Feasibility of outpatient coronary angiography with ‘‘ad hoc’’ angioplasty

Faisabilité ambulatoire d’un examen coronarographique avec angioplastie « ad hoc »

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KEYWORDS
Ad hoc angioplasty; Outpatients; Radial route

Summary To assess the feasibility and safety of coronary angiography combined, where necessary, with ad hoc angioplasty in an outpatient setting; a prospective, single-center study. The first 172 patients (154 men, 59 ± 11 years) considered at low risk for complications were enrolled for outpatient-coronary angiography with or without angioplasty via a radial approach. The inclusion criteria were clinical, not based on angiography. After angiography/angioplasty, creatinine and troponin were assayed (outside the hospital) within 24 h and patients were telephoned and asked about their clinical condition. Angioplasty was performed in 69 (40%) patients and 130 patients (75.6%) were discharged on the same day. In the angioplasty group, a history of coronary dilatation was more common in patients discharged on the same day (p = 0.05), whereas bifurcation lesions were more frequent in subjects who were kept in hospital (p < 0.0001). No serious complications occurred during the study. Of the 42/172 prolonged hospitalizations, eight were due to minor procedural complications, five due to failure of the radial route and three for indications for bypass surgery; the others were kept in for reasons unrelated to a complication (e.g., the examination was performed late in the day, a particularly complex procedure, etc.). Four (3%) of the 24-hour telephone calls led to a visit, but not hospital admission. Overall, performing angiography and ‘‘ad hoc’’ angioplasty in the course of a single outpatient visit makes it possible to foreshorten the hospital stay.

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and increase patient throughput with a given hospital capacity and, this, without increasing clinical risk. Exactly how these patients are selected remains to be defined and may certainly be improved compared to this initial experiment. An outpatient-coronary angiography and ad hoc angioplasty strategy is a viable option with a low risk for patients selected on the basis of simple clinical criteria. It combines the advantages of increased convenience for the patient and lower costs.

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Introduction

Coronary angioplasty is the most widely used coronary revascularization technique at the present time. There is a continuous and regular increase in demand and in the number of procedures because of the ageing of the population and improvement in diagnostic methods. Responding to this demand means increasing the number of coronary angiography examinations performed and, inevitably, foreshortening hospital stays because hospital care capacity is fixed.

A few studies have reported the feasibility of elective outpatient-coronary angiography or angioplasty. The purpose of our study [1–3] was to investigate the feasibility and safety of combining coronary angiography and angioplasty in the course of the same procedure (“ad hoc”). Patients were, therefore, selected without previous knowledge of the nature and number of their coronary lesions.

Methods

Population

Between September 2002 and August 2004, 172 patients aged over 18 years were admitted into the Pitié-Salpêtrière hospital cardiology department for outpatient coronary angiography combined or not with angioplasty, in the framework of a prospective registry.

Hospitalization was scheduled during a hospital cardiology visit during which patients were informed about the risks and benefits of the intervention and their informed consent was obtained.

Inclusion and exclusion criteria

In this initial experiment, inclusion and exclusion criteria were defined to select patients with a low risk of complications [4]. They are detailed in Tables 1 and 2.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Inclusion criteria for outpatient intervention.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Stable patient</td>
</tr>
<tr>
<td>2.</td>
<td>Patient accompanied for 24 h after the procedure</td>
</tr>
<tr>
<td>3.</td>
<td>Confirmed indication for coronary angiography and a scheduled examination</td>
</tr>
<tr>
<td>4.</td>
<td>Patients given a number to call if they have any questions or problems during the 24 h after the procedure</td>
</tr>
<tr>
<td>5.</td>
<td>Laboratory testing before catheterization</td>
</tr>
</tbody>
</table>
Procedures

Laboratory blood tests — a complete blood count, a coagulation workup, blood-typing with an abnormal agglutinin test, blood electrolytes as well as urea, creatinine and troponin — were performed within 48 h of admission into the outpatient clinic.

Aspirin and clopidogrel were systematically prescribed in the absence of contraindications and initiated at least three days before hospitalization. Patients came to the hospital with their laboratory results on the day of the intervention at least two hours beforehand. A physical examination and ECG were carried out and patients were kept hydrated by intravenous infusion of normal saline (1 l/12 h) until discharge.

Radial coronary angiography was conducted under local anesthesia with six French size equipment. The decision whether or not to conduct angioplasty and add anti-GP2B3A was left up to the operator. Intravenous Enoxaparin (0.5 mg/kg) was administered to all patients immediately after insertion of the introducer. If prescribed, anti-GP2B3A was administered through discharge. Post-procedure monitoring was begun in the cardiac catheterization room and continued in the hospital room. Patients were systematically examined for local complications at the puncture site and a 12-lead electrocardiogram was recorded on return to the examination room.

Criteria for prolonging hospitalization

Patients were discharged 4 h after release of radial compression, without neutralization of the anticoagulation by low molecular weight heparins. The patient was examined and a second reading of the coronary angiograms was made by a different hemodynamics specialist from that who had conducted the catheterization. Troponin Ic was assayed before discharge. Laboratory tests including an assay of creatinine and troponin Ic were performed within 24 h of the examination. Predefined criteria for prolonging hospitalization are given in Table 3. Patients were systematically telephoned on the day after the procedure. They were recalled to the hospital if they had symptoms of angina, a rise in troponin above 2 μg/ml or a 30% increase in creatinine.

Statistical analysis

Data were analyzed using State view statistics software (SAS institute Inc, version 5.0). 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

Population

The study population comprised 172 patients selected between September 1, 2002 and August 31, 2004.

The characteristics of the study population are summarized in Table 4. Overall, the ejection fraction measured by ultrasound or angiography was conserved and only 50 (29%) patients presented an ejection fraction less or equal to 50%.
Twenty-eight (16%) patients presented moderately impaired kidney function with a creatinine clearance less or equal to 60 ml/min and one subject had had a kidney transplant.

No selection was made for body weight as the values ranged from 43 to 117 kg.

A total of 69 (40%) patients underwent angioplasty of one or more vessels during the same intervention. For 103 (60%) patients, coronary angiography was either normal, showing neither lesions nor restenosis (in patients with a history of angioplasty) or it showed severe lesions requiring medical or surgical treatment.

Results

Description of the procedure and coronary lesions in the diagnostic coronary angiography and angioplasty groups

The results are summarized in Table 5.

A femoral approach was necessary in four patients. A humeral approach was used for one angioplasty. The radial route was possible for 97.1% of subjects.

In the coronary-angiography group without angioplasty, 69 (67%) patients had a normal or subnormal coronary angiography (without stenosis or significant restenosis). Four (3.8%) subjects presented complex involvement of the distal main trunk requiring surgical treatment. A single-vessel bypass graft was proposed in one patient with single-vessel disease after a third recurrence of LAD in-stent restenosis. The last 29 (28.2%) patients had distal-coronary lesions or an old occlusion not permitting revascularization and were given medical treatment.

A further 28 (16%) patients presented moderately impaired kidney function with a creatinine clearance less or equal to 60 ml/min and one subject had had a kidney transplant.

No selection was made for body weight as the values ranged from 43 to 117 kg.

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Description and results of angioplasty and stenting

Eleven (15.9%) patients were revascularized on two vessels during the same procedure and 18 bifurcation lesions were treated (Table 6). In 14 patients (20.3%), two stents were implanted during the same intervention and three stents were implanted in three (4.3%) patients. One in-stent restenosis was corrected by a drug-eluting stent: this subject has a past history of angioplasty on the unprotected left main coronary artery.

Events occurring during hospitalization

No death, infarct, hemorrhage, stroke or early major allergic reaction occurred in either population. Likewise, no emergency revascularization or bypass surgery was necessary for complications caused by the examination. However, one patient presented skin erythema, which rapidly regressed with corticosteroids.

Coronary-angiography group without angioplasty

Thirteen of the 103 patients (12.6%) not undergoing angioplasty remained hospitalized for the night after their examination, including six who had no complications. The reasons are given in Table 7.

The other seven had significant coronary lesions. Three patients with complex disease of the left main trunk and one patient with single-vessel disease were proposed surgical revascularization. Medical treatment was optimized for the three others.

<table>
<thead>
<tr>
<th>Table 5 Description of lesions in the diagnostic coronary angiography and angioplasty groups.</th>
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<tbody>
<tr>
<td>Table 6 Description of angioplasty procedures.</td>
</tr>
</tbody>
</table>

Table 7 Reasons given for prolonging hospitalization after coronary angiography or angioplasty.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Number of patients n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma of forearm</td>
<td>1</td>
</tr>
<tr>
<td>Myocardial ischemia (pain or postprocedure ECG abnormality)</td>
<td>6</td>
</tr>
<tr>
<td>Macroscopic hematuria</td>
<td>1</td>
</tr>
<tr>
<td>Approach</td>
<td></td>
</tr>
<tr>
<td>Femoral</td>
<td>3</td>
</tr>
<tr>
<td>Humeral</td>
<td>1</td>
</tr>
<tr>
<td>Late return from examination</td>
<td>2</td>
</tr>
<tr>
<td>Uncontrolled diabetes</td>
<td>1</td>
</tr>
<tr>
<td>Complex angioplasty procedures</td>
<td>8</td>
</tr>
<tr>
<td>Home monitoring impossible</td>
<td>1</td>
</tr>
<tr>
<td>Triple-vessel lesions with indication to reinforce medical treatment</td>
<td>1</td>
</tr>
<tr>
<td>Transfer to surgery for bypass</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
</tr>
<tr>
<td>Total for each group</td>
<td>29</td>
</tr>
<tr>
<td>Total n (%)</td>
<td>42 (24.4)</td>
</tr>
</tbody>
</table>

Angioplasty group
Twenty-nine (42%) of the 69 patients who underwent angioplasty were kept in the hospital after the procedure. The main reasons why hospitalization was prolonged are summarized in Table 7.

All the angiograms were read by an independent physician. Angioplasty was complicated by myocardial ischemia in six patients, in every case due to the loss of a collateral branch. No case required follow-up angiography and the highest troponin Ic peak was 5.19 μg/ml (for a normal value less than 0.1 μg/ml).

Complex procedures involved the implantation of two or more stents on bifurcation lesions or on several main arterial trunks: the monitoring was stepped up although no complication occurred during or after the intervention.

One patient, on aspirin, clopidogrel and Enoxaparin but not anti-GP2B3A, presented macroscopic hematuria within hours of the examination. This was caused by an undocumented neoplastic lesion of the bladder.

Finally, a hematoma of the forearm necessitated simple medical monitoring.

No bleeding was noted in the patients receiving anti-GP2B3A.

Factors associated with a prolonged hospital stay
We sought criteria that were associated with prolonged hospitalization. For the 172 patients in the study, there was no difference in age, gender, existence of symptoms, risk factors for atherosclerosis or past cardiovascular history between the outpatients and those who were kept in hospital. However, the performance of angioplasty was a significant criterion \( p < 0.0001 \) associated with delayed discharge and this association was strengthened by an episode of ischemia or a small rise in troponin. The presence of exertional dyspnea \( p = 0.03 \) and bifurcation lesions according to angiography \( p = 0.01 \) were associated with prolonged hospitalization in the angioplasty group. A history of angioplasty was more frequent in subjects who were discharged on the same day \( p = 0.05 \).

Events outside the hospital
One hundred and thirty patients (75.6%) were therefore discharged from the department on the day of the intervention. Four cases with symptoms were reported in the 24-hour telephone follow-up. None required emergency hospital readmission.

Diagnostic-angiography group
One patient presented moderate, delayed, cervical-allergic edema with no sign of seriousness; this rapidly regressed after outpatient treatment with an oral corticosteroid and antihistamine. Edema of the forearm was reported by another patient, but this required no additional intervention.

Angioplasty group
One patient with a LAD artery revascularized by a bare-metal stent suffered chest pain warranting investigation. Ischemia was ruled out on the basis of the characteristics of the pain, the electrocardiogram and the troponin concentration.

Lastly, high troponin I (8 μg/ml for a standard less than 0.1 μg/ml) was measured in an external test performed for an asymptomatic patient revascularized the day before by stenting of the right coronary artery, but this was a false-positive since a follow-up test at the hospital gave a negative result.

Laboratory parameters
Creatinine, creatinine clearance and troponin I measurements before and after the procedure are noted in Table 8.

During the study, no patient presented acute-kidney failure and average before and after creatinine and creatinine-clearance readings were not significantly different in either group. Troponin I was higher in the angioplasty
Table 8: Assay of creatinine, troponin I and creatinine clearance before and after procedure in the diagnostic coronary angiography and angioplasty groups

<table>
<thead>
<tr>
<th></th>
<th>Coronary angiography without angioplasty</th>
<th>Coronary angiography with angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 103</td>
<td>n = 69</td>
</tr>
<tr>
<td>Creatinine in micromoles/l</td>
<td>89.1 ± 18.3</td>
<td>91.8 ± 13.5</td>
</tr>
<tr>
<td></td>
<td>87.5 ± 17.4</td>
<td>84.8 ± 24.2</td>
</tr>
<tr>
<td></td>
<td>0.1 ± 0.00</td>
<td>0.39 ± 0.91</td>
</tr>
<tr>
<td></td>
<td>0.5 ± 0.20</td>
<td>0.01 ± 0.02</td>
</tr>
<tr>
<td></td>
<td>2.1 ± 0.25</td>
<td>0.12 ± 0.13</td>
</tr>
<tr>
<td></td>
<td>0.4 ± 0.13</td>
<td>15 ± 1.2</td>
</tr>
<tr>
<td></td>
<td>0.4 ± 0.13</td>
<td>5 ± 0.1</td>
</tr>
<tr>
<td>Creatinine clearance in ml/min</td>
<td>87.5 ± 17.4</td>
<td>92.4 ± 15.6</td>
</tr>
<tr>
<td></td>
<td>84.8 ± 24.2</td>
<td>84.2 ± 25.5</td>
</tr>
<tr>
<td></td>
<td>0.12 ± 0.13</td>
<td>0.12 ± 0.13</td>
</tr>
<tr>
<td></td>
<td>0.2 ± 0.25</td>
<td>0.3 ± 0.25</td>
</tr>
<tr>
<td>Troponin I in µg/ml</td>
<td>0.1 ± 0.00</td>
<td>0.1 ± 0.00</td>
</tr>
<tr>
<td>Troponin I &gt; 0.2 µg/ml</td>
<td>0</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Troponin I &gt; 2 µg/ml</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Cost savings costs of the procedure

A conventional procedure commonly involves two nights in hospital for an overall stay of three days. Performing the procedure on an out-patient basis makes it possible to increase patient throughput with the same number of beds and staff. Hence, in an ideal situation, the patient throughput of a 30-bed unit functioning five days per week with a mixture of outpatient and conventional activity (a traditional management unit with a two-night stay, operating six days a week) may be increased by up to 150%, assuming a proportion of 30% of patients staying in hospital after the intervention.

Discussion

Our study shows that outpatient-coronary angiography with ad hoc angioplasty is feasible with no increase in risk, under the conditions defined in this study. We found that the event rate was low in both outpatients and inpatients with no major complication occurring. Only four 24-hour follow-up phone calls incited investigation, that is, 3% of discharged patients: all the symptoms concerned were minor and none of the patients required readmission into hospital. The necessary conditions for such management are routine use of the radial approach, careful patient selection, a new form of organization and functioning of hospital structures and the will to change often deeply-engrained practices.

Patient selection and the prevention of procedure-related complications

Coronary angiography is associated with a number of morbidity factors, including low-ejection fraction, congestive signs, decompensated angina, kidney failure and aortic-valve disease [4].

These simple criteria were used in the study to include or exclude patients and this led to the selection of a population with a low risk of clinical complications who would therefore more likely be eligible for rapid discharge.

In our series, patients received an aspirin—clopidogrel combination, which was initiated more than three days before the procedure in order to reduce the risk of early in-stent thrombosis by significantly lowering platelet activity [5].

For this same reason, preoperative-coronary occlusion (even with reperfusion), arterial dissection (partially repaired by the stent or not), a thrombus or overlapping stents were systematically sought during a second reading of the coronary angiogram. As the presence of any of these is associated with an increased risk of thrombosis, their detection contra-indicated discharge [6—8].

The stability of kidney function after the intervention was probably explained by the exclusion of subjects presenting kidney failure (clearance below 30 ml/min) and the systematic intravenous hydration of all patients [9]. This...
probably also helped reduce the hemorrhagic complications of antithrombotic therapy [10,11]. The incidence of allergy to iodinated contrast agents has been evaluated at 0.15% in a series of studies. Severity is variable and difficult to predict. Hence, two (1.2%) patients in the study had a minor allergic reaction, one early with skin involvement, the other delayed with respiratory symptoms. As no history of allergy had been noted during the interview, these patients had not been prescribed any premedication [12]. These reactions may occur up to several days after administration of the iodinated products so that patients hospitalized for this intervention are affected in the same way [13].

Finally, vascular-bleeding complications were minimized by systematically using a radial approach, allowing immediate sheath withdrawal without restricting the use of effective antithrombotic treatments (clopidogrel, low-molecular weight heparin, anti-GPlll blla) [14–16]. The radial approach is essential for outpatient-coronary angioplasty as the risk of major local complications may be reduced to a value close to zero (whereas it is about 2% for the femoral route) [16].

Criteria associated with prolonged hospitalization

During the study, 42 (24.4%) of the patients remained for an additional night in the department, often as a precautionary measure in the context of this preliminary experiment. This rate was nevertheless lower than that observed in earlier studies where 28.5 to 46.8% of patients remained hospitalized [17,18]. No particular clinical criteria were associated with prolongation in our study population. In the angioplasty group, a higher proportion of the patients with a history of coronary dilatation were discharged on the day of the procedure, possibly because angioplasty for in-stent restenosis is an intervention with a lower risk of complications [19].

On the contrary, the involvement of an arterial bifurcation was more frequent in subjects who were kept in hospital. This may be explained by the fact that the patients in our series were not selected according to angiographic criteria, whereas such lesions have been exclusion criteria in previous studies. As the revascularization procedure was carried out at the same time as the diagnostic one, the complexity of the lesions could not be evaluated beforehand. Hence, 18 (26.1%) of the patients in the angioplasty group presented bifurcation lesions and 25 (36.2%) multivessel disease. Nevertheless, only eight (4.6%) patients remained in the department for a complication directly related to the procedure. A single case required several days of hospitalization for the investigation of macroscopic hematuria caused by a neoplastic lesion. This further shows the low risk of this intervention in selected patients and illustrates the fortuitous nature of reasons for prolonged hospitalization.

Advantages of outpatient intervention

Outpatient diagnosis and treatment have three main advantages:

- the first is the excellent safety of this type of procedure if the precautions taken during the study are respected that is, clinical selection of patients, use of a radial approach, monitoring of laboratory parameters and systematic patient follow-up;
- the second concerns the convenience to patients and their families as nights spent in the hospital are always a cause of anxiety;
- the third is the increased patient throughput for a given hospital capacity.

Outpatient-coronary angiography and angioplasty may be one way of adapting to the increasing demand for coronary interventions at a time when noninvasive imaging by computed tomography or NMR is rapidly growing. This type of activity must now be reassessed as current reimbursement policies do not encourage generalization of this strategy. Financial measures to promote outpatient interventions are required to encourage such an approach and lead to widespread adoption of this positive change in practice.

Conclusion

Outpatient-coronary angiography and ad hoc angioplasty is a viable option with no major risks for patients selected on the basis of simple clinical criteria. These criteria may be broadened in the future, once we have a better understanding of the strategy.

Outpatient intervention combines the advantages of increased patient convenience and reduced costs.

References


