BRIEF ARTICLE

Early Hospital Discharge (Within Six Hours) for Patients Undergoing Coronary Angioplasty

Estudio AHORA 6: Angioplastia coronaria con alta HOspitalaria RÁpida en 6 horas

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ABSTRACT

Background: 24-hour hospitalization is common practice in patients (P) who underwent scheduled coronary angioplasty (PCI). Previous experiences propose same-day discharge in selected P.
Methods: Prospective, comparative, randomized, single-blind study. P aged 18 to 75 years were included as candidates for a scheduled radial-access PCI with the possibility of accessing the emergency system in less than 40 minutes. P with left ventricular ejection fraction < 30%, creatinine > 1.5 mg/dL, heart failure, chronic obstructive pulmonary disease, decompensated diabetes or very complex coronary anatomy were excluded. The population was divided in two groups (G). G 1: same-day discharge in 6 hours. G2: discharge the next day. Primary endpoint: death or need for rehospitalization within 24 hours of the procedure. Follow-up was carried out by phone the night of the procedure and the next morning, in person at 48 hours, and by telephone after a month, six months and a year. Continuous variables were expressed as median and their respective interquartile range, and qualitative variables as percentages.
Results: 80 P were randomized. Six P (7.5%) presented exclusion criteria during the procedure. There were no deaths or major cardiovascular events in either groups. At one year of follow-up, 3.75% of in-stent restenosis was detected. Troponin elevation was detected in 20 P (25%); 4 were P excluded due to complications during PCI, in the remaining 16 it had no clinical repercussion.
Conclusion: In a population of patients between 55 and 75 years old, mostly male, with a high prevalence of previous myocardial infarction, and ventricular function depression, a scheduled radial-access PCI could be performed with same day discharge in 6 hours, with an adequate safety margin.

Keywords: Angioplastia - Length of Stay - Time Factors - Patient Discharge

RESUMEN

Introducción: Es de práctica habitual la internación durante 24 h en los pacientes (P) intervenidos con una angioplastia coronaria (ATC) programada. Experiencias previas proponen el alta post ATC en el mismo día en P seleccionados.
Material y métodos: Estudio prospectivo, aleatorizado, controlado, simple ciego. Se incluyeron P de 18 a 75 años candidatos a una ATC programada por acceso radial, con posibilidad de acceder al sistema de emergencias en menos de 40 minutos. Se excluyeron los P con fracción de eyección ventricular izquierda < 30%, creatinina > 1,5 mg/dL, insuficiencia cardíaca, enfermedad pulmonar obstructiva crónica, diabetes descompensada o anatomía coronaria muy compleja. Se dividió a la población en dos grupos (G). G 1: alta en 6 horas. G2: alta al día siguiente. Punto final primario: muerte o necesidad de rehospitalización dentro de las 24 h de realizado el procedimiento. Se realizó seguimiento telefónico la noche del procedimiento y a la mañana siguiente, presencial a las 48 h, y telefónico al mes, seis meses y un año.
Resultados: Se adjudicaron aleatoriamente 80 P. Seis P (7,5%) presentaron criterios de exclusión durante el procedimiento. No se produjo ninguna muerte ni evento cardiovascular mayor en ninguno de ambos grupos. Al año de seguimiento se detectó 3,75% de reestenosis intra stent. Se detectó elevación de troponina en 20 P (25%) de los cuales 4 habían sido excluidos por complicaciones durante la ATC. En los restantes 16, la elevación de la troponina no tuvo repercusión clínica.
Conclusión: En una población de pacientes entre 55 y 75 años, en su mayoría de género masculino, con alta prevalencia de infarto de miocardio previo, y depresión de la función ventricular, pudo realizarse una angioplastia programada por acceso radial con alta en 6 horas, con un adecuado margen de seguridad.

Palabras clave: Angioplastia - Tiempo de Internación - Factores de Tiempo - Alta del Paciente

INTRODUCTION

Cardiovascular diseases are the leading health problem in industrialized countries. (1) In this context, transluminal coronary angioplasty (PCI) is a safe and effective therapeutic method. (2)

Scheduled PCI is a procedure with very low chances of serious complications in the first 24 hours. (3) Associated with the above, radial access allows for rapid recovery and avoids bleeding due to femoral access site, which could cause serious complications. (2)

Rev Argent Cardiol 2022;90:206-209. http://dx.doi.org/10.7775/rac.v90.i3.20520

Received: 03/23/2022 – *Accepted:* 05/19/2022

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In 2009, the Society for Cardiac Angiography and Interventions (SCAI), with the approval of the American College of Cardiology Foundation, developed a consensus defining the criteria patients should meet to be considered for outpatient intervention. The April 2016 SCAI consensus on "Good Practice in the Cardiac Catheterization Laboratory" considered same-day discharge post-PCI as a standard practice. (5)

In 2021, the American College of Cardiology published new recommendations that provide a framework for the development of a same-day discharge PCI approach, excluding from this strategy only patients with acute coronary syndrome. (6)

Several studies on radial or femoral access for PCI with percutaneous closure devices have been published, in which same-day discharge could be granted, with positive outcomes. (7-10)

A recent multicenter study demonstrated the safety of same-day discharge after radial access PCI, even in complex procedures (multivessel PCI > 50%, bifurcations > 20%). (10) In Argentina, the ACA I and ACA II studies, published in 2009 and 2016 respectively, proposed this practice in selected patients, with successful outcomes. (12)

In this context, we conducted a study to assess the safety of early discharge (defined as discharge within 6 hours following the procedure) after scheduled radial access coronary angioplasty in low to moderate risk patients.

METHODS

We conducted a prospective, randomized, single-blind study. Patients aged 18 to 75 years with moderate clinical and angiographic risk were candidates for scheduled radial-access PCI.

The study population was divided into two groups (G): G1 or early discharge: the patient went home on the same day the procedure was performed, after a 6-hour stay in the recovery room; G2 or control: the patient stayed 3 hours in the recovery room, and then was admitted to the Cardiology ward until the following morning. Candidates did not know whether they would be discharged or not.

Patients had to come exclusively from the hospital program area, be accessible by telephone for follow-up, and have access to the emergency system in a vehicle (private, hired, or from the emergency system) in less than 40 minutes.

There were clinical, angiographic, procedure related and socioeconomic exclusion criteria.

- Clinical criteria:

a. Age < 18 or > 75 years
b. Acute coronary syndrome
c. Allergy to iodinated contrast
d. Coagulopathy or contraindication to dual antiplatelet therapy
e. Chronic kidney failure (creatinine >1.5 mg/dL or eGFR< 60mL/min)
f. Decompensated heart failure or chronic obstructive pulmonary disease (COPD)
g. Left ventricular ejection fraction (LVEF) < 30%
h. Diabetes without adequate control
i. Lack of optimized treatment

- Angiographic criteria:

a. Complex anatomy (lesion of the left main coronary artery, ostium of the circumflex and the anterior descending arteries, venous bypass graft to internal mammary artery, single patent vessel, coronary bifurcation treatment)

- Procedure-related criteria:

a. Hemodynamic instability
b. Need for glycoprotein-IIb/IIIa inhibitors or intra-aortic balloon pump
c. No reflow or TIMI flow < 3
d. Acute occlusion
e. Thrombus
f. Persistent coronary artery dissection
g. Conversion to femoral access
h. Occlusion of a major branch (> 2 mm, or causing symptoms)
i. Distal embolism
j. New, persistent ventricular or atrial arrhythmia

- Socioeconomic criteria:

a. Lack of adequate social support (family or caregiver to provide immediate care the night of the procedure)
b. No telephone for follow-up
c. Unable to access the emergency unit

The study primary endpoint was death or rehospitalization within 24 h of the procedure. Combined secondary endpoint included all-cause admission to the Coronary Care Unit, need for coronary reintervention and/or any vascular or non-vascular event leading to corrective intervention after PCI.

At each stage of the study, patients were evaluated by a group of interventional cardiologists (evaluation group, EG), including those directly involved in the procedure and the on-call interventional cardiologist.

The study was developed in consecutive scenarios.

a) Scenario 1: Interventional Cardiology Office

Routine evaluations for any procedure were performed: clinical status and the need for angioplasty, associated diseases, complementary and laboratory tests (blood count, blood chemistry with renal function and coagulation profile). For this purpose, the checklist approved by the SCAI in 2016 was used, translated into Spanish (Annex 1). A pre-procedural radial Doppler scanning was performed to all patients. Next, it was determined whether patients met any exclusion criteria to participate in the study. Admission to the study was proposed, and a general Informed Consent and a study-specific Informed Consent —approved by the Education and Research Committee and the Ethics Committee of our center— were signed. Dual antiplatelet therapy was then initiated.

b) Scenario 2: Interventional Cardiology Unit

Between 8-9 am, prior to PCI, the patient was reevaluated by the EG to confirm whether dual antiplatelet therapy had been administered. ECG was performed and a blood sample was drawn to measure baseline troponin levels. The risk of contrast-induced nephropathy, bleeding complications and death was calculated according to the SCAI 1:1 randomization score using a simple randomization program (OxMaR). At this time, the patient and the interventional cardiologist in charge of the procedure were unaware of the

randomization results.

Patients randomized to G1 continued with PCI. In the case of G2, inpatient bed availability was checked before continuing with PCI. If the bed was unavailable, the procedure was postponed up to a maximum of three times. On the third opportunity, patients were switched to G1 by protocol.

The patient was taken to the catheterization laboratory for radial access PCI, according to the approach followed. If any of the procedural complications listed in the exclusion criteria occurred, the patient was excluded from the study. Otherwise, PCI was terminated. Following the PCI procedure, the radial sheath was removed, and a compressive bandage was applied. Complications at the puncture site were ruled out.

c) Scenario 3: Recovery

The patient was taken to the recovery room, vital signs were checked, and the patient was asked for symptoms of ischemia and complications related to the procedure. An ECG was performed to rule out acute ischemic changes. The patient was allowed to ambulate after two hours with an accompanying person. After 3 hours in the recovery room, EG reevaluation was conducted. In case of good progress, G1 patients stayed in the recovery room until discharge (6 hours).

G2 patients were referred to the Cardiology ward for routine check. As in G1, the same procedures were performed and the same variables were recorded in G2. Patients received the usual post PCI care, and were discharged 24 hours post procedure.

Follow-up included telephone calls at night and in the morning after the procedure. In-person follow-up was also performed on the first working day, 48-72 hours post-procedure, including lab tests. Telephone follow-up was carried out at 1, 6 and 12 months..

RESULTS

A total of 80 patients were randomized. Baseline characteristics are summarized in Table 1. Six patients (7.5%) met the exclusion criteria during the procedure —3 in G1 (1 conversion to femoral access, 1 persistent dissection, 1 branch occlusion) and 3 in G2 (2 branch occlusions, 1 persistent pain)— and were transferred to the coronary unit after PCI. All patients were discharged within 24 hours.

No major cardiovascular events or deaths were detected at 1 month and 6 month follow- up in either group. At 1-year follow-up, angina was detected in 5% (4 patients in G1, none in G2), with 3.75% in-stent restenosis (3 patients in G1, none in G2).

Most patients (61, 76%) were tested for high-sensitivity troponin (HsT), and the rest for troponin I, showing high levels in 25% of the cases (n=20, 15 of them tested for HsT). Four patients were excluded due to complications during PCI (3 with lateral branch occlusion); in the remaining 16 patients, elevation had no clinical impact on the outcomes.

DISCUSSION

In many cases, the systematic post-PCI hospitalization for at least 24 h limits the scope for performing the procedure, with the resulting delay in solving the patient's problem.

When analyzing our previous experience, we found out that, in an unselected group of patients, the frequency of unwanted events was low. Importantly, more than 90% of those patients required no more than one day of hospitalization.

With the exclusion of those subjects for "high-risk coronary angioplasty" based on the SCAI consensus selection criteria, more than one third of the sample met criteria for scheduled low- or moderate-risk PCI. (2, 4) No deaths, major bleeding complications or contrast-induced nephropathy were found in this group of patients.

Additionally, the COVID-19 pandemic exposes cardiac patients to a double risk: the risk inherent to their disease and the risk associated with increased likelihood of infection during hospitalization. Postponing procedures in the context of the pandemic has already shown to increase cardiovascular mortality. (13)

The systematic care of these patients should be carefully followed, as we believe that the key to implementing a same-day discharge coronary angioplasty approach lies in ensuring patient safety.

Limitations

Unlike other experiences carried out in Argentina, we decided to conduct a randomized study; however, the low number of patients included and the low rate of events detected in this population prevented us from drawing definitive conclusions. Nevertheless,

Table 1. Baseline characteristics of the population

Variables	G1 (n=43)	G2 (n=37)	p
Age, years	65 ± 8	64 ± 10	ns
Female	21%	16%	ns
HBP	81.4%	86.5%	ns
DM	34.9%	40.5%	ns
DLP	58.1%	45.9%	ns
SMK	34.9%	24.3%	ns
Prior myocardial infarction	46.5%	56.8%	ns
Stroke	2.3%	2.7%	ns
Depressed LVEF	45.5%	66.7%	ns

HBP: high blood pressure; DM: diabetes mellitus; DLP: dyslipidemia; SMK: smoking; LVEF: left ventricular ejection fraction

Variables	GLOBAL	G1	G2	p
PEP	0	0	0	--
SEP	0	0	0	--
TROPONIN E.	25%	20.9%	29.7%	ns
Postponed due to UB	11.2%	0	24.2%	--
D&MCE at 30 days	0	0	0	--
D&MCE at 6 months	0	0	0	--
D&MCE at 12 months	5%	9.3%	0	ns
ISR	5%	6.97%	0	ns

Table 2. Results. PEP: primary endpoint; SEP: secondary endpoint; TROPONIN E.: troponin elevation; UB: unavailable bed; D&MCE: death and major cardiovascular events; ISR: intra-stent restenosis

the selected design prevented the physician-operator from deciding to include the patient in the same-day discharge group based on subjective elements, and allowed strict criteria for safety and follow-up to be established. Further studies with a larger number of patients may contribute to change the paradigm of post-procedural management in these cases.

CONCLUSIONS

In a population of patients between 55 and 75 years of age, mostly male, with a high prevalence of previous myocardial infarction and mild to moderate depression of ventricular function, scheduled radial access PCI within 6-hour discharge could be performed with an adequate safety margin.

The fact that nine procedures were postponed due to unavailable inpatient bed in the 24 h discharge group confirms the importance of new strategies in the management of these patients, even more during the COVID-19 pandemic.

Troponin elevation, predominantly high-sensitivity troponin, was observed in a high number of cases, but it had no impact on patient progress.

On the other hand, G2 patients undergoing PCI were hospitalized in the general Cardiology ward and not in the Coronary Care Unit, which, in itself, represents a significant change in post-PCI management

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