Research Article

Outpatient Coronary Angioplasty: Feasibility, Safety and Cost for the Creation of a Day Hospital Unit

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ABSTRACT

Same-day discharge after Percutaneous Coronary Intervention is a marginalized strategy mainly because of hemorrhagic and vascular risks, but also represents a topical approach by its ambulatory nature.

Objective of the study: Study the feasibility, safety and cost of ambulatory coronary angioplasty and to propose a plan for the creation of a day hospital unit at Mohammed VI University Hospital Center of Marrakech.

Patients and methods: This is an observational prospective study over a year, involving 100 cases with stable coronary artery disease with known coronary anatomy, admitted to the cardiology department Mohammed VI University Hospital Center Marrakech for an outpatient coronary angioplasty.

Results: The average age was 58,5±23,5 years. The sex ratio was 1,38. Coronarography is performed in 100%. Single-vessel damage exists in 44%, two vessels damage in 32%, and a three vessels damage in 24%. Vascular access was via the radial approach in 73% of cases. Dugs eluting stents were used in 90% of cases. The success of angioplasty was noted in all PCIs. The average length-of-stay following PCI was 330 minutes±90min.In addition to this, we found a significant difference between the cost of a day hospitalization (outpatient) and the conventional hospitalization, hence the value of creating a day hospital unit.

6 of the patients had persistent chest pain and 6% had a hematoma at the puncture site. No serious clinical event within 24 hours was found. For medium-term follow-up, an angina recurrence was observed in 6% of cases.

Conclusions: According to this study, we have shown that outpatient angioplasty is feasible, safe and less expensive than conventional angioplasty, so we have proposed a plan for the establishment of a day hospital unit to follow the patients.

INTRODUCTION

Coronary artery disease is one of the most common cardiovascular diseases with a very common life-threatening and longer-term prognosis. Coronary angioplasty was performed for the first time by Andreas Gruentzig in 1977. This major therapeutic revolution completely changed the approach to coronary heart disease and its prognosis [1,2]. In addition, with the birth of the stent in 1990 and the drug-coated stent in 2000, coronary angioplasty developed strongly. Gradually, it became possible to offer some patients an exit the same day, it is the outpatient angioplasty or Same-Day Discharge. This new offer of care is based on the observation of an absence of complications during the usual monitoring phase in post-angioplasty. The

first outpatient angioplasty pilot study was conducted in 1994. Laarman et al., [3] already suggested that an ambulatory angioplasty strategy could be safely performed in highly selected patients. The publication of two large randomized studies (EASY study 2006 and the 2007 EPOS study) [4] has given rise to a renewed interest in outpatient angioplasty, motivated in particular by economic considerations.

METHOD

This is a prospective observational study conducted in the cardiology department of Mohamed VI University Hospital of Marrakech between March 2017 and March 2018, with 100 patients with stable coronary artery disease with known coronary anatomy, admitted for coronary angioplasty programmed outpatient. Case collection was done from coronarography and angioplasty reports, and by phone contact. Our patients were contacted by phone 24 hours after their release, and reviewed in consultation on the 15th day and the 30th day. The main of our work is to study the feasibility, safety and cost of outpatient angioplasty; to propose a plan for the constitution of a day hospital unit.

The inclusion criteria:

- Patient with stable angina with known coronary anatomy.
- Absence of severe renal insufficiency (creatinine clearance greater than 30 ml / min)
- Percutaneous coronary intervention (PCI) success.
- Absence of chest pain at the end of the procedure.
- No complications of the vascular approach.

The exclusion criteria:

- All acute coronary syndromes.
- Persistent chest pain at the end of the procedure.
- Use of antiGPIIb / IIIa.
- Final TIMI flow <3.
- Significant complications of the procedure (acute coronary occlusion in periprocedure, coronary perforation, vascular complications).
- Hemodynamic instability during the procedure.
- Creatinine greater than 1.5 mg / dl without hemodialysis.
- Ventricular or atrial arrhythmia during the procedure.
- LVEF <30% or decompensated systolic heart failure.
- Uncontrolled diabetes.
- Patient living alone at home.
- Doubt about the patient's understanding.

RESULTS

The average age of our patients was 58.5 ± 23.5 years. Male predominance was noted (58%) with a sex ratio of 1.38. The majority of our patients were covered by the RAMED system (87 patents), 6 were mutualists and 7 patients were without social coverage. 52% of the patients were hypertensive, 31% of the cases were active smokers. Diabetes was present in 53% of cases. 19% of the patients had a ST-segment elevation coronary syndrome in their history and 2% a coronary syndrome without segment elevation. 91% of our patients consulted for chest pain, 5% for dyspnea. 53 patients had a normal electrocardiogram, 37% had a negative T-wave or an ST-segment offset. A lesion of the anterior interventricular artery was found in 43% of cases. The results showed single ventricular involvement in 44 patients, bitroncular involvement in 32% of cases and tritrocular lesion in 24% of cases. This study identified a type B lesion in 76 patients, type C in 21 patients and type A in 3 patients. Angioplasty was performed in all our patients with an indication of outpatient status. It was reported with significant truncal lesions, of which 62% involved the anterior interventricular artery, 27% the right coronary artery, 13% the circumflex artery, 7% the marginal artery and 1% the diagonal artery. The approach was radial in 73% of cases and femoral in 27% of cases. Medication during the procedure administered in our patients was: unfractionated heparin, clopidogrel, aspirin and intravenous nitrate derivatives. The drugs eluting stents were used in 90% of the cases. The catheters used were mainly of size 6 french (84% of the cases), against 16% of 5 french. The average stent length was 15 ± 5mm. Success has been achieved in all patients. The average length of stay after angioplasty was 330 min ± 90 min (5h30min ± 90 min).

The after angioplasty medical treatment was based on the systematic combination of aspirin with a dose of 75 to 100 mg / day for life, clopidogrel (Plavix* 75 mg / day) for 12 months of statins and betablockers for life and angiotensin

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converting enzyme inhibitors especially if left ventricle dysfunction.

As for the evolution, 15 patients required hospitalization in the hours following the intervention for different reasons:

- Persistence of chest pain in 6 patients (6%).
- Complicated angioplasty of hematoma in 6 patients.
- Difficult outpatient surveillance in 3 patients for blood pressure peaks.

The 85 patients left the same day of their intervention, after duration of surveillance ranging from 4 to 7 hours at most.

The change in less than 24 hours was marked by the persistence of chest pain in 6 patients (6%), palpitations in 11 patients and hematoma at the puncture site in 6 patients. The evolution of patients in the ambulatory group (n = 85) from day 24 to day 15 was marked by the appearance of pain in 5 patients (6%), palpitations in 6 patients (7%), bruising and hematoma at the puncture site in 14 patients (16%) and 15 patients (18%) respectively without thrombocytopenia, without electrical modifications. The progression from day 16 to day 30 was marked by the reappearance of palpitations in 9 patients (11%), and 22 patients had a recurrence of chest pain.

Health and dietary measures have been indicated in our patients to improve their lifestyle and control cardiovascular risk factors. In this study we emphasized the importance of good adherence to treatment. No patients stopped treatment, and all took Plavix * without changing this family. 7% of cases (6 patients) had complications one month after their angioplasty:

- One stroke in one patient (1.16%).
- Heart failure in two patients (2.34%).
- A myocardial infarction was noted in 3 patients (3.5%).

No cases of stent thrombosis, major bleeding or death were noted.

Day hospitals are a type of outpatient health care service that has been around for years. They were created in contexts where the primary concern was the introduction of more humane and less costly alternatives to hospitalization. The reconfiguration of services was designed to reduce costs and provide care closer to the living environment of people who would be less stigmatizing. The first day hospital opened in 1946 at the Allen Memorial Institute of Montreal (Goldman, 1989).

Outpatient angioplasty is defined as a programmed act, performed in a secure environment under local anesthesia followed by surveillance allowing an exit the same day of the intervention without additional risk. This is why it demands a meticulous organization and the support of all the stakeholders (cardiologists, paramedics, secretaries, stretcher-bearers, administrative staff, etc.) who are the guarantors of success for the opening and the perpetuation of such an activity. The arrangements for organizing the outpatient activity are based on three levers:

Prepare the setting up of the outpatient activity upstream

- Define the number of places for coronary angiography and angioplasty per day and per hour with the outpatient department.
- Train ambulatory staff to follow up on patients who have had coronary angiography and / or angioplasty (follow-up, radial bracelet management, complications..).
- Select patients compatible with ambulatory activity:
  - Cardiac stable patients.
  - Staying less than an hour from the hospital.
  - Having a companion for the return home.
  - Presence of a companion the night following the examination.

Organize the patient's day:

A. Making a phone appointment:

- Set the date and time with the patient and / or his cardiologist.
- Send by mail or mail:
  - The convocation specifying the date, time and service where the patient will be expected and the documents to bring back
  - The ambulatory instruction sheet.
  - The informed consent form

B. The day of the exam

- The patient presents to the outpatient department (day hospital) at the convocation time.

- The nurse takes care of the patient, directs him to his box and asks him to put on the block pajamas, warns the interventional cardiology department of the arrival of the patient.
- The secretary checks the file and the nurse in the catheterization room greets the patient and perfuses him.
- The patient is installed in the coronarography room.
- After the procedure, the patient is monitored for ½ hour in the Post-interventional Monitoring Room, with an armchair installation.
- Return to ambulatory service (surveillance and snack).
- Delivery of the report and specific instructions related to the outpatient, validation of the discharge by the interventional cardiologist.

This project requires equipment in line with the population welcomed.

✓ **THE FIRST STEP:** Presentation of the health facility

- Name of Institution: Day hospital for coronarography and ambulatory angioplasty.
- Status: Public.
- Number of beds and places according to the population welcomed.
- Main activities: Reception of patients scheduled for diagnostic coronary angiography and / or ambulatory angioplasty and their interventional follow-up.
- Cooperation with other institutions, in particular with Mohammed VI Hospital, cardiology department in Marrakech, and with other services

✓ **SECOND STEP:** Progress of the accreditation and authorization procedure of the project

This authorization procedure concerns the day hospital for coronary angiography and angioplasty for outpatient purposes, it consists in carrying out an evaluation by a multi-professional team and communicating the experts' report with the board of directors and the management board, and in particular, to communicate the project implementation modalities, and to evaluate the security of the proposed project. As well as observations and information complementary to the experts' report will have to be provided by the board of directors. And the latter then decides that the establishment covered by this report has or has not complied with the accreditation procedure.

✓ **THE THIRD STEP:** CLARIFYING THE MANAGEMENT AND OPERATION OF THE DAY HOSPITAL

- Rights and patient information:
- Organization of patient care and follow-up
- Financial management of the establishment:
- Human Resource Management:
- Management of logistics functions:

- **Local:**

We propose:

- A day hospital unit with a suitable area.
- A reception
- An independent pharmacy, dedicated only to patients in care. In the day hospital unit.
- Office of the Nurse Major.
- A room for doctors.
- A room for the nurses.
- Cloakroom for the staff

- **Equipment:**

We propose a day hospital unit made of:

- Four beds with scopes for angioplasty.
- Four chairs for diagnostic coronary angiography.
- An emergency cart.
- An electrocardiogramm.
- Four DINAMAPs (the DINAMAP patient monitor provides basic vital signs).

- **Personal:**

- A doctor assigned to the day hospital.
- A nurse major or responsible
- A day nurse
- A medical secretary
- A stretcher
- A maid

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The plurality of the staff and the diversity of the caregivers' roles, the quality, the coherence of the team are necessary conditions to develop long-term care projects, which require great vigilance in order to remain dynamic projects both for the sick only for his family.

DISCUSSION

The annual mortality rate for coronary artery disease was 2% in the SAPAT study; 1.1% in the APSIS study; 1.5% in the ACTION study; 2.4% in the BARI 2D study; and 3% in the IONA study [5,6].

In Morocco, a pathology remains at the forefront of public health concerns. Its morbidity remains high. Indeed, once the positive diagnosis is made, care must be taken as soon as possible to avoid complications and sometimes fatal outcome.

The average age in some studies is close to that of our service, which was 58.5 ± 23.5 years. A male predominance is found in all series with a sex ratio H / F ranging from 3.09 to 6.7 according to the work of Mehul Patel [7], Ziakas AA [8]. As for this series, the sex ratio M / W was 1.38.

Thoracic pain is the reason for consultation in 91% of our patients, compared to 93.4% in the RICA 2000 study [9], and 94% according to OSCAR [10].

The purpose of coronary angiography is to objectify revascularization-related coronary abnormalities that are proven to be effective. The systematic analysis of the images must specify: [11,12]

- The importance and topography of the lesions, their proximal or distal site, their number, their diffusion, and the quality of the downstream network.
- Collateralities
- The distribution of homo and contralateral anastomoses and their modalities of operation.
- Myocardial perfusion.

Our results showed a predominance of monotruncular involvement in 44% of cases, in agreement with AAZiakas and klinke [8] in 84.5% of cases, and in 42.7% for Ferrier and al [13].

The therapeutic means are based on:

A. Pharmacological treatment:

Therapeutic decision tree of stable coronary disease according to ESC recommendations

B. Coronary Angioplasty [14]:

On the basis of these studies (Brazilian MASS study, AVERT study, ACIP study), it seems legitimate to propose the optimal medical treatment associated with the correction of risk factors and first-line lifestyle modifications in most patients. few symptoms (CCS1 and 2) and to reserve the angioplasty for those with more severe symptoms (CCS3 and 4) and / or to preserve signs of ischemia even painless under treatment. A young and active patient wishing to maintain a physical activity will be more likely to revascularize.

The radial route is safer to avoid hematomas at the point of puncture. It offers the possibility of an immediate lifting of the patient. In this series, the approach was radial in 73% of cases. Against 97.5% according to Juan G 2017 [15], 100% according to Corvoisier P 2013 [16] and 7% according to Shailesh Khatri 2002 [17].

In this series, implantation of drugs eluting stents involved 90% of cases, ie 90 of our patients stented. At the French national level, it was 45% in 2008 [18] as well as in the work of Puymirat et al of the Georges-Pompidou European Hospital, the percentage of drugs eluting stents implanted was 35% [19]. And 49.3% in the study of Arnaud Chaumeil [20].

The introducer who introduced the angioplasty material is immediately removed to the catheterization room. Manual compression at the puncture point is performed. Then, a compressive bandage is set up at the arterial puncture site to prevent bleeding.

At the exit, a medical prescription was prescribed to all our patients,

- ✓ Prescription of long-term aspirin at a dose of 75 to 100 mg / day for life.
- ✓ Prescription of clopidogrel at a dose of 75 mg daily for 12 months in combination with aspirin.
- ✓ Prescription at the exit of long-term beta-blockers if left ventricle dysfunction or rhythm disorder or heart failure.
- ✓ Prescription of long-term statins with control of the lipid balance at 3 months.
- ✓ Prescription at the exit of inhibitor of the converting enzyme in the long run.

During the hospital phase [14], it is necessary to detect an ischemic recurrence, to ensure a monitoring of the arterial

pressure and the heart rate, to check the haemostasis of the point of puncture, to detect a haemorrhagic complication patent or latent by the surveillance of the Hematocrit, Remind and raise awareness of secondary prevention measures not only pharmacological but also dietary and hygiene.

During the after hospital phase, the risk of acute thrombotic stent occlusion is very low. For all that, this will be the first diagnosis to evoke in front of an anginal recurrence in the first days after angioplasty. Emergency hospitalization is therefore essential. It is essential to follow up regularly at 1, 3, 6 and 12 months following an intervention.

The success of angioplasty can be defined by angiographic, operative and clinical criteria [14]. In this study, the success rate of angioplasty was 100%. As well as that of the study " COURAGE " was of the order of 93%.

In regards to the feasibility and safety of outpatient angioplasty: [16,21]

a. The feasibility:

The success rate of angioplasty was calculated to evaluate the feasibility of outpatient angioplasty in selected patients. Success was defined by the absence of complications with optimal angiographic results and peri-procedural and after operative clinical stability during the observation period.

b. Security:

- Major complications, as defined by the recommendations of the Academic Research Consortium (ARC):
  - Death
  - Myocardial infarction with or without Q wave
  - Stent thrombosis
  - Need for repeated revascularization of the target vessel guided or not by the clinical picture.
  - Need for repeated revascularization of another ischemic vessel.
  - Major bleeding
  - Stroke: transient ischemic attack or ischemic / haemorrhagic stroke.
  - Renal insufficiency induced by the contrast medium.
  - Complications of vascular access requiring surgical treatment or involving major bleeding.
- Minor complications were those related to vascular access, requiring no admission or surgical treatment and not involving major bleeding.

The first outpatient angioplasty study reported by Kiemeneij et al [22] clearly demonstrated the safety of same-day discharge after transradial percutaneous coronary intervention. This was followed by a study of 922 patients reported by Koch et al [23], who showed that 4-hour surveillance was sufficient and safe for a same-day discharge after angioplasty.

The EPOS study, published in 2007, is a single-center Dutch study that randomized 800 patients and validated ambulatory femoral angioplasty.

The study by Juan G [15], published in 2017 is a Spanish, multicenter study that randomized 723 patients, showed that radial approach angioplasty in selected patients is a safe and feasible strategy.

We began this prospective study with the intention of studying the feasibility and safety of the patients included for symptomatic coronary artery disease under ambulatory care by angioplasty under local anesthesia. The rate of after angioplasty events is low and the mortality rate is nil comparable to other series of outpatient angioplasty.

The main conclusion of this series is that outpatient angioplasty is an effective and low risk technique.

These results are consistent with data from the literature since Juan G. [15], Muhel Patel [7], and other authors have significantly demonstrated the feasibility and safety of angioplasty in outpatient mode whatever the pathway first (radial or femoral).

The potential benefits of outpatient angioplasty:

Relieving the hospital sector and thus improving the availability of beds.
Optimize the management of hospital resources.
Patient satisfaction and de-dramatization of acts.
Quality and safety of care with fewer nosocomial diseases.
Reduce the cost of hospitalization.
Improve working conditions for caregivers, including reducing night work.
Better care for secondary prevention: Passage of the dietetic nurse, explanation of the need for a double platelet anti-aggregation by the doctor of the day hospital.

the main factors limiting the generalization of outpatient coronary angioplasty are the risk of stent thrombosis and complications at the point of puncture which we can easily imagine the otherwise more pejorative consequences in case of occurrence in the home.

In practice, an outpatient angioplasty strategy therefore requires a minimum of organization upstream of admission and must focus on securing as much as possible the 18 hours that make up the evening, the night and the morning following the procedure (Thrombosis of stent, Complications of the approach, Education of patients).

In the first part of our work, we studied the financial status of our patients, of which 87% were covered by the RAMED system, 6% were covered by the CNOPS and the CNSS and 7% did not have social security coverage. And according to this distribution we were able to estimate the cost of the angioplasty and the expenses of hospitalization either of day (the ambulatory maximum 7 hours) or conventional.

Knowing that in our cardiology department, we do not have a day hospital unit to accommodate our patients after any angioplasty scheduled outpatient, it forced us to put them during the surveillance period in the clinical sector or in the hospital, and therefore an occupation of a place usable for other emergencies.

Using the data developed by the Basic Compulsory Health Insurance (Table 1), we were able to highlight a significant difference in the cost of outpatient angioplasty versus the conventional one, usually involving two nights in the hospital for a global stay. three days. The least expensive procedure was outpatient angioplasty with a duration of stay of no more than 7 hours after procedure, compared with conventional angioplasty. The latter was more expensive regardless of the room of hospitalization: the clinical sector, or the intensive care unit. (Table 2,3)

In addition to this study, several studies have shown a financial gain generated by outpatient care, in the order of $ 1,200 / patient in North America. A French medico-economic study of "microcosting" [16] estimated the theoretical gain at € 1200 compared to the cost of a conventional hospitalization of short duration (usually 3 days / 2 nights). But the selection criteria do not yet appear explicitly in the international recommendations (Figure 1)

Shailesh Khatri et al [17], have highlighted the financial importance for hospitals to substitute outpatient procedures for conventional procedures, particularly in the case of angioplasty.

According to the data of Arnaud Chaumail et al [20], the execution of the outpatient procedure increases the flow of patients with the same number of beds and staff.

The lack of specific pricing for ambulatory angioplasty at the level of the Fiscal Assistance Office university hospital Mohammed VI of Marrakech, remains an unavoidable obstacle in our study.

Table 1: Fixed rates of acts of interventional cardiology.

DESIGNATION	RATE IN DH	PACKAGE ELEMENTS
DILATATION ARTERA CORONARY WITHOUT STENT	16 500,00	The package includes: - Hospitalization four days maximum in clinical sector - Hospitalization one day in intensive care unit (if necessary) - necessary medical procedures - Medical care…
DILATATION ARTERY CORONARY + 01 BARE STENT + PUT	24 500,00	
DILATATION ARTERY CORONARY + 02 BARE STENTS + PUT	32 500,00	
DILATATION ARTERY CORONARY + 01 DRUGS ELUTING STENT + PUT	46 500,00	
DILATATION ARTERY CORONARY +01 DRUGS ELUTING STENT +01 BARE STENT + PUT	54 500,00	

Table 2: Economic comparison of a day hospitalization (outpatient) versus conventional hospitalization (2 nights) according to the AMO.

	Price (in DH)	Price (in DH)/2 nights
Short-term hospitalization in the clinical sector	550,00 DH/ day + 1 night	1100,00
Short-term hospitalization in the intensive care unit (if lack of space in the clinical area)	1000,00 DH/ day + 1 night	2000,00
Day hospitalization (including a stay of less than 7 hours)	200,00 DH/ day	-

Table 3: Comparison of outpatient angioplasty and Conventional Angioplasty Cost.

Cost of dilation of coronary artery (s) with drugs eluting stent + day hospitalization (outpatient)	Cost of dilation of coronary artery (s) with drugs eluting stent + short-term hospitalization (2 nights) in the clinical sector
46 700 DH	**47 600 DH**

Hospitalisation de jour :
GHM 05K06T « endoprothèse vasculaire sans infarctus du myocarde, séjour de très courte durée ». Valorisation 1895,16 €.
Hospitalisation de courte durée (2 nuitées) :
GHM 05K061 « endoprothèse vasculaire sans infarctus du myocarde, séjour de niveau 1 » (en l'absence de complication). Valorisation 2689, 24 €.

Figure 1: Valorisation of coronary angioplasty (price 2017) These rates concern the valuation for hospitals in Ile de France (+ 7% compared to other French regions) [21].

RECOMMENDATIONS

– Ambulatory angioplasty for low-risk, carefully selected patients

– Outpatient procedure should not be considered in high risk patients.

– The radial approach is currently the path of choice for outpatient angioplasty.

– The importance of monitoring 4 to 7 hours after angioplasty, then phone conversation the next day and 1 month.

– At the end of this study, it is possible to think in depth about the feasibility, the safety of outpatient angioplasty in Morocco.

– We insist on the importance and interest of building a day hospital unit in order to welcome and follow patients after any scheduled cardiological intervention. This structure is an essential link between the catheterization room and the extra-hospital care of the patient.

⇒ Waiting for clear recommendations to develop and expand ambulatory activity in interventional cardiology.

CONCLUSION

Outpatient coronary angioplasty remains a topical approach because of its ambulatory nature, the advantages of which are the reduction of the length of stay, thus a limitation of the bed occupancy time and their availability, the reduction of the hospital costs, the comfort of the patients.

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