Feasibility and Safety of Same-Day Discharge after Transradial Percutaneous Coronary Intervention: A Tunisian Monocentric Study

Angioplastie coronaire ambulatoire : faisabilité et sécurité. Expérience monocentrique Tunisienne

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RÉSUMÉ

Introduction : L'augmentation des besoins et des couts de soins en cardiologie et les avancées techniques interventionnelles représentent le scénario idéal pour envisager un programme d'angioplastie coronaire ambulatoire (ACA).

But : Examiner la faisabilité et la sécurité de l'ACA.

Méthodes Nous avons mené une étude observationnelle comparative d'une une cohorte prospective (Avril 2017-Septembre 2017) où les patients ont effectivement bénéficié d'ACA à une cohorte rétrospective (Octobre 2016-Mars 2017) où les patients ont été géré conventionnellement. Nous avons établi des critères pré-procéduraux d'éligibilité et des critères per et post- procéduraux d'exclusion pour estimer la faisabilité de l'ACA. La sécurité a été évaluée à 24h et à 30 jours comparativement dans les 2 groupes.

Résultats : Nous avons réalisé 709 angioplasties coronaires durant l'année investiguée. L'éligibilité à l'ACA était de 17,2% (122 patients) et la faisabilité de 14,7% (104 patients). En définitive, 50/370 dans la cohorte prospective (groupe-ambulatoire) et 54/339 patients dans la cohorte rétrospective (groupe-contrôle) ont ou auraient pu bénéficier d'ACA. La voie radiale était prédominante (98,1%). 59,7% des lésions étaient de type B2 ou C, 53,8% siégeaient au niveau de l'interventriculaire antérieure et 29,8% étaient des bifurcations. Dans les deux groupes, aucune complication n'a été observée à 24h. A 30 jours, un infarctus du myocarde non-fatal lié à une thrombose de stent subaiguë est survenu dans le groupe-ambulatoire en rapport avec un arrêt intempestif du traitement antiagrégant.

Conclusion : L'ACA est faisable et sûre moyennant des critères de stratification stricts des patients avant de juger de leur sortie le même jour.

Mots-clés

Intervention coronaire percutanée ; soins ambulatoires ; faisabilité ; sécurité.

SUMMARY

Background: The continuing increase in care, needs and costs in cardiology with the advances in percutaneous coronary intervention (PCI) techniques represent the ideal scenario for considering same-day discharge (SDD) PCI program.

Aim: The primary endpoints were to examine feasibility and safety of SDD-PCI.

Methods: We conducted a comparative observational study of a prospective cohort (April 2017 to September 2017) where patients benefited from SDD-PCI with a retrospective cohort (October 2016 to March 2017) where patients were conventionally managed. We established pre-procedural eligibility criteria and per and post-procedural exclusion criteria to estimate feasibility of SDD-PCI. Safety was assessed at 24 hours and 30 days comparatively in both groups.

Results: In the one-year study period, 709 PCI were performed. The eligibility for SDD-PCI was 17.2% (122 patients) and feasibility was 14.7% (104 patients). Ultimately, 50 out of 370 patients in the prospective cohort (SDD-group) and 54 out of 339 patients in the retrospective cohort (control-group) had or could have benefited from SDD-PCI. The transradial access was the most used (98.1%). 59.7% of treated lesions were B2 or C type, 53.8% interested the left anterior descending artery and 29.8% were bifurcations. In both groups, no complications were observed at 24 hours. At 30 days, one single non-fatal myocardial infarction related to subacute stent thrombosis occurred in the SDD-group and was attributed to antiplatelet therapy interruption.

Conclusion: SDD-PCI is feasible and safe on the condition of strict stratification criteria of patients before judging their discharge the same day after PCI.

Key-words

Percutaneous coronary intervention; ambulatory care; feasibility; safety.

INTRODUCTION

About 500,000 and 900,000 percutaneous coronary intervention (PCI) are performed respectively in the United States and Europe each year (1,2). The exponential increase in PCI volume during the last decade has led to an increase in healthcare costs and bed occupancy with an extension of waiting periods for elective PCI. The recent advances in the field of interventional cardiology with the generalization of transradial access with lower rate of vascular complications (3,4), and the use of more effective antithrombotic strategies leading to a lower rate of stent thrombosis especially in the first 24 hours (5,6), have allowed to consider a same-day discharge (SDD) PCI strategy.

METHODS

Study design

This single-institution study aimed to assess feasibility and safety of ambulatory PCI in our center. For this purpose, we conducted retro-prospective comparative observational cohort study that analyzed data from all PCI performed during a one-year period between October 2016 and September 2017.

Study population

After review of literature, we established strict selection criteria for patients who can benefit from an outpatient PCI strategy. After adapting them to local conditions, these criteria were stratified into (Table 1):

Inclusion criteria: All PCI performed in our center during this period were included.

Non-inclusion criteria: Called also non-eligibility criteria. They concerned pre-procedural features related to the patient or to the lesion to be treated.

Exclusion criteria: These criteria were in relation with per-procedural complications or those occurring during the initial post-procedural monitoring period of a minimum duration of 4 hours.

2 study cohorts were designed: The first was a prospective cohort ("SDD or outpatient" group), comprising 370 patients who benefited from PCI in our center between April and September 2017. During this 6-month period, patients meeting selection criteria were effectively managed in a SDD strategy. The second was a retrospective cohort ("control" group), comprising 339 patients who underwent PCI in our center between October 2016 and March 2017. During this 6-month period, patients who met the same criteria were managed conventionally with an overnight observation.

Consents were obtained from all patients.

Table 1: The Study non-inclusion and exclusion criteria.

Non-inclusion pre-procedural criteria or eligibility criteria:
Related to patient:
STEMI, NSTEMI, UA < 8 days
Hemodynamic or rhythm instability
-Decompensated heart failure
-Ejection Fraction < 35%
-Chronic oral anticoagulation
-High risk of hemorrhage (thrombocytopenia, anemia, coagulopathy)
-GFR ≤60 ml / min / 1.73m²
-Impossible radial or ulnar access
-No caregiver at home, poor socio-economic conditions or home far from health resources (> 60 min)
Related to lesion:
-Thrombotic lesion
-Complex PCI procedure : unprotected left main coronary artery, chronic total occlusion, Two-stent technique for bifurcation lesions, coronary artery bypass graft, calcified lesions with need for rotational atherectomy
Per-Procedural exclusion criteria:
-Any complication related to vascular access
-Crossover from radial or ulnar to femoral access
-Clinical instability: chest pain, heart failure, ventricular arrhythmias, hypotension
-Residual stenosis >20% on the main branch or >50% on the side branch
-Any PCI complication: Perforation, residual thrombus, residual dissection, final TIMI flow <3, side branch occlusion, distal embolization
-Use of a high contrast volume
-Use of glycoprotein IIbIIIa antagonists
-Hypersensitivity to contrast media
Post-procedural exclusion criteria (in the post-PCI observation 4-6h period)
-Complication related to vascular access: hematoma, pseudoaneurysm, fistula
-Chest pain and / or electrical changes
-Hemodynamic or rhythm instability
-Hypersensitivity to contrast media
-Refusal of the patient

GFR, Glomerular Filtration Rate; NSTEMI, Non-ST Elevation Myocardial Infarction; PCI, Percutaneous Coronary Intervention; STEMI, ST Elevation Myocardial Infarction; TIMI, Thrombolysis In Myocardial Infarction; UA, Unstable Angina.

Procedural recommendations

Radial or ulnar access were mandatory to plan SDD PCI in the absence of femoral vascular closure devices in our center. Before PCI, all patients should have received dual antiplatelet therapy including: at least 100 mg aspirin, with an oral loading dose of Clopidogrel (600 mg), as it was the only available P2Y12 inhibitor, at least 2 hours before the procedure in P2Y12 inhibitor-naive patients (7,8); and received a single dose of 5000 IU heparin after sheath insertion. Standard elastic compression was recommended for hemostasis. If the procedure was uncomplicated and if no symptoms, no complications at the access site and no dynamic ECG changes occurred after an observation period of 4 to 6 hours, patients could have been discharged in the outpatient group. In this group, a phone call was made the next day to ask for complications and assess patient's satisfaction through a 7-question survey. Blood tests were planned to rule out contrast induced acute kidney injury. All patients in the two groups were reassessed one month later.

Definitions and study endpoints

Treated lesions were classified according to ACC/AHA types (9).

The primary endpoints of this study were to examine feasibility and safety of ambulatory PCI at 24-hour and 30-day follow-up, with an evaluation of patient satisfaction as secondary endpoint.

We noted any occurring complications at 24 hours and 30 days. Incidence of major cardiac and cerebrovascular adverse events (MACCE), a composite endpoint of death from any cause, non-fatal myocardial infarction (MI), need for any non-planned target vessel revascularization and stroke. Stent thrombosis according to the Academic Research Consortium (ARC) classification and major hemorrhagic events as defined by the Bleeding Academic Research Consortium (BARC) 3 or 5 were compared in both groups (7,10). Minor complications were also recorded, such as minor vascular complications on the access site. Patient satisfaction was measured by a patient satisfaction survey of 6 questions.

Statistical Analysis

Independent groups were compared using the Student's t-test for continuous variables and Mann and Whitney's test in case of reduced effectives, whereas the chi-square test or Fisher exact test were used to compare the categorical variables. p values <0.05 were considered statistically significant. Statistical tests were done with the IBM SPSS Statistics 22.0.0.0 software package for Windows (SPSS Inc, Arlington, VA).

RESULTS

709 PCI were performed in our center during the one-year investigated period: 370 in the prospective 6-month cohort with SDD strategy and 339 in the retrospective 6-month cohort with overnight observation after PCI.

Figure 1 shows the flow chart of SDD eligibility in the two cohorts: 122 (17.2%) among 709 patients were eligible for this strategy.

Following this screening phase, 18 patients (2.5%) were excluded due to: a per-procedural complication in 8 (1.1%) patients, to an initial observation phase complication in 5 (0.7%) patients and to a refusal of SDD in the prospective cohort expressed by 5 (0.7%) patients (Figure 2).

Finally, 104 (14.7%) of the 709 patients who underwent PCI between October 2016 and September 2017 were manageable in an ambulatory setting in both groups.

The baseline features are shown in table 2 with similar demographic and procedural characteristics between the 2 groups except for smoking habit. The mean age of the study population was 61 ± 6 years, 76.9% were male. There was a high percentage of smokers (72.1%), 47.1% had hypertension, and 42.3% had diabetes.

Most of the angiographic characteristics were comparable between the outpatient group and the overnight observation group. Among the 129 treated lesions: 53.8% concerned the left anterior descending coronary artery, 29.8% were bifurcations lesions and according to the ACC / AHA classification, 59.7% were B2 or C types. The 2 groups "outpatient" and "control" were comparable with respect to these criteria of lesion complexity.

The transradial access was the most used route (98.1%) in our series, where only 2 patients (1.9%) were treated by transulnar approach. The same vascular access site as previous catheterization was possible in 91.3% of cases. All PCI were performed through a 6 French introducer, except two in the outpatient group in whom a 5 French approach was needed to avoid femoral crossover.

The average contrast volume was 104.4 ± 33.2 mL. In the prospective SDD group, vascular compression time was 258 ± 18 min and length of post-procedural hospital stay was 282 ± 42 min.

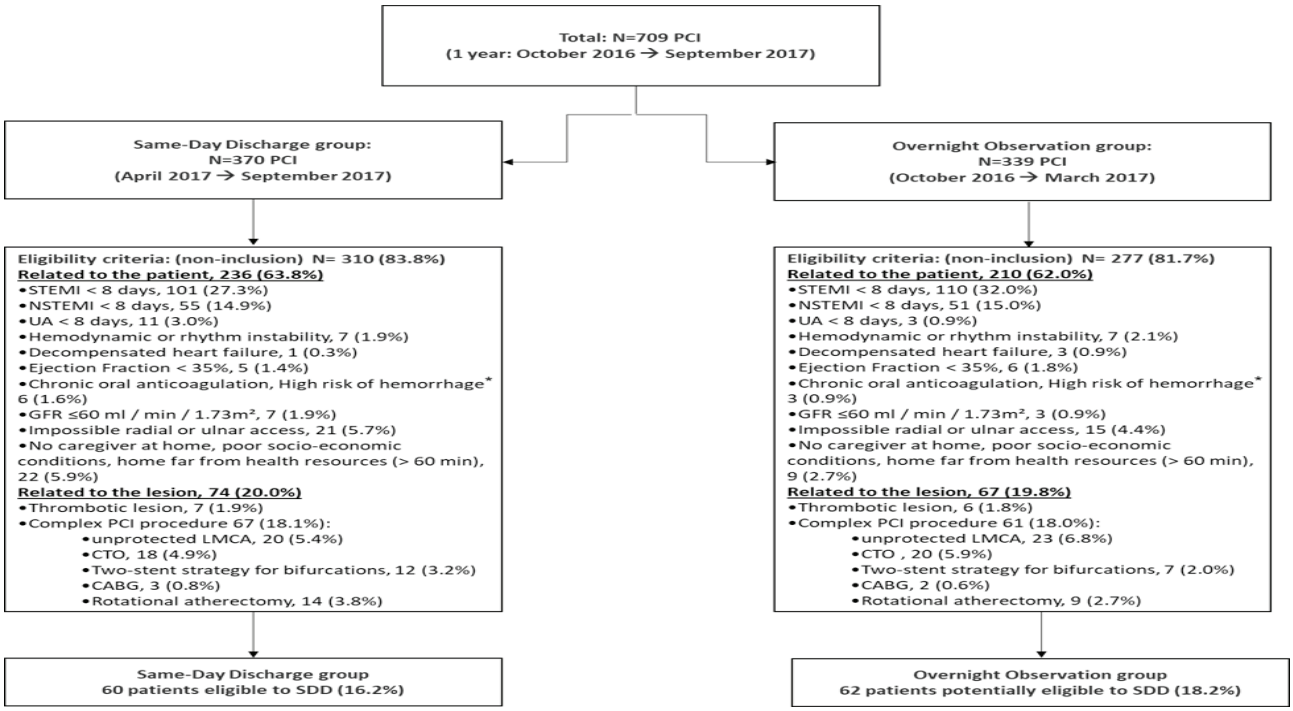

Figure 1: Study flow chart of eligibility for same day discharge percutaneous coronary interventions.
CABG : coronary artery bypass graft; CTO, Chronic Total Occlusion; GFR, Glomerular Filtration Rate; LMCA, Left Main Coronary Artery; NSTEMI, Non-ST Elevation Myocardial Infarction; PCI, Percutaneous Coronary Intervention; SSD, Same-Day Discharge; STEMI, ST Elevation Myocardial Infarction; UA, Unstable Angina. * : Thrombocytopenia, anemia, coagulopathy.

Table 2: Baseline Characteristics.

Demographic characteristics	Total (n = 104)	SDD group (n=50)	Control group (n=54)	p
Age, y	61.9 ± 9.3	61.4 ± 7.6	62.3 ± 10.8	0.624
Male sex	80 (76.9%)	41 (82.0%)	39 (72.2%)	0.237
Smoking	75 (72.1%)	41 (82.0%)	34 (63.0%)	0.031
Hypertension	49 (47.1%)	23 (46.0%)	26 (48.1%)	0.826
Diabetes mellitus	44 (42.3%)	20 (40.0%)	24 (44.4%)	0.647
Dyslipidemia	31 (29.8%)	16 (32.0%)	15 (27.8%)	0.638
Obesity	13 (12.5%)	9 (18.0%)	4 (7.4%)	0.103
Family history	9 (8.7%)	8 (7.7%)	1 (1.9%)	0.013
Previous stroke	6 (5.8%)	5 (10.0%)	1 (1.9%)	0.103
Previous MI	35 (33.7%)	19 (38.0%)	16 (29.6%)	0.367
Previous PCI	35 (33.7%)	16 (32.0%)	19 (35.2%)	0.731
Previous CABG	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Serum Creatinine (mL/min)	87.4 ± 18.4	84.6 ± 17.0	90.0 ± 19.6	0.133
LVEF (%)	54.4 ± 8.1	55.9 ± 8.1	53.0 ± 8.0	0.067

CABG, Coronary Artery Bypass Graft; LVEF, Left Ventricular Ejection Fraction; MI, Myocardial Infarction; PCI, Percutaneous Coronary Intervention.

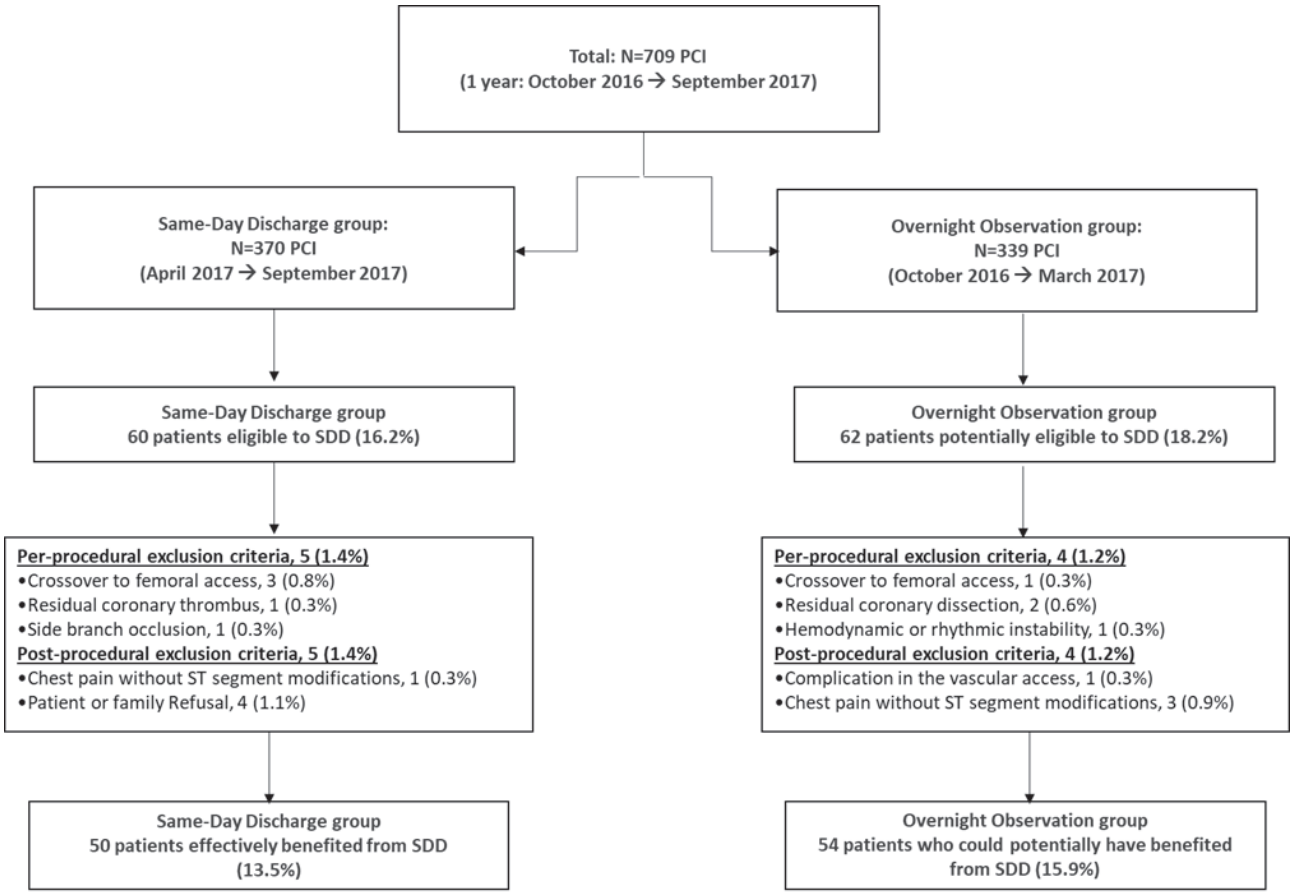

Figure 2. Study flow chart of feasibility of same day discharge percutaneous coronary interventions.
PCI, Percutaneous Coronary Intervention; SDD, Same-Day Discharge.

All patients were followed at 24 hours and 30 days. No MACCE were observed within 24 hours. At 30 days, only one case of non-fatal MI in relation with subacute stent thrombosis occurred in the outpatient group was reported and was due to dual antiplatelet therapy discontinuation. No minor complications were recorded nor at 24 hours neither at 30 days.

All patients in the SDD-group responded prospectively to the satisfaction survey. Only 88.8% of patients in the control group agreed to answer the satisfaction survey. Through this survey were withdrawn: a better level of therapeutic education as judged by the patients, a better overall satisfaction in patients who benefited from outpatient PCI strategy compared to the overnight observation group who judged hospitalization conditions often unsatisfactory ($p < 0.0001$) (Figure 3).

DISCUSSION

This study reported data from a Tunisian monocentric pilot strategy of SDD PCI management. The main findings were the safety and feasibility of outpatient PCI in well-selected patients with rigorous screening selection criteria.

Practice of SDD PCI varies between countries (14% in

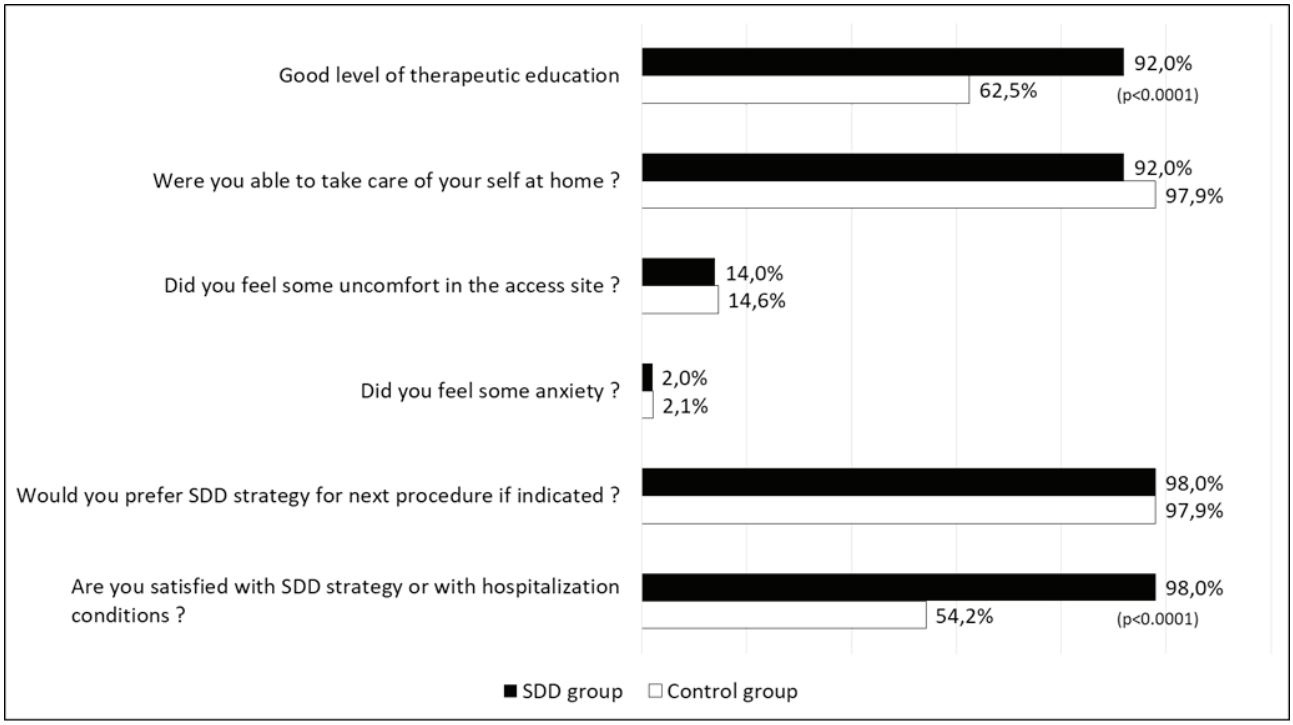

Figure 3: Satisfaction survey.
SDD, Same-Day Discharge.

the United States, 32% in Canada, and 57% in United Kingdom) and among cardiologists responding to that survey, the majority consider overnight observation strategy (12).

Although the majority of recent studies showed the safety of practicing SDD using radial access (13–17), most interventional cardiologists still practice overnight observation after PCI, because their concern about two major early issues: stent thrombosis and bleeding at vascular access site.

Early stent thrombosis physiopathology has mainly procedure-related mechanisms and stent underexpansion and malapposition have been identified as the most prevalent intravascular imaging abnormalities in patients with early stent thrombosis (18). Claessen et al. (19) also emphasized the important role of technical factors in the determinism of early stent thrombosis. Thus a suboptimal procedural result (slow flow, malapposition, underexpansion, residual dissection...) was an exclusion criterion in our study. Beyond these technical aspects, we followed in our study current recommendations for pre, peri and post antithrombotic treatment strategies in elective PCI (20).

Major ICP-related hemorrhagic and vascular access site complications have been controlled by transradial approach (3,4,21,22). Among recent observational studies, no major bleeding complications have been associated with outpatient PCI performed via the radial artery (13,15–17).

Last European revascularization guidelines did not integrated the concept of outpatient PCI (20). This issue was the main topic of a recent publication of the Society of Cardiovascular Angiography and Interventions/American College of Cardiology with an expert consensus which supported reasonable clinical decision making regarding postprocedure length of stay for a broad spectrum of patients undergoing PCI, rather than prescribing a specific period of observation for individual patients (23).

We did not perform cost-effectiveness evaluation in our study but the current increase in healthcare costs and the need of hospital beds affirm the necessity of developing

Table 3: Procedural Characteristics.

Procedural characteristics	Total (n=104)	SDD group (n=50)	Control group (n=54)	p
Scheduled PCI	95 (91.3%)	43 (86.0%)	52 (96.3%)	0.084
Ad-hoc PCI	9 (8.7%)	7 (14.0%)	2 (3.7%)	
Radial access	102 (98.1%)	49 (98%)	53 (98.1%)	1.0
Ulnar access	2 (1.9%)	1 (2.0%)	1 (1.9%)	
Previous catheterization through the same access route	95 (91.3%)	45 (90.0%)	50 (92.6%)	0.735
5 French introducer	2 (1.9%)	0 (0.0%)	2 (3.7%)	0.496
6 French introducer	102 (98.1%)	50 (100.0%)	52 (96.3%)	0.759
Number of treated lesions	**N=129**	**N=60**	**N=69**	
1 lesion	81 (77.9%)	40 (82.0%)	41 (75.9%)	0.617
2 lesion	21 (19.2%)	10 (20.0%)	11 (20.4%)	0.963
3 lesion	2 (1.9%)	0 (0.0%)	2 (3.7%)	0.496
Lesion location				
- LAD	56 (53.8%)	23 (46.0%)	33 (61.1%)	0.122
- DG	4 (3.8%)	1 (2.0%)	3 (5.6%)	0.619
- CX	19 (18.3%)	11 (22.0%)	8 (14.8%)	0.343
- OM	19 (18.3%)	11 (22.0%)	8 (14.8%)	0.343
- RCA	24 (23.1%)	12 (24.0%)	12 (22.2%)	0.830
- PDA	4 (3.8%)	1 (2.0%)	3 (5.6%)	0.619
- PL from RCA	3 (2.9)	1 (2.0%)	2 (3.7%)	1.000
Bifurcation	31 (29.8%)	18 (36.0%)	13 (24.1%)	0.184
ACC-AHA Type A / B1	52 (40.3%)	24 (40.0%)	26 (37.7%)	0.47
ACC-AHA Type B2 / C	77 (59.7%)	36 (60.0%)	43 (62.3%)	
Number of stents per patient	1.3 ± 0.7	1.3 ± 0.7	1.4 ± 0.7	0.684
Mean diameter of stents (mm)	2.96 ± 0.44	2.96 ± 0.47	2.96 ± 0.42	0.976
Mean length of stents (mm)	28.3 ± 11.7	27.2 ± 11.1	29.3 ± 12.2	0.313
DES only	79 (61.2%)	36 (59.0%)	43 (63.2%)	0.623
BMS only	46 (35.7%)	22 (36.1%)	24 (35.3%)	0.927
DES and BMS	4 (3.1%)	3 (4.9%)	1 (1.5%)	0.251
Predilation	49 (38.0%)	19 (31.7%)	30 (43.5%)	0.168
Postdilation	54 (41.9%)	22 (36.7%)	32 (46.4%)	0.265
Stent enhancement imaging	35 (27.1%)	23 (38.3%)	12 (17.4%)	0.008
Contrast volume (mL)	104.4 ± 33.2	102.4 ± 35.0	106.2 ± 31.7	0.558
Vascular compression time, min	-	258 ± 18	NE	-
Length of stay after PCI, min	-	282 ± 42	NE	-

BMS, Bare Metal Stent; CX, Circumflex; DES, Drug Eluting Stent; DG, Diagonal; LAD, Left Anterior Descending; NE, Non Evaluated, OM, Obtuse Marginal; PCI, Percutaneous Coronary Intervention; PDA, Posterior Descending Artery; PL , Posterior Lateral Artery; RCA, Right Coronary Artery; SSD, Same-Day Discharge.

outpatient PCI program in each country. In the United States of America, PCI is associated with costs of 10 billion dollars annually (24). In this study, authors concluded that practicing SDD PCI via radial route would result in savings of $ 3,689 per procedure compared to femoral PCI with overnight hospitalization (24). According to Lozano et al. a PCI procedure can be funded free of charge through the practice of four outpatient PCIs (13).

Similarly to our study, other reports showed a higher patient satisfaction with the SDD strategy compared to overnight observation after PCI (25,26).

The main limitations of this study were the monocentric design and the transradial only possible route for SDD strategy because of unavailability of femoral vascular closure devices in our center.

CONCLUSIONS

SDD in well-selected patients after uncomplicated PCI via transradial access and uneventful short post-procedural observation period of 4 hours can be safe and feasible. Beyond its cost-effectiveness, this strategy could be the solution to bed capacity and waiting time problems in cardiology.

Conflicts of interest: None

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