Original article

Percutaneous coronary interventions in very elderly patients referred due to symptomatic coronary disease

Intervenciones coronarias percutáneas en pacientes muy ancianos referidos por enfermedad coronaria sintomática

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ABSTRACT

The elderly population is increasing and has a high cardiovascular risk. This population has been systematically excluded from the clinical trials to the point that the evidence on what the best treatment is remains unknow to this date. We analyzed data from 63 consecutive patients > 85 years treated with percutaneous coronary intervention to assess the results of patients who were offered percutaneous treatment for the management of their symptomatic coronary artery disease. They were categorized into 3 clinical groups (unstable angina, NSTEMI or STEMI) and follow-up was divided into 2 groups (hospitalization after 1 month or after 1 year). The patients' mean age was 87.54 years (85 to 99), 66.7% were women, and 33.3% were men. A total of 33.3% presented with STEMI, 38% with NSTEMI, and 28.7% with unstable angina. On average, a total of 1.29 PCIs were performed (a minimum of 1 and a maximum of 4) and 1.21 stents being implanted (a minimum of 0 and a maximum of 3). Radial access was used in 36% of the patients.
Procedural complications were AKI (24%). A total of 2% of the patients required dialysis, 12% had major bleeding, and 5% perioperative AMI. No strokes were reported. The overall in-hospital cardiovascular mortality rate was 17% at the 1-month follow-up (being 5%, 13%, and 33% respectively for unstable angina, NSTEMI or STEMI, respectively), and 20% at 1 year. The mean hospital stay was 5.44 days (a minimum of 0 days and a maximum of 41 days).

Keywords: coronary interventions, angioplasty, elderly patients, risk.

RESUMEN

La población anciana está en progresivo aumento y presenta un elevado riesgo cardiovascular. El mejor tratamiento para ofrecerles no se conoce precisamente ya que esta población ha sido sistemáticamente excluida de los estudios clínicos. Con el objetivo de evaluar los resultados que obtuvieron nuestros pacientes ancianos a los cuales se les ofreció tratamiento percutáneo de su patología coronaria sintomática, analizamos los datos de 63 pacientes consecutivos > 85 años que fueron sometidos a intervención coronaria percutánea. Se dividieron en 3 grupos clínicos (angor inestable, infarto agudo c/ST o Infarto agudo s/ST) y el seguimiento en 2 grupos (hospitalización hasta el mes posterior, y al año). La edad promedio de los pacientes fue 87,54 (rango: 85-99), 66,7% mujeres y 33,3% hombres. El 33.3% se presentó con infarto agudo c/ST, el 38% con infarto agudo s/ST y el 28,7% con angina inestable.
Se realizaron en promedio 1,29 (1-4) PCI, con 1,21 (0-3) stents. El acceso fue radial en el 36%.
Las complicaciones relacionadas con el procedimiento fueron: 24% IRA o reagudización de una falla preexistente y el 2% requirió diálisis, 12% de sangrado mayor, 5% de IAM periprocedimiento. No hubo accidentes cerebrovasculares. La mortalidad cardiovascular global fue de 17% durante la internación y al mes (con 5%, 13%, y 33%, respectivamente, para angor inestable, infarto agudo s/ST o infarto agudo c/ST) y del 20% al año. La internación promedio fue de 5,44 (0-41) días.

Palabras clave: intervenciones coronarias, angioplastia, pacientes ancianos, riesgo.

INTRODUCTION

Life expectancy has been increasing parallel to the growth of the elderly population. According to the Census of 2010, the rate of people > 65 in Argentina was 10.2% compared to 7%[1] back in 1970. Old age *per se* is one of the greatest cardiovascular risk factors, and coronary artery disease is the most common cause of death among the elderly.[2] In this context, it is of paramount importance to implement effective treatments specifically aimed at elderly patients with coronary artery disease. However, little is known about the management and results of the treatment of coronary artery disease in this age group since these patients have systematically been excluded from clinical trials.[3]

This population poses a double challenge. On the one hand, they are a high-risk group to undergo percutaneous coronary interventions[4] since this population has a high-risk profile due to the associated comorbidities, physical frailty, polymedication, high ischemic load due to multivessel coronary artery disease, and severe coronary artery calcification. On the other hand, they can also benefit from a percutaneous coronary intervention, which means that the risk-benefit ratio should be carefully taken into consideration.

The objective of this study of "very elderly" patients (> 85 years) is to assess the results of coronary angioplasty in our hospital in the subgroup of patients we call very elderly.

MATERIALS AND METHODS

Retrospective, observational, and descriptive study including data from our hospital coronary care unit database and the patients' health records. Data from consecutive patients treated with coronary angioplasty who were > 85 years whenthe procedure was performed were extracted. The patients selected were subcategorized based on their clinical presentation into: ST-segment elevation myocardial infarction (STEMI), non-ST-segment elevation acute myocardial infarction (NSTEMI), and unstable angina (UA).
Patients were diagnosed with STEMI, NSTEMI based on the third universal definition of myocardial infarction

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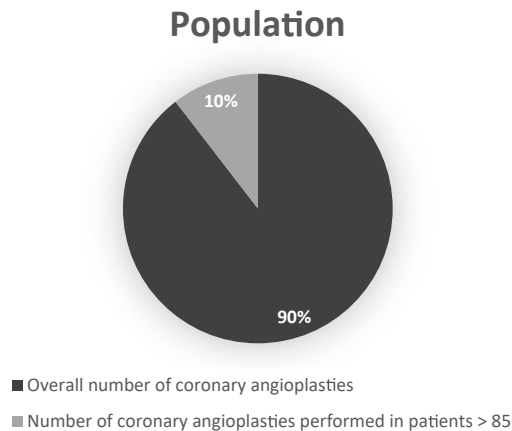2. Servicio de Cardiología, Hospital Privado Universitario de Córdoba.
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Population

- ■ Overall number of coronary angioplasties
- ■ Number of coronary angioplasties performed in patients > 85

Figure 1. *Chart showing both the general and the study population.*

Complications

- ■ Unstable angina ■ STEMI ■ NSTEMI ■ TOTAL

Figure 2. *Chart with the procedural complications.*

of 2012.[6] The group of patients with UA included "outpatients" with early-onset (< 0 = to 2 months) or late-onset angina (< 0 = to 2 months) despite the use of, at least, 2 antianginal agents who may or may not have ischemia provable in a non-invasive positive test like stress echocardiography or myocardial perfusion scintigraphy.

Decisions on the procedure, access site, use of adjuvant drug therapy, and type of stent were left to the operator's criterion. Only the index events of patients treated with staged procedures were included. These patients received another elective percutaneous coronary intervention (PCI) after the culprit vessel was previously treated.

All patients treated with PCI received heparin at a dose of 80 mg/kg, aspirin, ticlopidine or clopidogrel according to the standard effective regulations. Patients treated with drug-eluting stents received a 1-year minimum course of dual antiplatelet therapy.

Follow-up was divided into 2 different in-hospital disease progression follow-ups: 1) until the 30-day follow-up; 2) until the 1-year follow-up. **Follow-up took place at the doctor's office of at the treating center. Also, through phone calls with those who underwent followed-up in a different center.** All patients were informed and trained on the standard therapy of secondary prevention at discharge according to the recommendations applicable to this date.

Angioplasty-related adverse events at the follow-up were in-hospital mortality (defined as the appearance of death during the hospital stay after the procedure, after 30 days, and after 1-year). Cardiac death was defined as death due to arrhythmias, mechanical complications (myocardial ruptures or severe valvular compromise) or refractory heart failure. The remaining causes were defined as non-cardiogenic.

Reinfarction after acute myocardial infarction (R-AMI) is defined as the presence of, at least, 2 of the 3 following criteria: changes on the ECG, precordial pain (or other anginal equivalent) or elevated biomarker levels after the PCI.

Stroke was defined as the permanent loss of neurological function (including coma) following an ischemic or hemorrhagic vascular event as seen on the brain images obtained through computed tomography or magnetic resonance imaging.

Postoperative acute kidney injury (AKI) was defined as oliguria (production of urine < 30 mL/h) or anuria and was associated with a daily increase of serum creatinine and blood
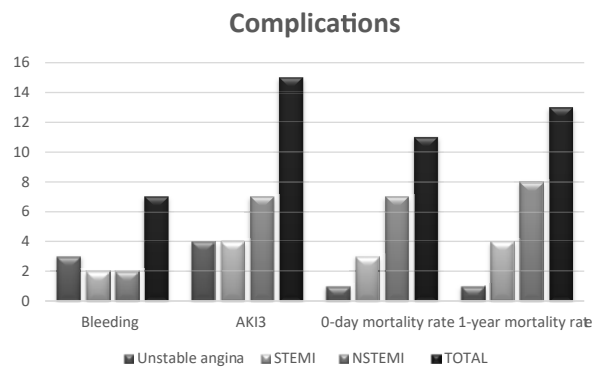
urea nitrogen of 0.1 mg/dL and 0.10 mg/dL, respectively or with the need for hemodialysis or peritoneal dialysis sometime after the coronary intervention and up to 10 days later. Patients were considered smokers following current or past smoking habits. The number of cigarettes smoked was disregarded to this point.

Hypertensive patients (HTP) were patients with a past medical history of systemic arterial hypertension or medicated against such condition. Patients with pressure levels > 140 mmHg.

Dyslipidemic patients (DLP) were those with a past medical history of hypertriglyceridemia, hypercholesterolemia or both. The ab results were: triglycerides > 150 mg/dL and cholesterol > 200 mg/dL.

Diabetic patients (DBP) were those with a past medical history of diabetes or treated with insulin or with some hypoglycemic agent.

Major bleeding was defined as the need for transfusion of, at least, 2 red blood cell units after the procedure.

The statistical analysis was performed using the statistical system Infostat (Universidad Nacional de Córdoba, 2014, free version). The categorical variables were expressed as percentage, and the continuous ones as mean and interquartile range.

RESULTS

From January 1994 through June **2019** our center performed **coronary angioplasties to 540 patients.** A total of 63 of these patients were > 85 **(figure 1)** with a mean age of 87.54 (85 to 99), 66.7% were women while 33.3% were men. A total of 33.3% presented with STEMI (anterior, 57%; inferior, 29%; lateral, 14 %), 38% with NSTEMI, and the remaining 28.7% were referred due to UA.

Regarding the cardiovascular risk factors (table 1) known at the time the PCI was performed, it was confirmed that 84% of the patients were HTP, 54% were DLP, 35% were past or present smokers, 12% had chronic obstructive pulmonary disease, 29% were DBP (and 6% of these were insulin-dependent patients). A total of 29% of the patients had had a previous acute myocardial infarction (AMI), 17% of the patients a previous PCI, and 10% of the patients had been treated with surgical revascularization (coronary artery bypass graft).

TABLE 1.GENERAL characteristics of the population.

	Unstable angina		NSTEMI		STEMI		Overall	
Total pts	18		24		21		63	
Age	86.5	(85-93)	88	(85-99)	88.24	(85-94)	87.54	(85-99)
Women	13	72.0%	15	62.5%	14	67.0%	42	66.7%
Men	6	33.0%	9	37.5%	7	33.0%	22	33.3%
AHT	17	94.0%	21	88.0%	15	68.0%	53	84.0%
Smoking habit	2	11.0%	11	46.0%	9	43.0%	22	35.0%
DLP	14	77.0%	11	46.0%	9	43.0%	34	54.0%
DBP	5	27.0%	9	38.0%	4	19.0%	18	29.0%
Insulin	0	0.0%	2	8.0%	2	10.0%	4	6.0%
CKD	5	27.0%	6	25.0%	3	14.0%	14	22.0%
Creatinine	1.12	(0.68-2.00)	1.21	(0.57-3.40)	1.03	(0.58-1.45)	1.12	(0.48 3.40)
HB	12.15	(8.40-15.90)	12.26	(9.70-16.80)	12.19	(5.30-15.70)	12.19	(5.30-16.80)
COPD	0	0.0%	4	17.0%	3	14.0%	7	12.0%
Ischemic stroke	1	5.0%	1	4.0%	1	5.0%	3	5.0%
Previous PCI	6	33.0%	2	8.0%	3	14.0%	11	17.0%
Previous AF	4	24.0%	4	17.0%	3	14.0%	11	17.0%
Previous AMI	10	55.0%	6	25.0%	2	10.0%	18	29.0%
DHF	6	33.0%	6	25.0%	1	5.0%	13	21.0%
CVS	2	11.0%	4	17.0%	1	5.0%	7	12.0%
CABG	2	11.0%	3	13.0%	1	5.0%	6	10.0%
Valve R	0	0.0%	1	4.0%	0	0.0%	1	2.0%
PM	2	11.0%	3	13.0%	1	5.0%	6	10.0%
ASA	16	88.0%	14	58.0%	8	38.0%	38	60.0%
Statins	8	44.0%	6	25.0%	1	5.0%	15	24.0%
Clopidogrel	4	22.0%	5	21.0%	0	0.0%	9	14.0%
OAC	2	11.0%	2	8.0%	0	0.0%	4	6.0%
LVEF pre-PCI	54%	(29%-70%)	58%	(30%-68%)	57 %	(36%-70%)	56%	(29% 70%)
LVEF post-PCI	51.4%	(20%-70%)	54%	(30%-70%)	47%	(30%-66%)	51%	(29%-70%)
Sinusal	17	94.0%	19	79.0%	18	86.0%	54	85.0%
AF post-PCI	2	11.0%	4	17.0%	1	5.0%	7	12.0%
RBBB	0	0.0%	3	13.0%	0	0.0%	3	5.0%

Abbreviations: AF, atrial fibrillation; AHT, arterial hypertension; AMI, acute myocardial infarction; ASA, acetylsalicylic acid; CABG, coronary artery bypass graft; CKD, chronic kidney disease; COPD, chronic pulmonary obstructive disease; CVS, cardiovascular surgery; DBP, diabetic patients; DHF, decompensated heart failure; DLP, dyslipidemic patients; H, hemoglobin; LVEF, left ventricular ejection fraction; OAC, oral anticoagulation; Pat, patients; PCI, percutaneous coronary intervention; PM, pacemaker; RBBB, right bundle branch block; valve R. heart valve replacement.

A total of 54% of the patients were in normal sinus rhythm, 12% had atrial fibrillation, and 10% were pacemaker carriers and had rhythms associated with such pacemakers. A total of 5% of these patients had complete right bundle brunch block (RBBB), and 13% complete left bundle brunch block (LBBB). According to the coronary angiography, 10% had significant left main coronary artery disease, 52% left anterior descending coronary artery disease, 40% right coronary artery disease, and 30% left circumflex artery disease. On average, the number of vessels that were significantly compromised (≥ 70% obstruction) was 1.89 (1.00 to 3.00), the mean number of PCIs performed was 1.29 (1 to 4), the average number of stents used was 1.21 (0 to 3) of which 22% were drug-eluting stents and the remaining ones, bare-metal stents. The access route was radial in 36% of the cases (table 2).

Regarding procedural complications (figure 2) we should mention that **no complications were reported intraoperatively**. Also, during the hospital stay, 24% of the patients developed AKI or preexisting failure relapse, and 2% required dialysis. A total of 12% of the patients had major bleeding, and 5% a perioperative AMI. No periprocedural ischemic or hemorrhagic strokes were reported.

The overall cardiovascular mortality rate was 17% during the hospital stay and at the 1-month follow-up (5%, 13%, and 33%, respectively if the clinical presentation is considered whether UA, NSTEMI or STEMI), and 20% at the 1-year follow-up. The mean hospital stay was 5.44 days (0 to 41).

DISCUSSION

In the routine clinical practice, the elderly patients are often prescribed with medical or conservative therapy instead of a PCI.[7] This is, in part, due to the fact that these patients are very challenging because they can have atypical clinical presentations and even late-onset clinical manifestations, more chances of having concomitant diseases, cognitive impairment, physical frailty, polymedication, and a more complex coronary artery disease (multiple vessels, tortuosity, and significant calcification), and even a greater ischemic load.[8] Many times it is believed that these challenges minimize benefits and increase the risk of complications associated with invasive treatment. Consequently, traditionally the management of very old patients has been more conservative compared to what the clinical practice guidelines actually recommend with suboptimal access to angiography, early revascularizations, and even optimal medical therapy.[9] However, there is strong evidence nowadays that high-risk patients benefit from PCI, which should bring the threshold down when it comes to the implementation of more aggressive strategies in this age group of unquestionable high risk.[10] Currently, primary PCI performed within the recommended time frames is the therapy of choice for patients with STEMI. Therefore, thrombolytic agents are spared for situations in which mechanical reperfusion is not available. Very elderly patients with STEMI treated with PCI have

TABLA 2. Intervención coronaria percutánea.

	Unstable angina		NSTEMI		STEMI		Overall	
LMCA	1	5.0%	2	8.0%	3	14.0%	6	10.0%
LAD	16	88.0%	18	75.0%	18	86.0%	52	83.0%
LCX	8	44.0%	12	50.0%	10	48.0%	30	48.0%
RCA	13	72.0%	16	67.0%	11	52.0%	40	63.0%
No. of vessels	1.95	(1-3)	1.91	(1-3)	1.90	(1-3)	1.89	(1-3)
No. of PCIs	1.32%	(1-3)	1.21	(1-3)	1.43	(1-4)	1.29	(1-4)
No of stents	1.16%	(0-3)	1.17	(0-3)	1.38	(0-3)	1.21	(0-3)
Bleeding >	3	16.0%	2	8.0%	2	10.0%	7	12.0%
AKI	4	22.0%	4	17.0%	7	33.0%	15	24.0%
Dialysis	1	5.0%	0	0.0%	0	0.0%	1	2.0%
Ischemic stroke post-PCI	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Hemorrhagic stroke post-PCI	0	0.0%	0	0.0%	0	0.0%	0	0.0%
AMI post-PCI	1	5.0%	0	0.0%	2	10.0%	3	5.0%
In-hospital CV death at 30 days	1	5.0%	3	13.0%	7	33.0%	11	17.0%
1-year CV death	1	5.0%	4	16.0%	8	38.0%	13	20.0%
Elevated ASA levels	18	100.0%	23	96.0%	19	91.0%	61	97.0%
Elevatedclopi./ticlo. levels	18	100.0%	24	100.0%	20	95.0%	62	98.0%
Elevated statins levels	17	94.0%	24	100.0%	20	95.0%	61	97.0%
Elevated BB levels	17	94.0%	22	92.0%	20	95.0%	59	93.0%
Elevated ACEI/ARB levels	17	94.0%	23	96.0%	20	95.0%	60	95.0%
Elevated diuretics levels	13	72.0%	15	63.0%	18	86.0%	46	73.0%
Hospital stay, days	2.58	(0-15)	5.50	(1-20)	8.19	(2-41)	5.44	(0-41)

Abbreviations:ACEI, angiotensin-converting enzyme inhibitors; AKI, acute kidney injury; AMI, acute myocardial infarction; ARB, angiotensin receptor blockers; ASA, acetylsalicylic acid; BB, beta-blockers; Clopi., clopidogrel; CV death, cardiovascular death; LAD, left anterior descending coronary artery; LCX, left circumflex artery; LMCA, left main coronary artery; No., number; OAC, oral anticoagulation;PCI, percutaneous coronary intervention; RCA, right coronary artery; Ticlo., ticlopidine.

lower morbidity and mortality rates compared to those treated with medical therapy or thrombolytic agents.[11] Regarding the specific comparison with fibrinolytic agents we have evidence in favor of the PCI regarding mortality, morbidity, and safety coming from randomized clinical trials that compared these strategies in very elderly patients.[12,13] Also, a meta-analysis of 22 randomized trials that compared the PCI vs fibrinolytic therapy and analyzed 410 octogenarian patients confirmed lower mortality rates favorable to the PCI (18.3 vs 26.4; $P = .04$).[14] In our series, the in-hospital mortality rate of patients with STEMI was 33%. This mortality rate is similar to the one reported by other studies that included octogenarian and nonagenarian patients (mean age, 88 years) like we did.[15] Complications occurred in 20% of the patients. Procedural complications were major bleeding (2%), perioperative AMI (10%), and AKI (33%).

In the case of very elderly patients with NSTEMI the situation is similar in the sense that these patients receive suboptimal medical therapy compared to the current recommendations.[15] However, this subgroup of patients benefits in terms of mortality, especially, morbidity when treated with percutaneous revascularization and even more when this therapy is complemented with the optimal medical therapy.[16] The CRUSADE trial confirmed a lower in-hospital mortality rate in elderly patients similar to ours treated with this invasive strategy.[17] Another recent study based on data from the Nationwide Inpatient Sample proved that, compared to an early conservative approach, an early invasive strategy in octogenarian patients with NSTEMI was associated with a lower in-hospital mortality rate, fewer acute ischemic strokes, intracranial hemorrhages, GI bleeding, and even shorter hospital stays.[18] In our own experience, elderly patients with this syndrome had a 13% mortality rate during the hospital stay with a 6% rate of overall complications (major bleeding, 8%, and AKI, 17%).

The European Society of Cardiology, the American College of Cardiology, and the American Heart Association recommend treating very old patients individually with a correct balance regarding the risk-benefit ratio. They also recommend taking into consideration ischemia, the risk of bleeding, life expectancy, and comorbidities including cognitive function, quality of life, and the patient's wishes before deciding on the most appropriate therapy.[19,20,21]

In the subgroup of patients treated with elective PCIs due to UA, the rate of complications was low (6%) (being chronic kidney disease, 22%, and major bleeding, 16% the most common complications of all). Also, only 1 patient died of retroperitoneal bleeding, meaning that this death was directly associated with the procedure. Studies comparing the invasive vs the conservative strategy in these patients conclude that anginal symptoms, and quality of life[22] do actually improve. Also, that there is a greater absolute reduction of the mortality rate.[23]

Regarding the stent that should be used to treat the coronary lesions of elderly patients we can say that, as it happens with the other patients, the benefit of using drug-eluting stents is a lower rate of target vessel revascularization and fewer acute myocardial infarctions at the follow-up. However, there does not seem to be a significant impact regarding mortality and strokes.[24]

We should mention the prevention of complications in these patients since these complications have an impact on survival. With this goal in mind, over the last 5 years, we have been using the radial approach in all our patients (except when this approach was unavailable). This approach reduced access site bleeding significantly to the point that patients treated with this technique never had major bleeding.

Our study limitations are those of an observational and retrospective study. That means that the possibili-

ty of selection bias, as well as the possibility that confounding factors never actually went away still stands. However, we believe that due to the lack of data from large randomized clinical trials, observational studies like ours are relevant because they provide us with valuable evidence.

CONCLUSION

The acute coronary syndrome in the elderly population is a serious complication. However, it can be treated invasively with some acceptable risks. We believe chronological age should not be the main determining factor in the decision to use invasive treatment.

WHAT DOES THIS STUDY ADD?

The growing number of elderly patients due to the increased life expectancy is associated with more of these patients ending up in cath labs to solve their acute coronary syndromes.
Due to their age, frailty, and common comorbidities these are high-risk patients to undergo percutaneous coronary interventions.
In our study we could confirm, and it is actually our biggest feat, the safety and effectiveness of the procedures performed in this age group.
Currently, as far as we know, no national experiences have been published specifically addressing that group of patients we call the elderly.

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