

Same-Day Discharge After Percutaneous Coronary Intervention: First experience in a Tunisian center

Angioplastie coronaire ambulatoire: première expérience d'un centre Tunisien

Lobna Laroussi^{1,2}, Nader Ben Salem², Zied Ibn El Haj^{1,2}, Sonia Marrakchi^{1,2}, Marouene Boukhris^{1,2}, Emna Bennour^{1,2}, Ikram Kammoun^{1,2}, Faouzi Addad^{1,2}, Afef Ben Halima^{1,2}, Salem Kachboura^{1,2}

1. University of Tunis El Manar, Faculty of Medicine, 1006, Tunis, Tunisia
2. Abderrahmen Mami Hospital, department of cardiology, 2080, Tunis, Tunisia,

Résumé

Introduction : Grâce aux progrès des techniques et du matériel et l'optimisation du traitement pharmacologique au cours des angioplasties coronaires, l'incidence des complications post procédurales a été considérablement réduite. Cependant, une hospitalisation en post angioplastie reste la stratégie adoptée par la plupart des centres de cardiologie interventionnelle.

But du travail : Rapporter l'expérience du service de cardiologie de l'hôpital Abderrahmene Mami en termes d'angioplastie coronaire ambulatoire (ACA) et évaluer sa faisabilité dans le contexte tunisien et ses résultats à moyen terme.

Méthodes : Notre étude est prospective, descriptive et analytique, incluant entre juillet 2015 et juin 2017, 115 patients ayant eu une ACA dans le service de cardiologie de l'hôpital Abderrahmene Mami. La survenue d'évènements cardiovasculaires a été évaluée après 24 h et à 3 mois.

Résultats : Au total, 115 patients (âge moyen $60,7 \pm 9,9$ années, 72,2% de sexe masculin) présentant 125 lésions coronaires, ont été inclus dans le protocole d'ACA. Les principaux facteurs de risque cardio-vasculaires étaient le diabète (69,9%), l'HTA (61,7%), la dyslipidémie (50,4%) et le tabac (35,7%). Soixante-seize pourcent de nos patients avaient un angor stable, 13,4% avaient un syndrome coronarien aigu, 5,2% avaient un angor instable et 5,2% avaient une ischémie myocardique silencieuse. Environ la moitié des patients étaient pluri tronculaires. Les lésions traitées étaient de type A, B1 (63,5%), type B2 (13%) et C (23,5%). La voie d'abord était la voie radiale (97,4%) et la voie cubitale (2,6%). Trois patients (2,6%) ont été finalement hospitalisés dont 2 pour causes cardiovasculaires (hématome de l'avant-bras). Aucun autre évènement cardiovasculaire n'a été noté durant les premières 24 h. Au cours du suivi, 1 cas de décès a été observé suite à une thrombose subaiguë de stent à J5. A 3 mois, la survie et la survie sans évènements cardiovasculaires étaient de 99,1% et 97,4%, respectivement.

Conclusion : L'ACA représente une approche intéressante et sûre chez des patients bien sélectionnés, avec très peu de complications et une excellente survie à moyen terme.

Mots-clés

Angioplastie, ambulatoire, évènements cardiaques majeurs

Summary

Background: Major advances in percutaneous coronary intervention (PCI) techniques have considerably reduced the incidence of post-procedure complications. However, overnight admission still constitutes the standard of care in most interventional centers.

Objectives : the aim of our study was to assess the safety and feasibility of ambulatory transradial-ulnar angioplasty in the Tunisian context.

Methods : We analyzed the outcomes of consecutive same-day discharge in 115 patients who underwent elective transradial-ulnar angioplasty without any procedural or hospital complication. Composite end point included 24 hour and 30-day major adverse cardiac cerebral events and bleeding/vascular complications.

Results : A total of 115 patients (mean age 60.7 ± 9.9 years, 72.2% male) with 125 coronary lesions were included in the ambulatory PCI protocol. Multi-vessel disease was found in the half of the patients. The treated lesions were type A, B1 (63.5%), type B2 (13%) and C (23.5%). The majority of procedures (97.4%) was performed via 6F radial approach. The procedural success rate was 100%. Three patients (2.6%) were finally hospitalized for one night, including 2 patients for cardiovascular causes (forearm hematoma). No other cardiovascular event was noted during the first 24 hours. During the follow-up, 1 case of death was observed following a subacute stent thrombosis carried by clopidogrel withdrawal. At 3 months, survival and survival without cardiovascular events were 99.1% and 97.4%, respectively.

Conclusion : In our center experience, ambulatory PCI represents an efficient and safe procedure in selected patients, with low rate of complications and good mid-term outcomes.

Keywords

Angioplasty, same day discharge, major cardiac events

Correspondance

Dr Lobna Laroussi
Abderrahmen Mami Hospital, department of cardiology, 2080, Tunis, Tunisia
email: Lobna_laroussi@hotmail.com

INTRODUCTION

Historically, percutaneous coronary interventions (PCI) have been considered an inpatient or short-stay procedure, usually involving up to 24 hours of observation. Technological advances, such as systematic stent implantation and improvements in adjunctive pharmacotherapy, have triggered a quantum shift in the location of care for PCI from the acute inpatient setting to the outpatient area.

Same-day discharge (SDD) after elective PCI is a potential strategy for improving the value of PCI as it is associated with greater patient satisfaction while simultaneously reducing costs [1,2]. Nevertheless, physicians have been resistive to these changes [3] for a multitude of reasons including: inertia, concerns of patient safety, ignorance about the changing outcomes of PCI procedures, and newer payer expectations for hospital reimbursement.

In a series of over 1000 transradial PCI's, Small et al. [4] confirmed that all post procedure complications could be and were identified within six hours of the procedure with complications between six and 24 hours being exceedingly rare.

The safety of same-day discharge following PCI has been demonstrated, provided that it is performed in selected patients [5]

The aim of this paper was to report the first experience

in a Tunisian center in terms of ambulatory PCI and assess its feasibility and its security in our context.

METHODS

Study population

We performed a prospective monocentric descriptive and analytical study including 115 patients who underwent ambulatory PCI at cardiology department of Abderrahmen Mami Hospital, Ariana between July 2015 and June 2017.

The study period was subdivided into 2 periods of equal duration: 1st period (July 2015 - June 2016) and 2nd period (July 2016 - June 2017)

Inclusion and exclusion criteria were summarized in the table 1.

STUDY PROTOCOL

Pharmacological Treatment: All patients were pre-treated with aspirin (100 mg/day) for more than 3 days. A 300-mg clopidogrel loading dose was administered to patients, including those already on maintenance clopidogrel treatment (75 mg/day). During the procedure, anticoagulation was achieved with a bolus of unfractionated heparin (70 IU/kg) injected immediately after insertion of the arterial sheath. After PCI, patients

Table 1: Inclusion and exclusion criteria of the study population

Inclusion criteria	- Age >18 years
	- Stable angina or silent ischemia
	- Non-ST elevation myocardial infarction (NSTEMI) stabilized with a delay between the PCI and the initial presentation greater than 5 days.
Non inclusion criteria	Clinical criteria
	- Symptomatic heart failure
	- Severe renal insufficiency (clearance <30 ml / min)
Exclusion criteria	Procedural criteria
	Social criteria
	- Failure of the radial or the ulnar access
	- Lesion-procedure: Procedure on left main coronary artery
	- Use of anti GPIIb/IIIa
	- Final flow <TIMI 3
	- Coronary dissection
	- Hemodynamic instability during the procedure
	- Ventricular arrhythmias during the procedure
	- Procedure completed after 15h.
- Non-cooperating patient or worry about treatment compliance	
- Travel time > 60 min between the patient's address and the hospital	
- Absence of family support	

were maintained on aspirin indefinitely and on clopidogrel according to current guidelines for bare metal stents and drug-eluting stents [3]. Other cardiac medications were continued as clinically indicated.

PCI procedure : The right radial access was the first intention way. In the absence of a right radial pulse, the choice between the right ulnar and the left radial was left to the discretion of the operator. PCI procedures were performed by 4 experienced operators according to international recommendations [6]. Haemostasis at the puncture site was achieved by a compressive bandage.

Patient discharge : At the end of the procedure, patients were transferred to the day hospitalization unit with permission to get up and eat 2 hours later. A clinical examination and an electrocardiogram were systematically performed. Patients were discharged in the absence of complications at the point of puncture, chest pain or electrical changes. Otherwise, patients were kept for overnight observation. Therapeutic education on the importance of compliance to treatment was performed in all patients and out-patients were informed about the need to consult promptly, directly to the service in case of symptoms occurring during the night. All patients were discharged from hospital four to six hours post sheath removal. They were requested to stay overnight within 60 minutes of the hospital.

Study end point

The primary end point of the study population was to evaluate the faisability and the safety of ambulatory PCI as assessed by the rate of complications within the first 24 hours of the procedure including :

- Major cardiovascular adverse events (MACE): MACE was defined as any myocardial infarction (MI), stroke, or cardiovascular (CV) death ;
- Hemorrhagic complications arising from arterial puncture or complicating anticoagulant and antiplatelet therapy are classified according to the BARC definition "Bleeding Academic Research Consortium"[4]
- re-hospitalization for cardiovascular cause in the first 24 hours
- Stent thrombosis

Successful ambulatory PCI was defined as absence of cardiac or vascular complications within 24 hr after discharge.

The secondary end point was to assess the rate of MACE at 1 month and at 3 months.

Statistical Analysis

Continuous variables were expressed as the mean plus or minus standard deviation, and quantitative variables were expressed as percentages. Variables were compared using Student's t test for quantitative variables and the chi-squared test for qualitative variables; a value of $p \leq 0.05$ was considered to be significant.

RESULTS

Patients

During the study period, 987 PCI were performed in our cardiology department, of which 115 were ambulatory (11.5%).with a marked increase during the second period of the study (7.5% during the first period versus 14.7% during the second period; $p < 0.001$).

Table 2 shows the baseline characteristics of the 115 patients finally included in the study and their comparison according to the study period. The mean age of the population was 67.73 ± 9.9 years, 73% were male, and there was a high percentage of diabetes (69.9%). Patients treated during the second period were older (62.3 ± 9.1 vs. 57.6 ± 11.5 years, $p = 0.007$) and had more significant higher rate of comorbidities (hypertension [$p = 0.002$]) and history of stroke [$p = 0.178$]

Table 2 : Baseline patients characteristics in the study population

	Patients N=115	1st Period N=35	2nd Period N=80	P
Age, y	60.7 ± 9.9	57.6 ± 11.5	62.3 ± 9.1	0.007
Male sex, n(%)	83 (72.2)	29 (34.9)	54 (65.1)	0.091
Diabetes mellitus, n(%)	70 (60.9)	18 (51.4)	52 (65)	0.170
Smoking, n(%)	41 (35.7)	21 (60)	20 (25)	<0.001
Hypertension, n(%)	71 (61.7)	14 (40)	57 (71.3)	0.002
Dyslipidemia, n(%)	58 (50.4)	15 (42.9)	43 (53.8)	0.282
stroke, n(%)	4 (3.5)	0	4 (5)	0.178
Renal failure, n(%)	6 (5.2)	2 (5.7)	4 (5)	0.874
Previous percutaneous coronary intervention, n (%)	55 (47.8)	16 (45.7)	39 (48.8)	0.764
Previous coronary artery bypass grafting, n (%)	8 (4.3)	1 (2.9)	7 (8.8)	0.253
EF, % ± standard deviation	52.8 ± 7.7	53.9 ± 7.2	52.5 ± 7.9	0.484
EF<40%, n(%)	2 (1.7%)	0	2 (2.5%)	0.345
PCI Indication (%)				
Stable angina	91 (79.1)	28 (80)	63 (78.8)	NS
Silent ischemia	3 (2.6)	1 (2.9)	2 (2.5)	NS
NSTEMI (delay>5 days),	21 (18.3)	6 (17.1)	15 (19.7)	NS

EF : Ejection fraction, NSTEMI : Non-ST-elevation myocardial infarction, NS : non significant

PCI procedure

The main angiographic and procedural characteristics are reported in table 3. The study population included a substantial proportion of patients with angiographically complex lesions and complex PCI procedures : multivessel coronary artery disease (n=59, 51,3%), multivessel intervention (n=10, 8,7%), restenosis (20 of 125 lesions, 16%), bifurcation lesions (11 of 125 lesions, 8,8%).

During the first period, more adhoc procedures were performed (48.6% vs. 12.5%, $p < 0.001$). Lesions treated

during the 2nd period were significantly longer (19.8 ± 7.7 vs. 17.2 ± 7.2 mm, $p = 0.038$).

Table 3 : Procedural characteristics in the study population

Angiographic characteristics	Total N=115	1st period N=35	2nd period N=80	P
Multivessel coronary artery disease	59(51.3%)	15(42.8%)	44(65%)	0.487
Lesions, n	125	36	89	NS
Location of lesion n(%)				
Left anterior descending artery	56 (44.8%)	23 (48.7%)	37 (43%)	NS
Circumflex coronary artery	25 (20%)	5 (12.8%)	20 (23.3%)	NS
Right coronary artery	44 (35.2%)	15	29 (33.7%)	NS
In stent restenosis, n(%)	20 (16%)	7 (19.4%)	13 (14.6%)	0.625
Bifurcation lesion, n (%)	11 (8.8%)	1 (2.8%)	10 (11.2%)	0.131
ACC/AHA lesion type				
A/B1	74 (59.2%)	23 (63.9%)	51 (57.3%)	NS
B2	15 (12%)	3 (8.3%)	12 (13.5%)	NS
C	36 (28.8%)	10 (27.8%)	26 (29.2%)	NS
Length of lesion, mm	18	17.2	19.8	0.038
PCI characteristics				
Ad hoc PCI	27 (23.5%)	17 (48.6%)	10 (12.5%)	<0.001
Final vascular access				
Right radial approach n (%)	99 (86.1)	30 (85.7)	69 (86.3)	NS
Left radial approach n (%)	13 (11.3)	4 (11.4)	9 (11.2)	NS
Ulnar route n (%)	3 (2.6)	1 (2.9)	2 (2.5)	NS
Drug eluting stent	72 (62.6)	19 (54.3)	53 (66.2)	NS
Bare metal stent	23 (20)	10 (28.6)	13 (16.3)	NS
Drug eluting balloon	17 (14.8)	6 (17.1)	11 (13.8)	NS
Balloon angioplasty	3 (2.6)	0	3 (3.7)	NS
Number of stents per procedure (mean±SD)	0.97 ± 0.56	0.91 ± 0.59	0.99 ± 0.58	0.522
Stent length, mm (mean±SD)	23.1 ± 8.7	22.9 ± 8.8	23.2 ± 8.8	0.946
Multivessel intervention, n(%)	10 (8,7%)	1 (2,9%)	9(11,3%)	0,142

ACC _ American College of Cardiology; AHA _ American Heart Association
NS: non significant

Observation and discharge

Of the 115 patients, 112 (97,4%) were discharged on the day of PCI. During the 4 h observation period, 2 patients developed a clinically significant puncture site hematoma with no need of blood transfusion requiring overnight admission.

Follow up and secondary end point

No re-admission and no MACCE occurred within the first 24h. The 1 month follow up showed one secondary end point. This event, occurring during the second period of the study was a fatal myocardial infarction 5 days after LAD PCI, caused by stent thrombosis (confirmed angiographically) and carried by clopidogrel withdrawal. At 3 months, survival and survival without cardiovascular events in our study were 99.1% and 97.4%, respectively.

DISCUSSION

Modern interventional cardiology has assisted in the past 30 years to an incredible evolution of techniques and technologies that nowadays allow the safe performance of procedures that, only a few years ago, were considered close to surgery. One of the major acquisitions is the shift from a femoral access to a radial one, as it is associated with fewer access-site complications and allows early ambulation [8,9]. This, together with the optimization of antiplatelet agents and advances in stents technology, reduced the rate of acute severe complications such as vascular access bleeding and acute stent thrombosis, questioning the need for a long hospital stay after uncomplicated PCI. Although several large scale prospective studies have assessed the feasibility and safety of same-day home discharge after PCI [table 5], additional data collected under the conditions of everyday practice are required before ambulatory PCI can be used on a routine basis. Our study showed that ambulatory transradial PCI was feasible and safe

These results are in agreement with previous studies of PCI using the transradial [10, 11] or transfemoral approach [11, 12 ,13].

The first study on same-day discharge reported by Kiemeneij et al [14] clearly demonstrated safety of early ambulation after transradial PCI. This was followed by the study on 922 patients reported by Koch et al. [15] that showed short-term triage of 4 h as sufficient and safe for same-day discharge. However, this was a highly selective study with guiding catheter size restricted to 6-F and only 20% use of stents. Because these patients underwent PCI using the femoral approach without the use of closure devices, a sizable number of patients were discharged back to the referring hospital for overnight care.

Knopf et al [16] reported a series of 90 patients randomly assigned to same-day discharge or overnight hospitalization. Of these, 33 patients underwent same day discharge. No complications occurred after discharge, and a satisfaction survey conducted with patients and relatives showed a high degree of comfort and preference for the same-day discharge procedure. Slagboom et al. [17] later reported safety of transradial PCI with 6-F guiding catheters and 40% usage of stents in the OUTCLAS (Outpatient Coronary Low-Profile Angioplasty Study) trial. Subsequent studies have demonstrated safety of the use of bivalirudin and GP IIb/IIIa inhibitors when discharging patients in the same day [18, 19]

To the best of our knowledge, our monocentric study was the first to evaluate the feasibility and security of outpatient PCI in the Tunisian context. It is also the first to evaluate such an approach in North Africa and in the

Table 5 : literature review of PCI with same day discharge

Reference	Year	Design	Access site	Eligible patients	Discharge patients	Anticoagulant	Procedure	Major complication from discharge to 24 hours	1 month (MACE) (%)
Kiemeneij, et al [14]	1994	Registry	Radial	188	100	regimen	PTCA/stent (BMS)	0	0%
Slagboom, et al [17]	2000	Registry	Radial	159	106	Heparin	PTCA/stent (BMS)	0	-
Netherlands	1999-2001	Registry	Radial	-	26	Heparin	PTCA/stent (BMS)	0	-
Gilchrist et al [18]	1998-2001	Registry	Radial	943	811	Heparin et abciximab	PTCA/Stent (BMS)	0	0.2%
Ziakas et al [20]	2003	retrospective	Radial/	644	375	Heparin	PTCA/Stent (BMS)	1	1%
Slagboom et al [11]	2003	Random	Femoral	150	120	Heparin	-	0	0.67%
Kumar et al [21]	2003-2005	Registry	Radial	504	443	Heparin et abciximab	PTCA/Stent (BMS+ DES)	N/A	1.6%
Bertrand et al [10, 22]	2001-2005	Random	Radial	442	387	Heparin et abciximab	PTCA/Stent (BMS+ DES)	0	0.68%
Wiper et al [23]	2005-2006	Registry	Radial	2189	1015	Heparin	PTCA/Stent	0	-
Small A et al [4]	2004-2007	Registry	Radial	450	12	Heparin/GPIIb/IIIa inhibitor	PTCA/Stent	0,2%	-
Jabara R et al [19]	2013	Registry	Radial	723	533	Heparin/GPIIb/IIIa inhibitor	PTCA/Stent	0,19%	0,56%
Co'rdoba-Soriano et al [24]	-	Registry	Radial and ulnar	115	112	NP	PTCA/Stent (BMS+ DES)	0	0.9%
Our study Tunisia	2015	Registry	Radial	-	-	Heparin	-	-	-
	2015-2017	(prospective)							

Arab world. . The majority of procedures (97.4%) was performed via 6F radial approach. The cubital access was the alternative way (2,6%). The procedural success rate was 100%. Two major concerns related to early discharge of PCI patients are bleeding risk and stent thrombosis.

Trans radial approach (TRA) was shown to reduce access site complications [25, 26]. Even with the use of aggressive antithrombotic agents, bleeding complication rates were extremely lower than for femoral access [27, 28]. The RIVAL study showed, for instance, that TRA is associated not only with a lower rate of local vascular complications in the overall population, but also with a reduction in mortality in the setting of acute PCI [29]. These results have been confirmed in another randomized study (the RIFLE-STEACS study), in which a relative reduction in access-site complications and in mortality of nearly 40% was found by ST-segment elevation myocardial infarction patients in cases of TRA (vs transfemoral approach) [30].

In our study, no major bleeding complications which required transfusion was observed despite intensive antithrombotic therapy. Two patients had forearm hematoma due to radial artery perforation with the guidewire and were successfully managed conservatively with pressure bandage.

In recent studies, which utilize dual antiplatelet therapy and high-pressure balloon inflations, the incidence of stent thrombosis is reported between 0.5% and 1.9% [31, 32]. Furthermore, with modern devices and antithrombotics, this rare complication occurs mostly in the first 6-hour period [33, 34]. In accord with the literature in our study, no patients had stent thrombosis during the 4th to 24th hours. During the follow-up, 1 case of death was observed following subacute stent thrombosis.

Our study has the advantage of being prospective and being performed in a center where all interventions were almost via the transradial route (98,5%). Complex PCI patients were also included in the study without the conflict of selecting a low-risk profile, and therefore, representing real-world practice. The study population included a substantial proportion of patients with angiographically complex lesions and complex PCI procedures : multivessel coronary artery disease (n=59, 51,3%), multivessel intervention (n=10, 8,7%), restenosis (20 of 125 lesions, 16%), bifurcation lesions (11 of 125 lesions, 8,8%).

Koutouzis et al [35] demonstrated that selected patients undergoing elective complex PCI using a forearm approach can be safely discharged home on the same day. Among the patients who underwent complex PCI (n = 166), twenty eight (16.9%) were discharged the same day. SDD after complex PCI was associated with younger age and more frequent use of forearm access. The 30-day incidence of major adverse cardiac events after complex PCI was 0% vs 3.6% (p = 0.59) in patients with SDD vs. overnight hospitalization.

More than half of our patients (51.3%) have multivessel coronary disease. This rate is similar to that reported by Le Corvoisier et al. [36] (52.3%) and higher than that found in the meta-analysis of Brayton et al. [37] (27.4%). In addition, with

experience, during the 2nd period, PCI procedures were performed in older patients, with higher cardiovascular risk, longer and more complex lesions, and more vascular axes were treated during the same procedure.

CONCLUSIONS

Same-day discharge with a 4-hour observation period is

safe and feasible after successful transradial PCI in appropriate patients. Although a minor number of complications occurred, these did not occur between the 4th and 24th hours. Same-day discharge after successful transradial PCI could be an alternative for better utilization of resources. Economic studies are also needed to determine the real impact of this strategy in Tunisia.

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