

Efficiency and Safety of Radial Access versus Femoral Access in Percutaneous Coronary Intervention

Eficiencia y seguridad del acceso radial versus el acceso femoral en la angioplastia coronaria

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ABSTRACT

Background: Radial access has been associated with many advantages in percutaneous coronary intervention compared with femoral access. However, many international registries have reported poor adherence to this technique.

Objectives: The aim of this study was to evaluate the safety, efficacy and operational efficiency of percutaneous coronary intervention according to the access site and the clinical presentation of the patient.

Methods: A single-center, retrospective registry of patients with coronary artery disease undergoing percutaneous coronary intervention was conducted from March 2009 to June 2018 according to the vascular access. A Cox proportional-hazards model was used to analyze the association between vascular access and risk of major cardiovascular events, and a logistic regression model was applied to assess the relationship between major bleeding and access site complications. Total hospital stay and total hospitalization costs were measured to evaluate the operational efficiency.

Results: A total of 8,155 percutaneous coronary interventions (mean follow-up of $1,448.6 \pm 714.1$ days), via radial access ($n=5,706$) or femoral access ($n=2,449$), were included in the study. At 30 days, the risk of major cardiovascular events was significantly lower with the radial access (HR 0.66 [0.5-0.88], $p=0.004$), at the expense of a reduction in all-cause mortality. In addition, radial access significantly reduced the risk of major bleeding (HR 0.33 [0.16-0.67], $p=0.002$) and access site complications (HR 0.72 [0.53-0.98], $p=0.038$). A significant interaction was observed between the vascular access site and the risk of events according to the clinical presentation on admission. Use of radial access was associated with a significant reduction in the length of total hospital stay ($\approx 30\%$) and total hospitalization costs ($\approx 15\%$).

Conclusions: The use of radial access in percutaneous coronary intervention was safe and effective compared with the femoral access, with lower rates of major cardiovascular events at 30 days, lower risk of major bleeding and of access site complications. Moreover, radial access was associated with greater operational efficiency during hospitalization.

Key words: Radial Artery -Femoral Artery - Percutaneous Coronary Intervention

RESUMEN

Introducción: El acceso radial se ha asociado a numerosos beneficios en angioplastia coronaria en comparación con el acceso femoral. Sin embargo, múltiples registros internacionales han reportado una escasa adherencia a esta técnica.

Objetivos: Evaluar la seguridad, la eficacia y la eficiencia operativa de la angioplastia coronaria según la vía de acceso utilizada y el cuadro clínico del paciente.

Métodos: Análisis de registro, unicéntrico y retrospectivo de los pacientes con enfermedad coronaria tratados con angioplastia coronaria desde marzo de 2009 a junio de 2018, según el acceso vascular. Se aplicó un modelo de regresión de Cox ajustado para evaluar la relación entre la vía de acceso y el riesgo de eventos cardiovasculares mayores y un modelo de regresión logística para evaluar la relación con el sangrado mayor y las complicaciones del acceso vascular. La eficiencia operativa se evaluó mediante la medición del tiempo de internación total y los costos totales asociados a esta.

Resultados: Se incluyeron 8155 angioplastias coronarias (seguimiento promedio $1448,6 \pm 714,1$ días), mediante acceso radial ($n=5706$) o acceso femoral ($n=2449$). A los 30 días, el riesgo de eventos cardiovasculares mayores se redujo significativamente con el acceso radial (HR 0,66 [0,5-0,88], $p=0,004$), a expensas de una reducción de la mortalidad total. A su vez, el acceso radial redujo significativamente el riesgo de sangrado mayor (HR 0,33 [0,16-0,67], $p=0,002$) y de complicaciones del acceso vascular (HR 0,72 [0,53-0,98], $p=0,038$). Se observó una interacción significativa entre la vía de acceso y el riesgo de eventos según el cuadro clínico al ingreso. Se observó una reducción significativa del tiempo total de internación ($\approx 30\%$) y de sus costos totales ($\approx 15\%$) mediante el uso del acceso radial.

Conclusiones: El uso del acceso radial en angioplastia coronaria es seguro y eficaz en comparación con el acceso femoral, con menores tasas de eventos cardiovasculares mayores a los 30 días, como, así también, un menor riesgo de sangrado mayor y complicaciones del acceso vascular. Asimismo, el acceso radial se asoció con una mayor eficiencia operativa durante la internación.

Palabras claves: Arteria radial- Arteria femoral -Intervención coronaria percutánea

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Abbreviations

CABGS	Coronary artery bypass graft surgery	MACE	Major adverse cardiovascular events
CKF	Chronic kidney failure	AMI	Acute myocardial infarction
COPD	Chronic obstructive pulmonary disease	OA	Oral anticoagulants
ED	Early discharge	PCI	Percutaneous coronary intervention
FA	Femoral access	PVD	Peripheral vascular disease
HT	Hypertension	RA	Radial access
LVEF	Left ventricular ejection fraction	UA	Unstable angina

INTRODUCTION

Percutaneous coronary intervention (PCI) has undergone great changes since it was first introduced 40 years ago. The increasing complexity of patients and of the different coronary anatomies has challenged interventional cardiologists and the endovascular technology industry to develop new vascular approaches to increase the safety and efficacy of the procedures. The miniaturization of devices resulted in the routine use of the radial access (RA) which, despite having approximately half the caliber of the femoral access (FA), offers multiple advantages over the latter. (1)

Radial access has decreased the risk of vascular complications, major bleeding (2) and the need for red blood cell transfusions, (3) and has been associated with lower mortality in patients with ST-segment elevation acute coronary syndrome (STE-ACS). (4) In addition, RA allows early ambulation, improving patient experience and reducing hospital stay. (5)

However, many registries have described poor adherence with this approach. (6) Furthermore, as with any invasive practice, the learning curve is essential for achieving adequate results.

In our center, RA has become the standard of care for coronary artery procedures, irrespective of the clinical presentation and complexity of the coronary anatomy. The aim of this study was to report the efficacy, safety and operational efficiency of the vascular access site used in patients undergoing PCI.

METHODS

The database of the Interventional Cardiology and Endovascular Therapy Unit of Instituto Cardiovascular de Buenos Aires was used for the study. This contains information about the patients treated at the institution from 2009 to the present day and serves as a platform for an adequate 30-day and annual follow-up, with periodical updates of patient characteristics and the outcome of our practice in the short-, mid- and long-term. The following variables are included in the database: demographic data, comorbidities, cardiovascular history, treatments used, procedure characteristics, and in-hospital, 30-day and annual outcome in more than 15,000 procedures.

The PCI procedures performed between January 2009 and June 2018 were analyzed according to the initial vascular access site (radial or femoral) and the clinical presentation on admission:

- Stable patients: Elective PCI in patients with a pattern

of stable angina >3 months.

- Non-ST-segment elevation acute coronary syndrome (non-STE-ACS): PCI in patients with a pattern of unstable angina, without ST-segment elevation on the electrocardiogram and either elevated biomarkers (non-ST-segment elevation acute myocardial infarction, STEMI) or normal biomarkers (unstable angina, UA).
- ST segment elevation acute coronary syndrome (STE-ACS): PCI in patients undergoing primary or rescue PCI or a pharmacoinvasive strategy within 24 h from the onset of symptoms.

Patients treated with a dual vascular access (radial-femoral, biradial or bifemoral), via brachial access and those with cardiogenic shock on admission (blood pressure <100 mm Hg, heart rate >100 bpm, poor distal perfusion requiring inotropic drugs or mechanical circulatory assist devices) were excluded from the study.

A composite endpoint of major adverse cardiovascular events (MACE) including all-cause mortality, non-fatal acute myocardial infarction (AMI) and stroke at 30 days was analyzed.

Access site complications were defined as the presence of major bleeding at the puncture site expressed as pseudoaneurysm, hematoma at the puncture site >5 cm, retroperitoneal hematoma or arteriovenous fistulas. The occlusion of the artery used as vascular access was not consecutively collected except in case of clinical manifestations.

Bleeding was defined according to the classification of the Bleeding Academic Research Consortium (BARC). (7)

Statistical analysis

Qualitative variables were expressed as percentages and were compared using the chi square test. The normality of quantitative variables was evaluated using the Kolmogorov-Smirnov test or the Shapiro-Wilk test, as applicable, with measurement of kurtosis and skewness. Variables with normal distribution were expressed as mean \pm standard deviation (SD) and non-normal variables as median and interquartile range (IQR).

A Cox proportional-hazards model was used to analyze the association between the vascular access site and the composite outcome, as well as the individual components at 30-days. The association with total bleeding, major bleeding and access site complications was assessed using binary logistic regression adjusted for age, sex, hypertension (HT), dyslipidemia, diabetes, smoking habits, prior PCI, prior coronary artery bypass graft surgery (CABGS), procedure year, prior AMI, chronic kidney failure (CKF), chronic obstructive pulmonary disease (COPD), clinical presentation on admission, peripheral vascular disease (PVD), oral anticoagulants (OA) and left ventricular ejection fraction (LVEF). The corresponding 95% confidence interval (CI) of regression parameters was calculated using the bootstrapping method. (8)

An interaction term between the vascular access site and the clinical presentation was developed to evaluate the influence of the latter on the relationship between the vascular access and the composite endpoint, access site complications and total bleeding.

Total hospital length of stay (in hours) and total hospitalization costs (in ARS) in the population of patients with stable coronary artery disease (n=3,507) were evaluated to quantify the operational efficiency of RA in PCI. Three propensity score models were generated to reduce selection bias: a) a logistic regression model to predict the use of RA, b) a logistic regression model to predict the probability of early discharge, and c) a multinomial logistic regression model to predict the probabilities of RA + early discharge (ED, discharge on the same day of PCI), FA + ED, RA + hospitalization, and FA + hospitalization. The following variables were used as predictors in each model: age, sex, HT, dyslipidemia, diabetes, smoking habits, prior PCI, prior CABGS, procedure year, prior AMI, CKF, COPD, clinical presentation on admission, PVD, OA and LVEF. A generalized linear model was used to estimate costs, where the dependent variable was the total cost and the vascular access (RA vs. AF) was the predictor variable adjusted for the previously obtained propensity scores as covariates. Another generalized linear model was generated, where the dependent variable was the total hospital length of stay and the vascular access site (RA vs. FA) was the predictor variable adjusted for propensity scores. (9)

Statistical analysis was performed using SPSS 22.0 statistical package (SPSS, IBM Corporation, Armonk, New York).

Ethical considerations

The study protocol was evaluated and approved by the insti-

tutional Ethics Committee and the Scientific Committee, as it endorses the usual standards of care.

RESULTS

Baseline characteristics

A total of 8,155 PCI procedures were included; 5,706 via the RA (70%) and 2,449 through the FA. Mean follow up was $1,448.6 \pm 714.1$ days. Table 1 shows the significant differences in the baseline characteristics between both groups. Patients in the RA group were younger and had lower prevalence of previous PCI, CABGS, CKF, AMI, PVD and LV dysfunction (EF <30%).

The characteristics of the procedure are detailed in Table 2. Although there were no significant differences in the clinical presentation on admission, there was a higher rate of PCI procedures to the left main coronary artery and coronary artery bypass grafts and of larger devices in the FA group. The prevalence of OA was greater in patients undergoing RA.

Trends in the use of radial access

During the study period, there was an increasing use of RA compared with FA (Figure 1 A, p-trend <0.0001). There was a remarkable preference towards the use of the FA in 2009, as it was the access of choice in 75% of the procedures. However, nowadays, 82% of PCI procedures are performed via RA, even in more complex interventions (Figure 1 B, p-trend <0.0001). This trend was observed independently of the clinical presentation (Pint 0.422).

Table 1. Baseline characteristics of the population

	Radial access (n=5,706)	Femoral access (n=2,449)	p
Age \pm SD, years	68.43 \pm 11	72.09 \pm 10.8	< 0.0001
Male sex, %	84.7	79.1	< 0.0001
Cardiovascular risk factors			
Hypertension, %	75.2	78.4	0.002
Dyslipidemia, %	77.6	78.6	0.301
Obesity, %	17.6%	12.3	< 0.0001
Noninsulin-requiring diabetes, %	18.6	21.4	0.003
Insulin-requiring diabetes, %	3.6	3.6	0.97
Former smokers, %	44.3	46.3	0.09
Current smokers, %	16.6	15.4	0.159
History of cardiovascular diseases			
Percutaneous coronary intervention, %	37.1	44.5	< 0.0001
Coronary artery bypass graft surgery, %	6.9	31.2	< 0.0001
Myocardial infarction, %	18	22.9	< 0.0001
Stroke (%)	3.2	3.7	0.245
Atrial fibrillation, %	2.9	3.1	0.613
Peripheral vascular disease, %	6.5	9	< 0.0001
History of bleeding, %	1.2	1.5	0.338
Severe/moderate-severe aortic stenosis, %	2.8	3.5	0.088
Other diseases			
Chronic kidney dysfunction, %	2.4	5.6	< 0.0001
Chronic obstructive pulmonary disease, %	3.5	3.1	0.358
Ejection fraction <30%, %	3.6	7.3	< 0.0001

Operational efficiency

The use of RA was associated with a significant reduction in the length of total hospital stay (mean 16.6 ± 13.2 h). Hospital length of stay was 15.9 ± 13.1 h for the RA and 20.6 ± 13.2 h for the FA. After applying a generalized linear model adjusted by propensity score, the reduction in length of stay with the RA was -4.89 h (95% CI -7.39- -2.38, p=0.001), which represents an overall reduction of 29.2% of the average length of stay.

A marked reduction was observed in hospitalization costs (excluding costs related with the intervention) with the use of RA (average global cost \$43,117±17,329). While the average cost in this group of patients was \$41,877±\$16,604, this was \$49,567±\$19,381 in patients with FA. Applying a generalized linear model adjusted by propensity score, the use of RA resulted in a decrease of -\$7072 (95% CI -11,269- -2,876, p=0.001), which represents a reduction of approximately 15% of the total hospitalization cost.

Clinical outcomes

The overall rate of MACE at 30 days was 4.1% and was observed in 3.2% of the patients in the RA group and in 6.3% of those with FA (Table 3). The adjusted risk of MACE at 30 days was significantly lower with

RA (HR 0.66, 95% CI 0.50-0.881, p=0.004), mainly because of a significant decrease in 30-day mortality (HR 0.53, 95% CI 0.33-0.84, p=0.008).

The rate of global bleeding at 30 days was 2%, reported in 1.3% of patients in the RA group and 3.6% in the FA group (Table 3). The adjusted risk of total bleeding was significantly reduced by the use of RA (OR 0.383, 95% CI 0.232-0.632, p <0.0001). In our series, age, female sex, multivessel PCI, anticoagulated patients, and patients with acute coronary syndrome were other variables associated with higher 30-day risk of bleeding. The rate of major bleeding according to the BARC classification was 0.6% with RA and 2.4% with FA (OR 0.33, 95% CI 0.163-0.675, p=0.002) (Table 3).

The rate of access site complications was 3.3% reported in 2.8% of patients in the RA group and 4.5% in the FA group (Table 3). The adjusted risk for this outcome was lower for RA (OR, 0.721; 95% CI, 0.532-0.984; p=0.038).

Outcomes according to the clinical presentation on admission

The occurrence of MACE at 30 days was the only clinical outcome measured with interaction with the vascular access site according to the clinical presentation, and was greater in the FA group, particularly in

	Radial access (n=5,706)	Femoral access (n=2,449)	p
Clinical presentation			0.078
Stable chronic angina, %	43.1	42.7	
NSTE ACS*, %	42.8	43.5	
STE ACS#, %	13.3	12.5	
Medical treatment			
Clopidogrel, %	69.3	78.1	< 0.0001
Prasugrel, %	11.3	14	< 0.0001
Ticagrelor, %	19.4	7.9	< 0.0001
GP IIb/IIIa inhibitors, %	3.5	3.6	0.712
Oral anticoagulants, %	6.1	4.4	0.002
Vessel involved			
Left main coronary artery, %	2.9	5.5	< 0.0001
Left anterior descending coronary artery, %	32.7	24.4	< 0.0001
Left circumflex coronary artery, %	23.7	27	0.002
Right coronary artery, %	23.6	23.2	0.716
Grafts, %	1.2	6.9	< 0.0001
Access size			< 0.0001
6 French, %	93.5	78.2	
≥7 French, %	6.5	21.8	
Results of the procedure			
Successful, %	98.3	95.6	< 0.0001
Complete revascularization, %	74	69.4	< 0.0001
PCI complicationsμ, %	2.2	4.2	< 0.0001

Table 2. Characteristics of the procedure

*Non-ST segment elevation acute coronary syndrome.

#ST segment elevation acute coronary syndrome.

μPercutaneous coronary intervention complications: residual dissection, non-reflow phenomenon, coronary artery perforation, stent deformation.

patients with acute coronary syndromes (Pint 0.05). In stable patients, the risk of events at 30 days was similar in both groups (HR, 0.862; 95% CI, 0.600-1.239; p=0.422), while in patients with non-STE ACS and STE ACS the risk was lower with AR (HR, 0.486; 95% CI, 0.263-0.900; p=0.022, and HR, 0.469; 95% CI, 0.260-0.847; p=0.012, respectively) (Figure 2A). There was no significant interaction between the other outcomes and the clinical presentation at the moment of PCI (Figure 2B and C).

DISCUSSION

The present analysis on the use of RA in PCI across the entire spectrum of coronary artery disease deserves the following observations: a) there was a progressive increase in the selection of RA in PCI, irrespective of the clinical presentation and the complexity of the coronary anatomy; b) RA was associated with a lower adjusted risk of MACE at 30 days compared with FA; c) RA was associated with a significant decrease in the adjusted risk of total bleeding and major bleeding; and d) operational efficiency improved.

Since it was first introduced, PCI has been perfected over the years and has now achieved high success with low complication rates. Most of this performance is due to the greater development of dedicated devices, and to the trend toward miniaturization of vascular accesses for the interventions.

Anatomically, the radial artery has a superficial course (1) that allows easy access, as well as a simple and safe compression plane. The learning curve

to achieve adequate competence to perform cardiac catheterization is also fast. In this sense, the expertise acquired after 20-50 PCI procedures using the RA is similar to the operator’s experience with a case volume >300 cases. (10) According to the National Cardiovascular Data Registry, decreased fluoroscopy time and contrast use were nonlinearly associated with greater operator experience in transradial percutaneous coronary intervention as from >30–50 cases. (11)

Nowadays, the radial artery has become the preferred arterial access to perform PCI in many countries throughout the world. (6) In our experience, RA has progressively gained a position as an option for PCI and is even used in more complex cases, as multivessel disease, left main coronary artery stenosis and PCI in bypass grafts. The trend towards a greater use of the RA in our routine practice has been independent of the clinical indication for the procedure (Pint 0.422) and of the anatomical complexity, as evidenced in Figure 1B.

In our protocol, we prefer the right radial artery and we leave the left radial artery for patients with history of CABGS or for elderly patients in whom the left subclavian artery presents less tortuosity. In this sense, the TALENT study, which compared right RA vs. left RA, showed a modest yet significant reduction in fluoroscopy time and radiation exposure (quantified by the dose area product), with the left RA only in the population >70 years. (12) However, in the REVERE trial, which randomized patients undergoing PCI to right RA, left RA or FA, left RA was associated

Fig. 1. A. Trend in the use of radial and femoral access in the general population. **B.** Increasing trend to perform percutaneous coronary intervention procedures using the radial access (ptrend< 0.0001 for all the groups).

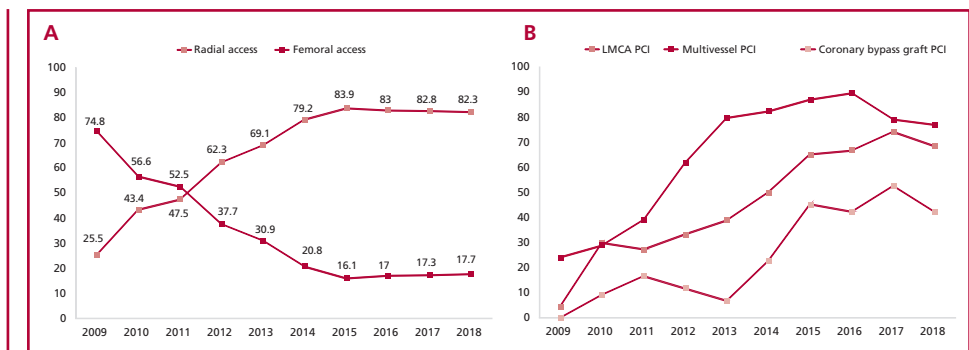


Table 3. Outcomes at 30 days

	Radial access (n=5,706)	Femoral access (n=2,449)	Risk (95% CI)	p
Mortality/AMI/stroke at 30 days, %	3.2	6.3	0.66 (0.5-0.88)	0.004
Mortality at 30 days, %	1.1	3	0.53 (0.33-0.84)	0.008
AMI at 30 days, %	2.1	2.9	0.81 (0.56-1.19)	0.298
Stroke at 30 days, %	0.2	0.9	0.41 (0.17-0.96)	0.042
Total bleeding at 30 days, %	1.3	3.6	0.38 (0.23-0.63)	< 0.0001
Major bleeding, %	0.6	2.4	0.33 (0.16-0.67)	0.002
Access site complications, %	2.8	4.5	0.72 (0.53-0.98)	0.038

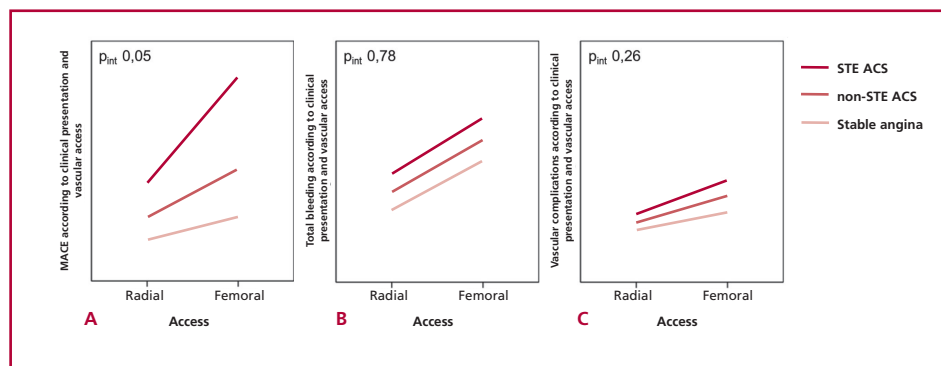


Fig. 2. A. Significant interaction between the vascular access and MACE according to the clinical presentation (P_{int} 0.05). **B.** Interaction between the vascular access and bleeding according to the clinical presentation. **C.** Interaction between the vascular access and access site complications according to the clinical presentation.

with significantly higher operator radiation exposure than were the other vascular accesses. (13) A recent sub-analysis of the British PCI dataset did not show significant differences in mortality or major bleeding, but the patients undergoing left RA had lower rate of stroke. (14) This result should be evaluated in larger randomized studies, since it emerges from the analysis of registries and the previous randomized studies did not evaluate these outcomes. (12, 13)

The potential benefits of RA have been thoroughly studied, with lower rates of bleeding, complications and shorter hospital stays. (1) In our analysis, we have observed a reduction of about 35% in the adjusted risk of MACE at 30 days, at the expense of lower mortality. Application of an interaction term evidenced that the use of RA was associated with lower risk of MACE, particularly in unstable patients (non-STE/STE ACS) (Figure 2 A, P_{int} 0.05). These results are consistent with other reports, which included a large volume of patients (15) and were confirmed in a meta-analysis of randomized trials that found a reduction of about 16% in MACE, particularly at the expense of lower all-cause mortality in \approx 29%. (16)

The anatomical characteristics of the radial artery and the fact that it is easy to compress explain the reduction in bleeding rate and access site complications. In our cohort, RA was associated with a significant decrease in the adjusted risk of total bleeding \approx 60%, major bleeding \approx 70% and access site complications \approx 30%.

The use of RA as primary vascular access has not been associated to lower efficacy and safety of the FA, (17) particularly in centers with experience with this approach. However, in our practice, RA using 6 or 7 Fr sheaths allowed us to approach patients with different anatomical complexities in which we had previously preferred the FA (Figure 1B).

Finally, the use of RA was associated with a significant reduction in the total hospital stay of about 5 h, representing 30% reduction of the average total hospital stay. This could be explained by the possibility of early ambulation, which has markedly improved patients' experience. In the PREVAS study, patients who had undergone both vascular accesses preferred the RA due to lower risk of bleeding, the possibility

of early ambulation and shorter hospital stay. (18) In addition, we have observed a 15% reduction in total hospitalization costs. In line with our results, an analysis conducted among Medicare beneficiaries in the United States found that shifting to RA and same-day discharge programs for PCI would reduce costs by 30%. (19)

These advances have allowed us to increase the number of same-day discharge PCI procedures to 63% over the past years, even in high-risk patients. (20) At the same time, this experience has motivated us to launch a diagnostic and therapeutic catheterization room (radial lounge) for low-risk coronary or peripheral procedures in an ambulatory area that does not resemble a hospital facility, but with the same standards of safety and quality of care. The radial lounge allows patients to enter the catheterization room without having to remove their clothes to undergo procedures via the radial access and eliminates the need for fasting, improving patients' experience while increasing the operational efficiency of hospitalization areas to accommodate patients of higher clinical and anatomical complexity. (21)

Our study has important limitations worth mentioning. The differences observed between the two groups could be subject to biases and confounders regarding variables not measured in our database due to the observational nature of the study. However, sample size and the analysis of an unselected population of treated patients are attributes that make the results relevant for our daily practice. Finally, cross-over between groups was not documented, constituting another potential limitation. Assuming a higher rate of crossover from RA to FA, this bias could contribute to the higher number of high-risk patients in the latter group.

CONCLUSIONS

The implementation of the RA as a standard approach in PCI is safe and effective compared with the FA, with lower adjusted rate of MACE at 30 days and bleeding. This approach significantly reduces total hospital length of stay, increasing patients' satisfaction and a rapid social reinsertion, and improving hospital operational efficiency.

Conflicts of interest

None declared.

(See authors conflicts of interest forms on the website/ Supplementary material).

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