	0.07
	uncON	7.6	9.1	9.2	9.8	12.8	12.1	10.8	13.8	
Access site	SDD	28.9	36.9	41.1	43.1	40.7	38.6	34.6	35.9	<0.001
	uncON	22.6	23.6	29.5	37.8	40.9	42.7	34.3	37	
Femoral only	SDD	0.0	0.0	0.0	0.0	0.4	0.3	1.0	1.4	0.96
	uncON	0.0	0.0	0.2	0.2	1.7	1.6	4.3	5.7	
Radial only	SDD	74.1	61.6	59.0	49.0	40.1	36.6	35.5	38.4	0.49
	uncON	81.8	78.8	71.9	65.0	60.0	56.1	50.7	45.3	
Multiple/Other	SDD	24.1	38.4	40.2	47.6	57.4	60.3	61.7	58.3	
	uncON	17.5	20.4	26.7	32.3	36.2	41.3	45.1	51	
Mortality 30 day	SDD	1.9	0.0	0.8	3.4	2.5	3.1	2.8	3.3	
	uncON	0.7	0.8	1.3	2.7	3.8	2.6	4.2	3.7	0.52
	SDD	0.0	1.5	0.4	0.0	0.4	0.3	0.2	0.7	
	uncON	0.9	0.6	0.8	0.0	0.7	0.7	0.7	1.1	

^a BMS=Bare metal stent; DES = Drug-eluting stent; GP = Glycoprotein; LMS = Left Main Stem; PCI= Percutaneous Coronary Intervention; SD = Standard Deviation; SHA = Strategic Health Authorities; SDD = Same Day Discharge; uncON = uncomplicated Overnight stay.

Table 3

Multivariable logistic regression (with adjusted ORs) on the overall Left Main SDD cases. An OR < 1 implies decreased odds of SDD^a.

	OR for SDD vs unCON	[95% CI]	P > t
Age per year	0.99	[0.98–0.99]	<0.001
Female	0.85	[0.74–0.98]	0.030
Caucasian	0.82	[0.68–1.00]	0.05
Medical history			
Previous MI	0.93	[0.81–1.07]	0.306
Previous CABG	0.97	[0.83–1.12]	0.669
Previous PCI	1.00	[0.88–1.13]	0.949
High cholesterol	0.95	[0.83–1.08]	0.427
Hypertension	0.94	[0.83–1.07]	0.392
Peripheral vascular disease	0.68	[0.54–0.86]	0.002
Q Wave on ECG	0.86	[0.69–1.06]	0.154
Previous stroke	1.18	[0.91–1.54]	0.220
Diabetes	0.96	[0.84–1.11]	0.596
Renal disease	0.37	[0.24–0.57]	<0.001
Smoking			
Never	Ref.		
Ex-smoker	1.05	[0.91–1.22]	0.482
Current smoker	1.14	[0.91–1.43]	0.260
LVEF			
Good	Ref.		
Moderate	0.95	[0.80–1.13]	0.562
(LVEF 30–50%)			
Poor	0.85	[0.62–1.15]	0.290
(LVEF<30%)			
MVL disease	1.03	[0.89–1.20]	0.684
Valvular heart disease	0.78	[0.56–1.09]	0.149
Severe LMS stenosis pre-PCI	0.73	[0.63–0.84]	<0.001
Medication received			
Warfarin	0.86	[0.54–1.36]	0.515
Bivalirudin	0.43	[0.14–1.31]	0.138
Clopidogrel	1.43	[0.99–2.07]	0.056
GP inhibitor	0.24	[0.19–0.31]	<0.001
Offsite surgical cover	1.31	[1.11–1.54]	0.001
Ad hoc PCI	0.76	[0.65–0.89]	<0.001
MVL attempted	1.10	[0.95–1.26]	0.192
Stent use			
No stent	Ref.		
BMS only	0.45	[0.33–0.60]	<0.001
DES only	0.45	[0.37–0.56]	<0.001
Both	0.43	[0.31–0.60]	<0.001
Largest stent (mm)	0.80	[0.71–0.90]	<0.001
Longest stent (mm)	1.00	[0.99–1.00]	0.845
Rotational atherectomy	0.51	[0.40–0.66]	<0.001
Intravascular imaging	0.97	[0.85–1.12]	0.765
Penetration catheter	0.23	[0.12–0.45]	<0.001
Access site			
Femoral	Ref.		
Radial	1.76	[1.55–2.00]	<0.001
Multiple/Other	1.00	[0.69–1.46]	0.984
Year	1.09	[1.06–1.12]	<0.001
SHA			
London	Ref.		
North East	1.25	[0.92–1.68]	0.148
North West	1.67	[1.27–2.18]	<0.001
Yorkshire and the Humber	0.50	[0.37–0.68]	<0.001
East Midlands	1.42	[1.11–1.81]	0.005
West Midlands	0.86	[0.65–1.13]	0.274
East of England	0.97	[0.75–1.27]	0.839
South East Coast	1.02	[0.78–1.33]	0.891
South Central	1.17	[0.89–1.54]	0.246
South West	1.64	[1.26–2.13]	<0.001
Wales	2.43	[1.78–3.31]	<0.001

^a BMS=Bare metal stent; CABG = Coronary Artery Bypass Graft; CI=Confidence Interval; DES = Drug-eluting stent; ECG = Electrocardiogram; GP = Glycoprotein; LVEF = Left ventricular ejection fraction; LMS = Left Main Stem; MI = Myocardial infarction; MVL = Multivessel; ON=Overnight stay; OR = Odds Ratio; PCI=Percutaneous Coronary Intervention; SDD = Same Day Discharge; SHA = Strategic Health Authorities.

Table 4

Multivariable logistic regression (with adjusted ORs) on 30 days mortality for the overall left main cases^{a,b}.

	OR	[95% CI]	P > t
SDD	0.70	[0.30–1.65]	0.417
Age per year	1.01	[0.98–1.05]	0.456
Female	0.70	[0.28–1.76]	0.451
Caucasian	0.54	[0.18–1.57]	0.257
Medical History			
Previous MI	1.74	[0.79–3.86]	0.170
Previous CABG	0.20	[0.08–0.48]	<0.001
Previous PCI	0.73	[0.34–1.56]	0.416
High Cholesterol	3.10	[1.12–8.56]	0.029
Hypertension	1.15	[0.50–2.68]	0.741
Peripheral Vascular Disease	0.82	[0.26–2.61]	0.739
Q Wave on ECG	1.02	[0.36–2.86]	0.975
Previous Stroke	1.57	[0.42–5.87]	0.501
Diabetes	1.72	[0.82–3.58]	0.150
Renal Disease	2.33	[0.71–7.69]	0.165
Smoking			
Never	Ref.		
Ex-smoker	1.18	[0.53–2.63]	0.687
Current smoker	1.16	[0.32–4.19]	0.825
LVEF			
Good	Ref.		
Moderate	1.50	[0.60–3.74]	0.380
(LVEF 30–50%)			
Poor	2.62	[0.80–8.51]	0.109
(LVEF<30%)			
MVL	4.13	[1.53–11.15]	0.005
Severe LMS stenosis pre-PCI	1.14	[0.52–2.48]	0.742
Medication received			
Warfarin	1.77	[0.20–15.50]	0.604
Bivalirudin	14.29	[2.54–80.48]	0.003
GP inhibitor	1.60	[0.63–4.07]	0.326
Offsite surgical cover	1.28	[0.54–3.02]	0.575
Ad hoc PCI	0.48	[0.18–1.33]	0.158
MVL attempted	0.69	[0.29–1.64]	0.399
Stent use			
No stent	Ref.		
BMS only	0.93	[0.12–7.44]	0.948
DES only	1.30	[0.28–6.09]	0.736
Both	3.98	[0.70–22.64]	0.120
Largest stent (mm)	0.48	[0.25–0.91]	0.026
Longest stent (mm)	0.99	[0.97–1.02]	0.515
Rotational atherectomy	0.94	[0.29–3.05]	0.912
Intravascular imaging	1.22	[0.56–2.69]	0.619
Penetration catheter	1.10	[0.10–11.46]	0.937
Access site			
Femoral	Ref.		
Radial	0.82	[0.6–1.84]	0.631
Multiple/Other	0.40	[0.04–4.28]	0.449
Year	1.07	[0.90–1.27]	0.448
SHA			
London	Ref.		
North East	2.27	[0.21–7.47]	0.792
North West	1.44	[0.31–6.70]	0.638
Yorkshire and the Humber	0.19	[0.02–1.82]	0.149
East Midlands	1.54	[0.42–5.61]	0.512
West Midlands	0.50	[0.09–2.75]	0.426
East of England	1.32	[0.35–4.98]	0.684
South East Coast	1.00	–	–
South Central	1.43	[0.36–5.71]	0.615
South West	0.42	[0.07–2.56]	0.351
Wales	2.79	[0.83–9.42]	0.098

^a Clopidogrel use and Valvular heart disease were excluded from the analysis because of perfect prediction due to the low counts of mortality.

^b BMS=Bare metal stent; CABG = Coronary Artery Bypass Graft; CI=Confidence Interval; DES = Drug-eluting stent; ECG = Electrocardiogram; GP = Glycoprotein; LVEF = Left ventricular ejection fraction; LMS = Left Main Stem; MI = Myocardial infarction; MVL = Multivessel; ON=Overnight stay; OR = Odds Ratio; PCI=Percutaneous Coronary Intervention; SDD = Same Day Discharge; SHA = Strategic Health Authorities.

for the LMS PCI has increased from 20% to 39% over our study period, although ON monitoring still remains the most common model of treatment for elective LMS PCI cases. Our analysis suggests that LMS PCI SDD cases are increasingly complex, increasingly undertaken in older

patients, who were increasingly comorbid and with increasingly complex disease patterns such those that underwent PCI with rotational atherectomy use or with multi-vessel PCI. In spite of more complex

LMS PCI cases increasingly being undertaken as SDD cases, 30 day mortality rates were in line with those estimated by the national risk score prediction model suggesting that SDD is not inferior to ON stay in higher risk cases that underwent LMS PCI. Finally, our analysis suggests significant regional heterogeneity of SDD adoption for LMS-PCI, which strengthens the need for national guidelines.

Previous studies examining the safety of SDD after PCI have excluded (unprotected) LMS cases or have actively included them in the criteria for hospital admission [5,25–30]. In studies in which LMS PCI was not a formal exclusion criterion, only small numbers of LMS PCI as SDD were undertaken [2–4,9,12,32,41], which makes studying outcomes in this cohort of patients challenging. In the present analysis we observed a 2-fold increase in the adoption of SDD for elective LMS PCI and at the same time we observed increasingly comorbid patients treated as SDD, characterised by the greater prevalence of poor left ventricular function, valvular heart disease and comorbidities, such as diabetes, peripheral vascular disease, previous stroke, hypertension and renal dysfunction. The complexity cases also increased over time in the SDD group, i.e. use of rotational atherectomy or penetration catheters and multiple attempted vessels, suggesting that operators feel more comfortable of discharging cases of higher risk on the same day. Our data demonstrate that factors such as old age, female gender, peripheral vascular disease, renal impairment, use of glycoprotein IIb/IIIa inhibitor, rotational atherectomy, penetration catheters, and multivessel PCI are independently associated with ON observation. Previous studies have shown an independent association of many of these clinical and procedural features, in addition to LMS, with death and major adverse cardiac events, and contemporary PCI risk scores include them as risk factors [35,42–45].

Our study results show that the transradial access site was increasingly used for LMS SDD PCI, and was the strongest independent predictor of SDD, after adjustment of patient case-mix. This is consistent with our recent study that examined access site practice for LMS PCI which showed that transradial PCI was associated with shorter length of stay and reduced in-hospital complications [23].

Patients with LMS disease are at higher risk for adverse clinical outcomes compared with patients undergoing PCI to other areas of the coronary circulation because anticipation of serious complications is high and admission to ON observation is commonly practised. The EXCEL

randomised controlled trial reported 4.9% major adverse cardiac or cerebrovascular events (MACCE), including death, stroke or myocardial infarction, at 30 days [46]. A similar RCT focusing on unprotected LMS, reported 0.02% MACCE events at 30 days, including death, non-procedural MI, repeat revascularisation and stroke [47]. To examine the safety of SDD in LMS diseased patients after PCI, we compared the observed 30 day mortality for both SDD and ON stay with predicted values of 30 day mortality, which were calculated from the BCIS mortality risk model –a risk adjustment model used for national public reporting of PCI outcomes. With this method we added an analysis were direct comparison between SDD and ON was avoided, as higher risk cases, will always be more likely to involve ON stay, and a direct comparison between SDD and ON would therefore tend to favour outcomes associated with SDD. In addition, we have excluded cases with peri- or early post-procedural complications, since these cases are, by default, admitted to ON observation, and early complications are highly associated with post-discharge major adverse events [48–50]. Our data show that the observed 30 day mortality rates for SDD were in line with those predicted from the BCIS model, even though the risk profile of the SDD cases after elective LMS PCI has increased over time. These results show no evidence that SDD after LMS PCI is not safe or feasible for patients selected by the usual criteria. In addition, our data may suggest that even if SDD patients were admitted for overnight observation, this would not prevent the mortality outcome. Most of patients' mortality was recorded at 3 days following PCI, apart from one case where mortality was recorded at the first day following PCI and there is uncertainty of whether overnight stay would prevent that event due to lack of data regarding the exact timing of death (i.e. early in the morning or late at night).

A previously published study examining the variation of SDD practice following elective PCI among different healthcare systems and practitioners, showed that only 14% of cardiologists practiced SDD in the US, 32% in Canada and 57% in the UK. At that study, 2% of the US cardiologists and 11% of the non-US reported SDD for LMS PCI. However, 59% of all the practitioners included in the study were unaware of any official guidelines for SDD after elective PCI in general and, therefore, after elective LMS PCI in particular [51]. In 2009, SCAI published a document defining the appropriate length of stay after elective PCI stating that LMS

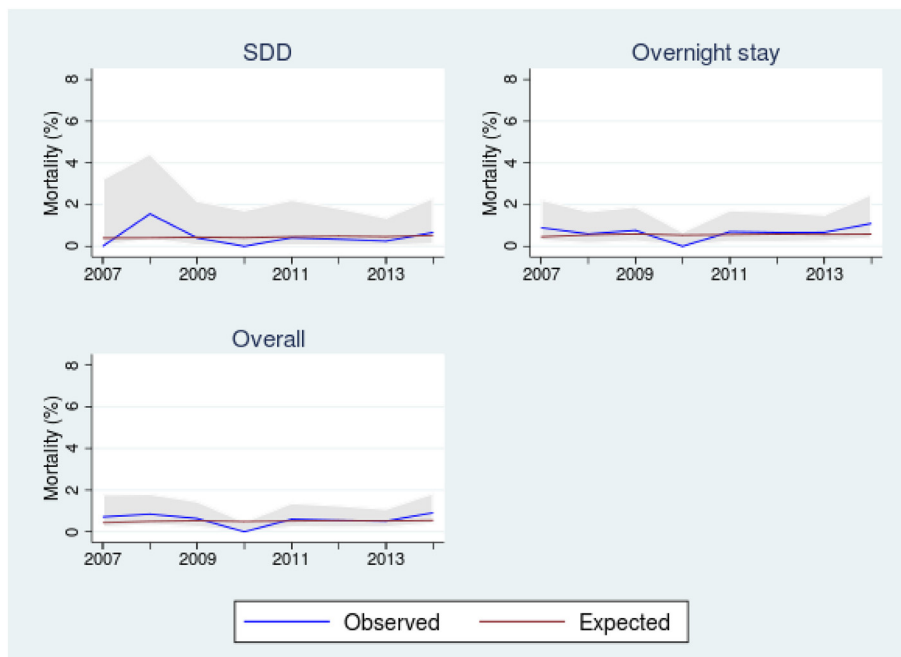


Fig. 5. Expected and observed (with 95% CI) 30 days mortality over time in the overall LMS cohort.

diseased cases should be always admitted for ON observation [31]. However, elective PCI has evolved to a safer procedure with less adverse outcomes driven by advancements in technology, medication and access site changes [52], and more recent guidelines about the length of stay or about LMS PCI provide no information about the appropriateness of SDD following elective PCI [33,34]. This lack of information results in uncertainty at the operator level which may explain the significant heterogeneity in adoption of LMS PCI SDD that we have observed. More detailed guidelines, informed by an evolving evidence basis, such as data presented in this analysis, are required, and are of even higher significance during the current era of the Covid-19 pandemic as SDD is equivalent to shortened length of stay in the hospital which subsequently provides: (i) less exposure of patients to the virus, and (ii) increased bed availability for the increased demand in the hospitals due to Covid-19.

The present study has several limitations. First, this is an observational study and patients were selected for SDD or ON stay based on operator's discretion. Our data do not provide insight on whether the decision for SDD was taken before the PCI procedure was undertaken (intention to treat) or if the operator's decision for SDD was altered due to peri-procedural complexity or emergence of complications during the observational period. Second, the present analysis also lacks information about the length of the post-PCI observational period, the time of day that the procedure was undertaken, patient preference, family preference, patient circumstance (living distance from the hospital and presence of a companion in case of complications), procedural concerns or other factors that are likely to inform a clinicians' decision for SDD. Similarly, our dataset does not include information about radial lounge monitoring, which has been found to be associated with increase in SDD, although no study has examined their association specifically for LMS PCI [53,54]. In addition we are uncertain how operators choose which patients are SDD or are kept in for ON monitoring, how much of it relates to lesion/procedural complexity and how much is informed by local practices/guidelines. Third, our dataset only captures 30 day mortality outcomes and lacks information on post-discharge complications, such as MI, stroke, target vessel revascularization, or unplanned readmissions which limits the safety endpoints we are able to study. Nevertheless, significant major complications post discharge in the SDD cohort would have been manifest with an increased mortality risk at 30 days that we have not observed. Furthermore, ON monitoring would only capture complications sustained in the first 24 h. Fourth, the limited number of deaths after SDD LMS-PCI did not allow us to examine which SDD patients' characteristics are associated with higher mortality risk and perhaps distinguish those patients for whom SDD is safe and feasible after elective LMS PCI. Finally, our analysis only includes data from 2007 to 2014 which raises questions about more contemporary practice of SDD in the elective LMS setting.

5. Conclusion

SDD following elective LMS PCI has become increasingly adopted in England and Wales, with increasingly complex cases undertaken over time, in elderly patients with more complex disease requiring rotational atherectomy, and with a greater prevalence of comorbidities, such as diabetes, previous stroke and peripheral vascular disease. Our analysis, found no evidence that SDD for LMS PCI is not safe in terms of 30 day mortality, and may help inform guidelines in this complex group of patients.

Author contributions

Dr. Taxiarchi had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Taxiarchi, Mamas.

Acquisition, analysis, or interpretation of data: Taxiarchi, Kontopantelis, Martin, Mamas.

Drafting of the manuscript: Taxiarchi, Mamas.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Taxiarchi, Martin, Kontopantelis.

Administrative, technical, or material support: Rashid, Mamas.

Study supervision: Kontopantelis, Mamas.

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Declaration of Competing Interest

All authors declare that there is no competing conflict of interest relevant to this study or any content presented in the manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcard.2020.07.038>.

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