Cardiovascular Revascularization Medicine 20 (2019) 875–882

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

The Feasibility and Safety of Ambulatory Percutaneous Coronary Interventions in Complex Lesions

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ARTICLE INFO

Article history:
Received 2 September 2018
Received in revised form 5 December 2018
Accepted 5 December 2018

Keywords:
Angioplasty
Same day discharge
Outpatient

ABSTRACT

Background: The safety and feasibility of ambulatory PCI has been demonstrated in selected patients with "simple" lesions, but it is not well known whether it could be applied in more "complex" scenarios.
Methods: Main objective is to assess the feasibility and safety of ambulatory complex PCI. Prospective multicentre registry of 1047 consecutive patients planned for ambulatory trans-radial PCI. Outcomes in patients with "complex angioplasty" (CA group: 313 (30%)) were analysed and compared with those of "simple angioplasty" (SA group: 734, 70%). The feasibility (% of patients finally discharged) and safety (MACE at 24 h and at 1 month) were compared between groups. We also analyse admissions, visits to the emergency department and minor vascular complications.
Results: Feasibility was higher for SA (80.6% vs. 63.6%, OR 1.89, 95% CI 1.52–2.35, $p < 0.001$). Ambulatory PCI was very safe in both groups. In CA no MACE occurred at 24 h (vs. 0.17% SA) or 30 days (vs. 0.68% in SA). There were also no differences in re-admissions, visits to the emergency department or minor vascular complications (there was a non-significant tendency to higher rate of radial occlusion at 1 month in the CA group, 5.5% vs. 2.7%, p: 0.07).
Conclusions: The feasibility of ambulatory PCI in selected patients with complex lesions is lower than in simple lesions, however when it is possible, it is as safe as in selected patients with simple lesions.

1. Introduction

Percutaneous coronary intervention (PCI) has experienced great advances in the last decade. The huge experience acquired, as well as the refinement and sophistication of the tools for PCI, now allow us to perform increasingly complex procedures in what were previously considered high-risk anatomies, with high success and safety rates.

Both observational and randomized studies have demonstrated the safety of same-day discharge PCI in selected patients with "simple" lesions [1], [2], [3]. Despite the good results of studies and the recommendations established by scientific societies, the majority of PCI are performed with 24–48 h of admission, regardless of complexity, and the recently updated recommendations are not widely known or practiced by interventional cardiologists [4], [5], [6].

The safety of ambulatory angioplasty (AA) for more complex lesions has been less studied, with only small single-centre retrospective studies that have had good results. Current developments in interventional cardiology now allow the safer performance of more complex PCI, and the step to be taken towards ambulatory performance of such procedures. This must be done with prudence and without trivialising PCI, but it brings greater comfort for the patient and considerable savings in cost.

2. Materials and methods

2.1. Design and population

Between January 2013 and September 2015, an AA registry was conducted in three centres with a volume of PCI > 700 per year, wide experience with trans-radial approach (> 85%) and an established AA programme. This registry verified the high feasibility and safety of AA

Abbreviations: AA, ambulatory angioplasty; CA, complex angioplasty; COPD, chronic obstructive pulmonary disease; CKI, chronic kidney injury; HF, heart failure; PCI, percutaneous coronary intervention; LAD, left anterior descending; LIMA, left internal mammary artery; SA, simple angioplasty.

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https://doi.org/10.1016/j.carrev.2018.12.001
1553-8389/

in selected patients with stable ischaemic heart disease and non-complex lesions [7]. From September 2015 to November 2017, patients continued to be included in the registry, and AA was also performed for more complex scenarios. The patients considered a priori for AA had to meet the criteria of Table 1, but the consideration of a candidate for AA was made at the discretion of the interventional cardiologist who performed the procedure. Each centre included their data in an anonymised database, designed for the study, and patients were prospectively followed up, at 24 h and at 30 days. The ethics committee of the centre promoting the registry approved the study, and the same centre performed data analysis.

All patients were informed of their inclusion in the registry and underwent PCI on the same day. All received antiplatelet drugs with at least acetylsalicylic acid prior to PCI, and clopidogrel or another P2Y12 inhibitor, and were able to receive loading of the second antiplatelet agent in the catheterization laboratory before PCI. All underwent elective PCI for stable mono or multivessel coronary disease through radial / ulnar access. In the case of a complex lesion, the intention to perform intervention on an outpatient basis was also at the discretion of the operator responsible for the case. After the procedure, patients were monitored by specialised nurses for an observation period of 4–12 h, according to each centre's protocol and the usual practice. All patients were then evaluated by the physician before discharge, and in person or by telephone at 24 h and at 30 days. If they reported complications with the vascular access (haematoma), they were always evaluated in person. The computerised clinical record of each patient was also reviewed in cases where any complications or pre-specified adverse events occurred. Table 1 also summarises the established criteria for admission of patients who were candidates for AA. Once the data were collected, the group of patients with complex lesions who were candidates for AA included in the registry was compared with the non-complex lesions group in terms of feasibility and safety.

2.2. Objectives and definitions

The main target of the study is to describe the feasibility and safety of AA in patients with complex lesions selected at the discretion of the operator, compared to a contemporaneous group of patients with simpler lesions also selected for AA. Definitions used in this study are the next.

Table 1
Criteria for inclusion and exclusion in the registry.

Inclusion criteria	Exclusion criteria
• Chronic Ischemic Cardiomyopathy: Stable angina or Silent ischemia. • Elective PCI (*Scheduled*/ad hoc). • Intention of PCI through Radial/Ulnar access.	**Patient** • Decompensated heart failure. • Glomerular filtration rate < 40 ml/min. • Chronic oral anticoagulation. • Absence of caregiver at home, inability to understand the procedure or residence far from health resources (>60 min). • Clinical instability. • Negative of the patient or relatives. **Procedure** • Elective Femoral Access
Admission criteria after PCI	
• Criteria of physician responsible. • Clinical instability after PCI: Persistent chest pain, heart failure, arrhythmias, syncope or other comorbidities. • Complication during PCI: Acute occlusion of the main vessel or secondary branch > 1 mm, residual dissection, no reflow/final TIMI < 3, perforation, residual thrombus. • Radial-Femoral crossover. • Major complication with vascular access. • >400 ml of contrast.	

Ambulatory angioplasty: PCI performed as outpatient. Patients come for PCI and are discharged the same day. **Complex lesion:** Bifurcation that involved side branches >2 mm treated with two-stent techniques, chronic total occlusions, protected and unprotected left main disease, venous or arterial aorto-coronary grafts, last remaining vessel, need for rotational atherectomy and multivessel angioplasty (2 or more lesions in 2 or more different vessels). **Feasibility:** Percentage of AA success, defined as intervention performed without complications, achieving an optimal angiographic result, with clinical stability during and after PCI and with the patient finally discharged. **Safety:** Complications appeared before discharge, and between 24 h and 30 days. Major complications and minor complications were analysed separately. **Major adverse cardiovascular events (MACE)** defined according to the recommendations of the Academic Research Consortium (ARC) [8] were: **Death:** all-cause mortality. **Acute myocardial infarction with or without Q wave**: includes acute periprocedural myocardial infarction and spontaneous acute myocardial infarction. Sudden death before the determination of biomarkers is also included in this section. **Stent thrombosis:** definitive, probable and possible. **Need for new revascularization on treated lesion (TLR):** guided or not by ischaemia and by new PCI or surgery. **Need for new revascularization on treated vessel (TVR):** guided or not by ischaemia and by new PCI or surgery, in the vessel treated, prior or beyond 5 mm proximal or distal to the lesion treated. **Need for new revascularization on another vessel (non-TVR):** non-scheduled PCI guided or not by ischaemia, on a different vessel. **Major bleeding**: according to the definitions of the Bleeding Academic Research Consortium (BARC 3 or 5) [9]. **Stroke:** transient ischaemic attack or ischaemic/haemorrhagic stroke defined as focal or general, transient or persistent neurological deficit with cerebral, medullary or retinal involvement. **Acute Kidney Injury (AKI):** Renal insufficiency induced by contrast that requires admission or treatment with renal support techniques. **Major vascular complications:** those requiring intervention or resulting in admission or major bleeding. **Minor complications** were considered those related to vascular access that did not require admission or surgical treatment and did not result in major bleeding. **The haematomas** were classified according to the EASY classification [10].

The **need for urgent attention** and the **need for admission** were also registered within the security objective.

2.3. Statistical analysis

Qualitative variables are expressed as frequency and percentage, and were analysed using the parametric chi-square test or the Fisher exact test (nonparametric) when needed, according to the distribution of the variable analysed. Quantitative variables are expressed as mean standard deviation or median [interquartile range] according to the distribution of the variable. Normality of distribution of the variables was assessed using the Kolmogorov-Smirnov test and they were compared using the Student *t*-test. Medians of time were analysed using the non-parametric Mann–Whitney *U* test. A p value of <0.05 was used as a cut-off for statistical significance for a 95% confidence interval (95% CI). All analyses were conducted using the SPSS 17.0 software package for Windows (SPSS Inc., Chicago, Illinois, United States).

3. Results

3.1. Baseline characteristics

Overall, 1047 consecutive patients undergoing AA were included in the registry. Angioplasty was considered complex (CA) in 313 (30%) patients, according to the criteria described above. Table 2 shows the global patient baseline characteristics and characteristics of patients who were finally discharged (791) and admitted (256), as well as a comparison based on angioplasty on simple lesion (SA) or complex lesion (CA). The majority of patients were male, with a mean

Table 2
Demographic characteristics.

Demographic Characteristics	Total ($n = 1047$)				Admitted ($n = 256$)				Discharged ($n = 791$)			
	Total	Simple Lesion ($n = 734$)	Complex Lesion ($n = 313$)	p	Total	Simple Lesion ($n = 142$)	Complex Lesion ($N = 114$)	p	Total	Simple Lesion ($n = 592$)	Complex Lesion ($n = 199$)	p
Age (years ± SD)	66 ± 10	66 ± 10	66 ± 10	0.94	67 ± 10	66 ± 10	66 ± 10	0.91	66 ± 10	66 ± 10	67 ± 10	0.64
Age range (years)	25–90	25–90	36–86		34–90	34–90	39–82		25–87	25–87	36–86	
Male *n* (%)	808 (77.2%)	558 (76%)	250 (79.9%)	0.17	197 (77%)	113 (79.6%)	84 (73.7%)	0.77	611 (77.2%)	445 (75.2%)	166 (83.4%)	0.02
BMI (kg/m^2 ± SD)	29 ± 4	29 ± 4	29 ± 4	0.81	29 ± 4	29 ± 3	29 ± 4	0.82	29 ± 4	29 ± 4	29 ± 4	0.98
HTN *n* (%)	801 (76.5%)	564 (76.8%)	237 (75.7%)	0.69	195 (76.2%)	110 (77.5%)	85 (74.5%)	0.91	606 (76.6%)	454 (76.7%)	152 (76.4%)	0.92
DLP *n* (%)	740 (70.7%)	520 (70.8%)	220 (70.3%)	0.85	182 (71%)	104 (73.2%)	78 (68.4%)	0.92	558 (70.5%)	416 (70.3%)	142 (71.4%)	0.77
DM *n* (%)	417 (39.8%)	296 (40.3%)	121 (38.7%)	0.61	103 (40.2%)	59 (41.5%)	44 (38.6%)	0.74	314 (39.7%)	237 (40%)	77 (38.7%)	0.73
Smoker *n* (%)	191 (18.2%)	130 (17.7%)	61 (19.5%)	0.49	56 (22%)	31 (21.8%)	25 (22%)	0.22	135 (17.1%)	99 (16.7%)	36 (18.1%)	0.65
Previous I.C. *n* (%)	527 (50.3%)	359 (48.9%)	168 (53.7%)	0.15	138 (54%)	71 (50%)	67 (58.7%)	0.61	389 (49.2%)	288 (48.6%)	101 (50.8%)	0.61
PAD *n* (%)	52 (5%)	25 (3.4%)	27 (8.6%)	0.001	20 (7.8%)	9 (6.3%)	11 (9.6%)	0.09	32 (4%)	16 (2.7%)	16 (8%)	0.001
GFR				0.94				0.14				0.86
>60 ml/m^2	871 (83.2%)	608 (82.8%)	263 (84.2%)		211 (82.4%)	111 (78.2%)	100 (87.7%)		660 (83.4%)	497 (84%)	163 (82%)	
60–30 ml/m^2	168 (16%)	121 (16.5%)	47 (15.2%)		40 (15.6%)	29 (20.4%)	11 (9.6%)		128 (16.2%)	92 (15.5%)	36 (18%)	
<30 ml/m^2	6 (0.6%)	4 (0.55%)	2 (0.64%)		4 (1.5%)	2 (1.4%)	2 (1.8%)		2 (0.26%)	2 (0.34%)	0 (0%)	
Haemodialysis	2 (0.2%)	1 (0.15%)	1 (0.32%)		1 (0.4%)	0 (0%)	1 (0.9%)		1 (0.14%)	1 (0.16%)	0 (0%)	

BMI: Body Mass Index; DLP: Dyslipidaemia; DM: Diabetes Mellitus; GFR: Glomerular Filtration Rate; HTN: Hypertension; I.C.: Ischemic Cardiomyopathy; PAD: Peripheral Artery Disease.

age 66 ± 10 years and high percentage of diabetes (40%). Patients with CA more frequently presented peripheral arterial disease, and in the subgroup that was finally discharged, a higher percentage of males were observed in the CA group.

3.2. Feasibility

Overall, it was possible to discharge 791 patients of the 1047 a priori selected for AA, which represents 75.5% of included patients. When we compared feasibility by procedure complexity, we found that discharge is more feasible after SA (80.6% vs. 63.6%, 95% CI, $p < 0.001$). The main reason for admission in CA group (64.7%) was clinical, due to the persistence of chest discomfort, arrhythmias, other comorbidities or at decision of the physician in charge. Other reasons for admission were: suboptimal angiographic result (20%), crossover to femoral (1.3%), vascular access complication (4%), rejection by the patient or relatives (0.5%), excess contrast (1%) and a miscellany of other reasons (8.5%). In general, patients admitted only at their physician criteria without more specifications were due with the physician's grade of confident with this practice and their sensations during the procedure and the surveillance period. In the group of CA, despite without significate differences, patients tend to be admitted after longer and ad hoc rather than scheduled procedures, with more contrast volume and if the procedure was LM, CTO or rotational atherectomy PCI rather than other subgroups of CA. These patients also tended to present more peripheral artery disease and GFR 30–60 ml/min (in patients with GFR < 40 ml/min, admission was recommended (Table 1)). More time of surveillance at the Cath Lab holding and with more vascular compression time until decision for admission or discharge were also observed. The median of admission for these patients was 1 day (1–64), therefore in the majority there were no serious early complications precluding discharge after 24 h of admission.

3.3. Procedure

Table 3 describes the procedure characteristics of the total population and the finally discharged patients, comparing CA to SA. Both in the global (48.2% vs. 56.5%, CI: 95%, $P = 0.01$) and patients discharged (44.3% vs. 52.3%, CI: 95%, $P = 0.05$) groups, PCI was performed more frequently ad hoc in the case of CA. In CA group, procedures were through the radial/ulnar artery in 96.5% with a 3.5% of crossover to femoral. Of these last 11 patients, the physician in charge finally discharged 3. In all crossover patients, vascular closure devices were used. The use of 7F sheaths and a larger number of stents was more frequent in the CA group, with longer procedures, a longer stay for surveillance before discharge and a longer vascular compression time.

3.4. Multivessel angioplasty

The CA group consisted mostly in multivessel PCI (186 patients, 59.4%), being the LAD territory the most frequently treated. In 38.7% (72) of patients, PCI was performed on 3 vessels. Of the patients initially considered for AA, 68.8% were discharged, with a slightly higher frequency among patients who underwent a 2-vessel angioplasty.

3.5. Angioplasty with rotational atherectomy

We included 21 intended AA patients, who underwent rotational atherectomy, of whom 9 (43%) were discharged. The PCI was most frequently scheduled vs. ad hoc, with higher sizes of sheaths, and in older patients. A 1.25 mm burr diameter was used in most cases, and no cases were performed with burrs larger than 1.5 mm.

Table 3
Procedure characteristics.

Procedure	Total (n = 1047)				Admitted (n = 256)				Discharged (n = 791)			
	Total	Simple lesion (n = 734)	Complex lesion (n = 313)	p	Total	Simple lesion (n = 142)	Complex lesion (n = 114)	p	Total	Simple lesion (n = 592)	Complex lesion (n = 199)	p
PCI type *n* (%)				0.01				0.91				0.05
Scheduled	516 (49.3%)	380 (51.8%)	136 (43.5%)		91 (35.5%)	50 (35.2%)	41 (36%)		425 (53.7%)	330 (55.7%)	95 (47.7%)	
Ad hoc	531 (50.7%)	354 (48.2%)	177 (56.5%)		165 (64.5%)	92 (64.8%)	73 (64%)		366 (46.3%)	262 (44.3%)	104 (52.3%)	
Final vascular access *n* (%)												
Radial	1013 (96.7%)	715 (97.5%)	298 (95.2%)	0.34	238 (93%)	135 (95%)	103 (90.3%)	0.17	775 (98%)	580 (97.9%)	195 (98%)	0.72
Ulnar	11 (1.1%)	7 (0.9%)	4 (1.3%)		4 (1.6%)	1 (0.7%)	3 (2.6%)		7 (0.9%)	6 (1%)	1 (0.5%)	
Femoral (crossover)	23 (2.2%)	12 (1.6%)	11 (3.5%)		14 (5.4%)	6 (4.3%)	8 (7.1%)		9 (1.1%)	6 (1%)	3 (1.5%)	
Sheath size *n* (%)				0.001				0.001				0.001
5 Fr	15 (1.4%)	9 (1.2%)	6 (1.9%)		3 (1.2%)	0 (0%)	3 (2.6%)		12 (1.5%)	9 (1.5%)	3 (1.5%)	
6 Fr	958 (91.5%)	694 (94.6%)	264 (84.2%)		224 (87.5%)	130 (91.5%)	94 (82.5%)		734 (92.8%)	564 (95.3%)	170 (85.4%)	
7 Fr	74 (7.1%)	31 (4.2%)	43 (13.8%)		29 (11.3%)	12 (8.5%)	17 (14.9%)		45 (5.7%)	19 (3.2%)	26 (13.1%)	
Time of procedure (minutes) (mean ± SD)	60 ± 30	57 ± 27	80 ± 30	0.05	84 ± 30	72 ± 20	85 ± 30	0.07	57 ± 25	52 ± 22	72 ± 26	0.025
Contrast volume (ml) (mean ± SD)	274 ± 28	294 ± 34	226 ± 95	0.3	283 ± 25	233 ± 96	301 ± 34	0.36	287 ± 86	313 ± 40	208 ± 67	0.33
Coronary territory treated *n* (%)												
LAD	531 (50.7%)	337 (45.9%)	194 (62%)	0.001	135	81 (57%)	54 (47.3%)	0.001	396 (50.1%)	256 (43.2%)	140 (70.4%)	0.001
CX	318 (30.4%)	159 (21.7%)	159 (50.8%)	0.001	72	31 (21.8%)	41 (36%)	0.001	246 (31.1%)	128 (21.6%)	118 (59.3%)	0.001
RX	384 (36.7%)	238 (32.4%)	146 (46.6%)	0.001	70	35 (24.6%)	35 (30.7%)	0.001	314 (39.7%)	203 (34.3%)	111 (55.8%)	0.001
Multivessel PCI *n* (%)	186 (17.8%)		186 (59.4%)				58 (50.8%)		128 (16.2%)		128 (64.4%)	
LM *n* (%)	20 (1.9%)		20 (6.4%)				12 (10.5%)		8 (1%)		8 (4%)	
LIMA *n* (%)	8 (0.8%)		8 (2.6%)				1 (0.8%)		7 (0.9%)		7 (3.5%)	
Saphenous *n* (%)	12 (1.1%)		12 (3.8%)				2 (1.7%)		10 (1.3%)		10 (5%)	
Bifurcation *n* (%)	16 (1.5%)		16 (5.1%)				5 (4.4%)		11 (1.4%)		11 (5.5%)	
Rotational atherectomy *n* (%)	21 (2%)		21 (6.7%)				12 (10.5%)		9 (1.1%)		9 (4.5%)	
CTO *n* (%)	50 (4.8%)		50 (16%)				24 (21%)		26 (3.3%)		26 (13.1%)	
Number stents (mean ± SD)	1.5 ± 0.8	1.3 ± 0.7	1.9 ± 0.9	0.005	1.6 ± 0.9				1.4 ± 0.7	1.2 ± 0.6	1.8 ± 0.9	0.001
Post-PCI surveillance time[a] (minutes) (*median* (R.I.))	309 (118–677)	300 (120–677)	381 (118–658)	0.01	420 (240–650)	401 (240–600)	435 (240–650)	0.2	320 (118–677)	305 (120–677)	414 (118–658)	0.001
Vascular compression time (minutes) mean ± SD)	191 ± 96	184 ± 91	192 ± 85	0.57	210 ± 80	212 ± 70	242 ± 80	0.04	191 ± 76	187 ± 79	202 ± 64	0.01
Patients discharged *n* (%)	791	592 (80.6%)	199 (63.6%)	0.001								

CTO: Chronic Total Occlusion; CX: Circumflex artery; Fr: French; LAD: Left anterior descending artery; LIMA: Left Internal Mammary Artery; PCI: Percutaneous coronary intervention; RX: Right coronary Artery; SD: Standard deviation; Fr: French.
[a] Time of stay at the Interventional Cardiology Holding before decision on discharge or admission.

3.6. Angioplasty of the Left Main (LM)

Twenty patients were initially selected for outpatient LM PCI, of whom 18 were unprotected and 8 (40%) were discharged. Intravascular ultrasound (IVUS) was used in all cases. In 18 a single-stent technique was performed.

3.7. Angioplasty on Chronic Total Occlusion (CTO)

Initially, 50 CTO patients were selected for AA but only 26 (52%) were discharged. All cases were performed by anterograde approach and were more frequently scheduled than ad hoc. Success was achieved in 90% of patients. Although infrequently, this group suffered more haematomas and a higher rate of radial occlusion on discharge and at 24 h.

3.8. Angioplasty in bifurcation lesions

The most frequently performed technique in this group was TAP. Of the 16 patients selected for AA, it was possible to discharge 11 (68%). There were no differences with respect to the SA group in terms of baseline characteristics or complications.

3.9. Angioplasty on venous and arterial grafts

A total of 20 patients with grafts were included, of whom 12 were patients with saphenous vein grafts and 8 arterial grafts (all were left internal mammary artery (LIMA)). Regarding the saphenous grafts, 10 patients were discharged (83%) and no distal protection devices were used. Of the PCI on LIMA patients, 7 of the 8 were discharged (87.5%). Most interventions were performed on the body of the graft in the case of vein grafts and in anastomosis, or beyond it in the case of arterial grafts. PCI were more frequently ad hoc, in this group.

3.10. Safety

Table 4 shows the clinical events and complications recorded in patients who were finally discharged. In the CA group, no MACE were recorded at 24 h or 30 days, whereas in the SA group the MACE rate was 0.17% at 24 h (major bleeding not related to vascular access) and 0.68% at 30 days (a subacute stent thrombosis, PCI on a different vessel for unstable angina, and a TIA). <1% of discharged patients visited an emergency department at 24 h, most of them did so for haematomas that did not require extraordinary medical actions. Regarding minor complications, 2.9% of haematomas and 2.1% of arterial occlusions were recorded at 24 h. The rate of arterial occlusion at 30 days tended to be more frequent in the CA group and reached 5.5%.

4. Discussion

The results of this study confirm the high safety of ambulatory PCI for selected patients and more complex lesions than those previously reported by our group [7]. None of the patients in the CA group presented MACE, and only one required emergency care, due to a haematoma that did not require measures beyond routine compression. Feasibility is, however, lower in these complex lesion patients, usually due to the operator's decision. With these results, we can conclude that if the PCI has been performed successfully, without complications and after a mandatory monitoring period of a median 6 h, it is possible to select the patients that can go home safely after the procedure, regardless of its complexity. Several factors to consider for performing complex PCI on an outpatient basis according to our results are the following:

1. Vascular approach
   A great contribution to the safety of PCI has been the generalisation of vascular access through the radial, which has clearly shown a reduction in mortality, MACE, major bleeding and vascular complications throughout the spectrum of coronary disease compared to femoral access [11]. The majority of procedures on complex lesions can now be performed through this access, thanks to both greater experience and to the smaller size and better profile of devices [12], [13]. In this registry, it was possible to perform almost 85% of complex cases with 6F sheaths and the crossover rate was only 3.5% in this group. It is noteworthy that the combination of radial access and same-day discharge after PCI is associated with a saving of >3000 USD/procedure with a lower rate of complications compared to transfemoral access and non-same-day discharge. [14].
2. Definition of complex lesions
   The definition used for complex PCI in the present study is extrapolated from usual clinical practice and the current developments in interventional cardiology; it has also been previously used in other studies [15]. Specifically, scenarios considered complex such as LM intervention with the use of DES, guided by IVUS the treatment of bifurcation lesions with double stent techniques or the performance of rotational atherectomy following expert guidelines can now be performed more safely than years ago [16], [17], [18]. Multivessel angioplasty has also been considered in this subgroup, a scenario not

Table 4
Safety outcomes after discharge.

Patients discharged (n = 791)	24 h				1 month			
	Total n = 791	Simple n = 592	Complex n = 199	p	Total n = 791	Simple n = 592	Total n = 791	Simple n = 592
MACE								
Death n (%)	0	0	0		0	0	0	
Stent thrombosis n (%)	0	0	0		1 (0.13%)	1 (0.17%)	0	NS
AMI n (%)	**0**	0	0		1 (0.13%)	1 (0.17%)	0	NS
TLR n (%)	**0**	0	0		0	0	0	
TVR n (%)	0	0	0		0	0	0	
Non-TVR n (%)	0	0	0		1 (0.13%)	1 (0.17%)	0	NS
Stroke n (%)	0	0	0		1 (0.13%)	1 (0.17%)	0	NS
Bleeding or need for transfusion n (%)	1 (0.13%)	1 (0.17%)	0	NS	0	0	0	
AKI requiring admission or dialysis n (%)	0	0	0		0	0	0	
Major vascular access complication n (%)	0	0	0		0	0	0	
Minor vascular complication n (%)								
Moderate-severe haematoma	23 (2.9%)	17 (2.9%)	6 (3%)	0.96	0		0	
Arterial occlusion	17 (2.1%)	11 (1.8%)	6 (3%)	0.33	27 (3.4%)	16 (2.7%)	11 (5.5%)	0.07
Visit to emergency department n (%)	7 (0.8%)	6 (1%)	1 (0.5%)	0.51	22 (2.8%)	20 (3.3%)	2 (1%)	0.07
Admission n (%)	2 (0.2%)	2 (0.3%)	0 (0%)	0.41	9 (1.1%)	6 (1%)	3 (1.5%)	0.5

AKI: Acute Kidney Injury; AMI: Acute myocardial Infarction; MACE: Major adverse cardiovascular events; TLR: Target Lesion Revascularization; TVR: Target Vessel Revascularization; Non-TVR: Non- Target Vessel Revascularization.

contemplated in the 2009 *SCAI* document but recently included in the current one together with others such as bifurcation or chronic total occlusion procedures [4], [5]. In our opinion, this update of the recommendations was necessary, as Gilchrist et al. suggested in their comparative study of those guidelines with actual practice, in which they found only 15 of 100 consecutive patients discharged on the same day (22% complex lesions) when following all the previously established criteria [19]. The AHA classification of coronary lesions dates from 1988 [20], and although it has characteristics that are present in complex lesions, it is not routinely used for PCI planning in our centres, and was not, therefore, used in this study. Currently available data on angioplasty with same-day discharge for complex lesions are scarce. Table 5 summarises interventions on lesions considered complex in different published studies. Koutouzis et al. published their findings for 28 patients with complex lesions, similarly defined to those in this registry and treated by trans-radial approach [21]. They excluded patients with multivessel PCI, and among 166 patients with complex lesions, same-day discharge was only possible for 28 patients (17% feasibility), but those 28 selected patients did not present MACE at 30 days. The 30-day MACE rate in the Hodkinson's study, where up to 41% of patients had complex lesions and 98% underwent transradial approach, was only 0.85% [22].

3. Scenario
   The patients included in this study were patients with stable ischaemic heart disease, but previously reported data even showed that it is possible to safely establish an angioplasty program with same-day discharge after PCI in an acute setting such as NSTE-ACS [22], [23]. Our results and those of other studies therefore show that the risk of complication after PCI depends more on the final result of the PCI than on the type of lesion treated and the context in which it is carried out.
4. Surveillance after PCI
   The average post-PCI stay of our patients was between 5 and 7 h, and it was somewhat longer for those with complex lesions. We consider this period of surveillance sufficient to detect the patients who can be discharged safely. In the DISCHARGE study, it was retrospectively observed that among 1174 patients considered at high risk for complex lesions (B2–C of the AHA), there was no complication in the time window between 6 h after PCI and the next 24 h [24]. These authors concluded that a time of 6 h is sufficient to screen the patients who can be discharged, and that hospitalisation does not prevent the development of later complications, since they occur after 24 h. Similar results were obtained in the STRIDE study [25]. Some authors also suggest that surveillance during this period of time could be performed safely and more comfortably in a place specifically dedicated which they have called *radial lounges* and not necessarily in classic inpatient holdings with bedding [26]. Finally, in our study, no routine determination of biomarkers was performed to detect subclinical periprocedural infarctions, since in our opinion small troponin elevations do not influence the occurrence of events in the follow-up, as has been proven prospectively in some previous studies [27].

4.1. Factors precluding same day discharge after complex angioplasty

Some other patient, procedure and anatomical features should be taken into account when performing outpatient PCI. Patients features indicated in Table 1 are of key importance to get success with this strategy. First of all, it is necessary a good family and social support along with an adequate access to an emergency department. Second, in

Table 5
Summary of studies assessing SDD PCI in complex lesions or complex scenarios.

Study	n	Access	Complex lesions included	Outcomes	Comments
2003: Ziakas et al. [31]	943	TF (100%)	Multivessel 146, Saphenous 35, Simple Angioplasty 210	MACE 30 days: 6 (0.6%)	Retrospective. Elective PCI. LM excluded. Two deaths due to stent thrombosis >24 h.
2006: Bertrand et al. [23]	1005	TR (100%)	Multivessel 149, LM 7, Saphenous 7	MACE 30 days: 9 (0.9%)	Randomized trial. N-STEMI. PCI + abciximab bolus vs. PCI abciximab bolus + perfusion. Feasibility SDD 88%.
2006: Wiper et al. [32]	442	TR (94%)	Multivessel 148, Grafts 12.	MACE 30 days: 3 (0.68%)	Retrospective. Safety and Feasibility of a single-centre same-day discharge programme. One death and 2 stent thrombosis 24–72 h.
2007: Heyde et al. [33]	403	TF (100%)	Multivessel 71, LM 4, Saphenous 5, Bifurcation 83, CTO 97.	MACE 30 days: 1 (0.3%)	Randomized Trial. Feasibility 81%. TF Access without closure devices: 1 Pseudoaneurysm and15 hematomas. No deaths.
2007: Small et al. [24]	1174	TR (100%)	LM 24, Saphenous 25, LIMA 3, Multivessel 265	MACE 6–24 h: 0 (0%)	Retrospective. Assessing time window of complications after complex PCI. All patients were admitted.
2010: Patel et al. [34]	2400	TF (99.5%)	Bifurcation 350, CTO 98, RA 17.	MACE 30 days: 8 (0.3%)	Retrospective. Single-centre. Elective PCI in stable I.C. LM, Grafts, last remained vessel and proximal bifurcation excluded. TIMI minor bleeding: 14, 1 pseudoaneurysm.
2011: Rao et al. [35]	1339	TF (97%) TR (3%)	Multivessel 189, Bifurcation 194.	MACE 30 days: 129 (9.6%) **	Retrospective. Elective PCI in stable I.C. Femoral closure devices 65%. Deaths at 30 days: 3. Major vascular complications: 10 (0.75%).
2013: Antonsen et al. [36]	355	TF (100%)	Multivessel 31, LM 7.	MACE 30 days: 1 (0.3%)	Retrospective. Femoral closure with device 100%. N-STEMI after stabilization included (22%). Hematomas needing for admission: 2; pseudoaneurysm 1.
2013: Hodkinson et al. [22]	1059	TR (98%); TF (2%)	Multivessel 134, Bifurcation 332, Saphenous 26, LIMA 3, LM 37.	MACE 30 days: 12 (0.85%). 4 Death ((0.38%)2 cardiac death).	Prospective. Followed up by telephone at 30 days. The 27.7% of patients included were in acute phase (22.1% N-STEMI and 5.6% recent STEMI).
2013: Le Corvoisier et al. [37]	220	TR (100%)	Multivessel 31, Bifurcation 60, CTO 24, Saphenous 1.	MACE 30 days: 1 (0.3%)	Prospective. Feasibility 96.8%. Saving costs: 441 euros/procedure.
2017: Koutouzis et al. [15]	28*	TR (82%) TU (18%)	Bifurcation 6, Saphenous 3, LIMA 1, LM 10, CTO 6, RA 2.	MACE 30 days: 0 (0%)	Retrospective. $N = 1190$ Elective PCI with intention to SDD: 166 complex PCI, 96 multivessel. Low Feasibility but safe when it was possible: Only 28 patients were discharged.

CTO: Chronic Total Occlusions; IC: Ischemic Cardiomyopathy; LIMA: Left Internal Mammary Artery; LM: Left Main; MACE: Major Adverse Cardiovascular Events; PCI: Percutaneous Coronary Intervention; RA: Rotational Atherectomy; STEMI: ST-elevation Myocardial Infarction; N-STEMI: Non-ST-elevation Myocardial Infarction; TF: Trans-Femoral; TR: Trans-Radial; TU: Trans-Ulnar; SDD: Same-day discharge.

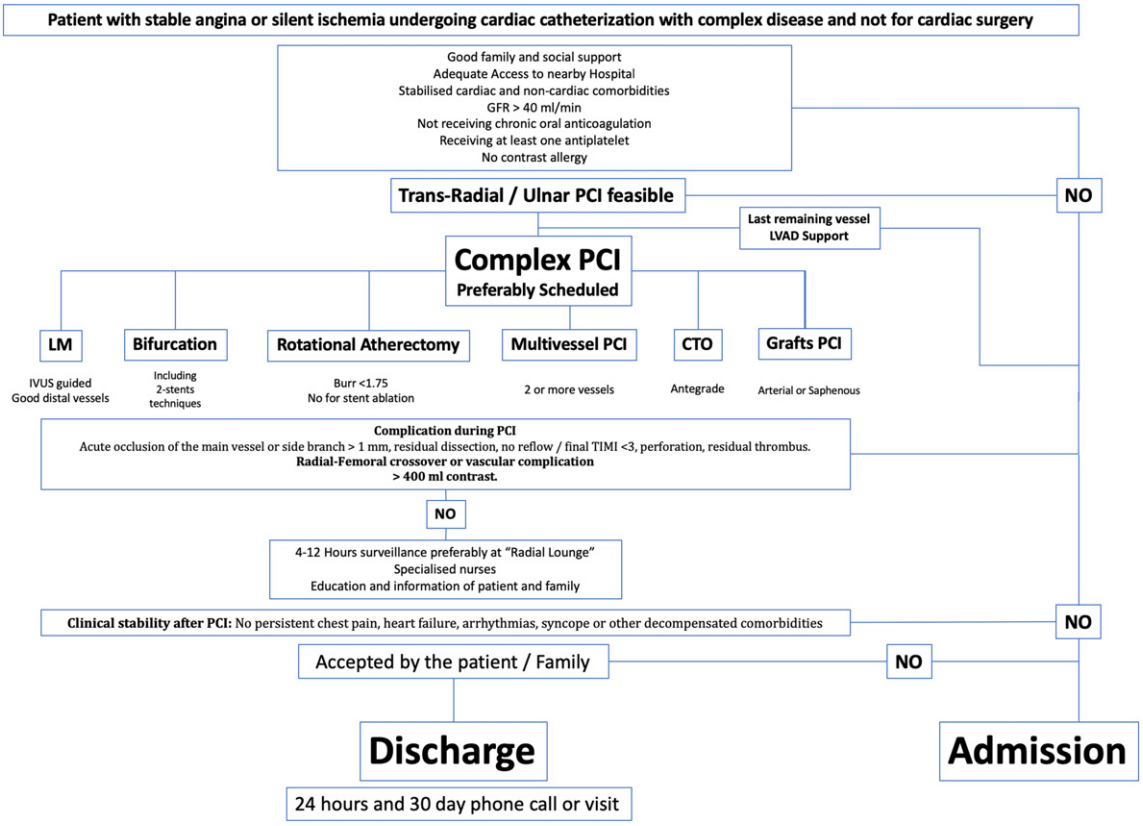

Fig. 1. Decision algorithm for ambulatory percutaneous coronary interventions in complex lesions. CTO: Chronic Total Occlusion; GFR: Glomerular Filtration Rate; IVUS: Intravascular Ultrasound; LM: Left Main; LVAD: Left Ventricle Assistant Device; PCI: Percutaneous coronary intervention.

order to avoid complications associated with comorbidities such as COPD, CKI, HF etc., all of these must be compensated. The case of more advanced CKI or end-stage renal disease requiring haemodialysis is a condition that in our opinion requires admission for early detection of impairment or to perform hydration or haemodialysis before discharging. A recent study showed that >1 half of readmissions 30 day after PCI were due to these comorbidities rather than cardiac reasons [28]. Regarding the procedure, to discharge patients with unsuccessful PCI, with no TIMI 3 flow or with complications such as no reflow, side branch closure, perforation or not sealed dissections, must be avoided. Every PCI in the same point of the anatomy is different, but probably due to the small population of this study, no clear anatomical conditions have been identified to be risker. The operators used to not discharge patients after LM or rotational atherectomy procedures more frequently than other cases, probably because they felt less comfortable. Despite we consider that the outcomes depend more of the final result than the procedure itself, probably in more complex LM procedures (double-stent techniques, atheterectomy, poor distal vessels), longer procedures in calcified lesions, CTO requiring more complex retrograde or dissection-reentry techniques and procedures in last remaining vessel, where a complication out of the hospital could be devastating, it should be indicated at least 24 h of admission. Finally, patients must be admitted after procedures supported by left-ventricle assist devices requiring femoral access with large-bore sheaths. An algorithm to guide the correct selection of patients undergoing outpatient PCI is purposed in Fig. 1.

5. Conclusions

The feasibility of ambulatory PCI for clinically well-selected patients and on lesions classically considered to be of greater complexity is lower than for simpler lesions; however, once the patient has been discharged, the safety of this strategy is very high.

6. Limitations

Several limitations of the present registry must be considered. The sample size of complex lesions included is not high, and it would be desirable to use registries with a higher number of lesion and patients. A survey of acceptance and patient opinion has not been systematically performed, so it cannot be concluded from this study that outpatient PCI is more comfortable for them, although previous studies appear to confirm this statement [29]. Likewise, no cost analysis has been carried out, but previous studies also show savings [30]. Finally, the possibility of selection bias inherent to the prospective nature of the registries constitutes another limitation, mainly in this registry where despite patients were consecutively included, the final decision for inclusion was under criteria of the responsible physician.

Acknowledgements

We thank the nursing staff of the different Interventional Cardiology Units for their help in the collection of data and their excellent work in the care of patients.

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