

Risk factors and temporal trends for vascular access-related complications in coronary procedures: evolving from femoral to radial approach

Factores de riesgo y variaciones temporales para complicaciones vasculares asociadas a procedimientos coronarios: evolución de la vía femoral a la radial

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Abstract

Introduction: Radial access is the gold standard for ST-elevation myocardial infarction; nevertheless, there is scarce information in Mexico. **Objectives:** The objectives of this study were to describe the differences in radiation exposure, intervention time, fluoroscopy time, complications and temporal trends, and risk factors among radial and femoral access for coronary procedures. **Materials and Methods:** A total of 493 patients underwent coronary interventions by femoral or radial access. Sociodemographic and procedural data were recorded. A logistic regression model to determine risk factors for complications was performed. **Results:** The population included 346 men and 147 women, with a median age of 63 years, 159 underwent radial and 334 femoral approaches. Complications occurred in 18 patients (3.6%), 11 in radial and 7 in femoral access, with a higher trend in the first 5 months ($n = 14$). Vasospasm was the most common ($n = 9$) complication. Median fluoroscopy time was 12 min for radial and 9 min for femoral groups, with a total radiation dose of $2282 \mu\text{Gm}^2$ and $2848 \mu\text{Gm}^2$, respectively. Temporal trends showed that complications occurred most frequently during the first 6 months of the study. The main predictors for complications were intervention time and one-vessel disease. **Conclusions:** Radial access had higher frequency of complications than femoral approach and they were more common during the first 6 months. The main risk factor was intervention time longer than 60 min.

Key words: Cardiac catheterization. Radial artery. Femoral artery. Coronary angiography. Angioplasty. Mexico.

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Resumen

Introducción: El abordaje radial es el de elección para infarto de miocardio con elevación del segmento ST, sin embargo se desconoce información en México. **Objetivos:** Describir las diferencias en exposición a radiación, tiempo de intervención, tiempo de fluoroscopia, complicaciones y sus variaciones temporales, además de los factores de riesgo entre el abordaje radial y el femoral para procedimientos coronarios. **Método:** Se incluyeron 493 pacientes que fueron sometidos a estudio angiográfico o intervenciones coronarias por abordaje radial o femoral. Se recabaron datos sociodemográficos, antecedentes y variables del procedimiento. Se realizó un modelo de regresión logística para determinar los factores asociados a complicaciones. **Resultados:** Se incluyeron 346 hombres y 147 mujeres, con mediana de edad de 63 años. A 159 se les realizó acceso radial y a 334 femoral. Las complicaciones ocurrieron en 18 pacientes (3.65%): 11 en radial y 7 en femoral, teniendo mayor incidencia en los primeros 5 meses ($n = 14$) y siendo el vasoespasma el más común ($n = 9$). La mediana de tiempo de fluoroscopia fue de 12 minutos para el radial y de 9 minutos para el femoral, con una dosis total de radiación de $2,282 \mu\text{Gm}^2$ y $2,848 \mu\text{Gm}^2$, respectivamente. Las tendencias temporales indicaron que las complicaciones fueron más frecuentes durante los primeros 6 meses. Los principales predictores fueron el tiempo de intervención y la enfermedad de 1 vaso. **Conclusiones:** La vía de acceso radial tuvo más complicaciones que la femoral. Se observaron más complicaciones en los primeros 6 meses del estudio. El principal predictor de complicaciones fue el tiempo de intervención mayor a 60 minutos.

Palabras clave: Cateterismo cardiaco. Arteria radial. Arteria femoral. Angiografía coronaria. Angioplastia. México.

Introduction

Radial access is the preferred puncture site for ST-segment elevation acute myocardial infarction (STEMI) treatment, due to lower complication rates such as bleeding, shorter hospitalization days, and similar success rates compared to femoral approach¹⁻⁴. On the other hand, femoral access has several advantages including lower radiation exposure, more familiarity with this technique, more availability of devices, and higher procedural success rates, which have made this access the gold standard for many decades^{5,6}. Nevertheless, controversies still exist regarding which vascular approach is better in diagnostic angiographic studies and non-ST-segment elevation myocardial infarction (NSTEMI)¹. Therefore, the aim of this study was to compare the differences in intervention time, fluoroscopy time, frequency, temporal trends, and risk factors for complications, in both radial and femoral access in a third-level hospital in Mexico City.

Materials and methods

This was a cross-sectional study made in the Interventional Cardiology Service from the Hospital Central Sur de Alta Especialidad PEMEX Picacho in Mexico City during October 2009-January 2011. We included 493 patients in which coronary procedures were performed for stable coronary artery disease and acute coronary syndromes (both diagnostic and therapeutic). Before the interventional procedure, Allen's maneuver was performed in each patient to examine ulnar collateral flow. The choice of radial or femoral approach was left to the interventional cardiologist discretion. For radial

approach with the Seldinger technique, puncture site was identified by palpation of the radial region (2-3 cm proximal to the radial styloid process) and local anesthesia (2% lidocaine, 10-15 ml) was applied to subcutaneous tissue. Puncture was done at 30-40° and the needle was directed toward the flow direction. After obtaining flow, a guidewire was advanced and the needle was withdrawn. A dilator was later advanced through the guidewire and saline solution with heparin was injected. Finally, an introducer sheath was placed for the passage of guide wires or stents, as needed by each patient. For femoral approach with Seldinger technique, we identified the puncture site 2 cm below the inguinal ligament at the intersection between the anterosuperior iliac spine and the pubic symphysis. The same steps as for radial approach were later repeated. We recorded demographic variables such as age, weight, height, and hospitalization days from the medical history, as well as comorbidities such as hypertension, diabetes, chronic stable angina, previous myocardial infarction, hyperuricemia, dyslipidemia, and smoking. Angiographic procedural data such as type of vascular approach (radial or femoral), complications, intervention time, fluoroscopy time, amount of contrast media, dose-product area, and location of artery disease were taken from the interventional cardiology files.

Statistical analysis

Data were analyzed with STATA/IC v13 (StataCorp, College Station, Texas). For the descriptive analysis, binary variables were described as frequencies and

Table 1. Population baseline characteristics

Invariables	Overall (n = 491), n (%)		Radial approach (n = 159), n (%)		Femoral approach (n = 334), n (%)		p
Men	346 (70.18)		131 (82.39)		215 (64.37)		0.00
Women	147 (29.82)		28 (17.61)		119 (35.63)		
Hyperuricemia	196 (39.75)		58 (36.71)		138 (41.82)		0.28
CKD	87 (17.64)		36 (22.78)		51 (15.45)		0.04
Previous MI	251 (50.91)		79 (50)		172 (52.12)		0.66
Dyslipidemia	245 (49.69)		72 (45.57)		173 (52.42)		0.15
Smoking	163 (33.06)		59 (37.34)		104 (31.52)		0.20
Hypertension	332 (67.30)		107 (67.72)		225 (68.18)		0.91
Diabetes mellitus	237 (48.07)		74 (46.84)		163 (49.39)		0.59
Stable angina	224 (45.90)		71 (44.94)		153 (46.36)		0.76
ACS	89 (18.24)		63 (19.09)		28 (20.14)		0.48
Variables	n	Median (IQR) (minimum-maximum)	n	Median (IQR) (minimum-maximum)	n	Median (IQR) (minimum-maximum)	p
Age (years)	460	63 (55-70) (23-88)	128	62 (54-69.5) (42-83)	332	63 (56-70) (23-88)	0.35
Height (cm)	437	166 (160-170) (144-190)	112	168 (160-170) (144-185)	325	165 (158-170) (140-190)	0.03
Weight (kg)	438	77 (69-83) (35-125)	112	80 (74-85) (51-125)	326	75 (66-82) (35-125)	0.03
Hospitalization days	488	5 (4-8) (2-92)	157	4 (3-8) (2-68)	331	5 (4-8) (2-92)	0.03

CKD: chronic kidney disease; MI: myocardial infarction; ACS: acute coronary syndrome; IQR: interquartile range.

proportions, and they were analyzed with Pearson's independence test (χ^2) or Fisher's exact test, according to the number of individuals per case in the 2 by 2 table. Quantitative variables were analyzed first with Shapiro-Wilks normality test, and according to this, they were described as parametric (mean, standard deviation, and minimum-maximum) or non-parametric (median, interquartile range, and minimum-maximum). Bivariate analysis was done with Student's t-test for parametric variables, and with Mann-Whitney's U-test for non-parametric variables. We constructed a logistic regression model for determining the risk factors for complications. $p < 0.05$ was considered statistically significant.

Results

We included 493 patients who underwent a percutaneous coronary intervention of diagnostic angiography, of which 70.18% were men and 29.82% were women, with a median age of 63 years, median height of 166 cm,

median weight of 77 kg, and median of 5 hospitalization days (Table 1).

Regarding comorbidities, 50.91% ($n = 251$) had previous myocardial infarction, 67.3% ($n = 332$) hypertension, 48.07% ($n = 237$) diabetes, 63.48% chronic stable angina, 49.69% dyslipidemia ($n = 245$), 39.7% ($n = 196$) hyperuricemia, 17.64% ($n = 87$) chronic kidney disease, and 33.06% ($n = 163$) were smokers. The subgroup analysis showed significant differences between radial and femoral approach in sex, chronic kidney disease, hospitalization days, height, and weight (Table 1).

From the whole population, 30.08% did not have significant coronary disease or underwent diagnostic angiography for other reasons (i.e. congenital heart disease or valvulopathy); on the other hand, 36.17% had three-vessel disease. The most frequently diseased coronary artery was the left anterior descending, which was affected in 51.5% and 48.2% in the radial and femoral approach, respectively (Table 2).

The femoral vascular access was more commonly used in this study – 334 interventions. Complications

Table 2. Description of coronary artery lesions by femoral or radial approach

Variables	Radial approach (n = 159)	Femoral approach (n = 334)	p
Normal coronary arteries	28 (20.14)	71 (23.28)	0.46
1-vessel disease	33 (23.74)	52 (17.05)	0.09
2-vessel disease	26 (18.78)	55 (18.03)	0.86
3-vessel disease	52 (37.41)	126 (41.31)	0.43
Left anterior descending	82 (51.57)	161 (48.20)	0.48
Circumflex artery	68 (42.77)	130 (38.92)	0.41
Right coronary artery	68 (42.77)	150 (44.91)	0.65
Left main coronary artery	150 (44.91)	44 (27.67)	0.29
Intermediate artery	31 (19.50)	60 (17.96)	0.68
Diagonal arteries	43 (27.04)	96 (28.74)	0.69
Marginal arteries	38 (23.90)	78 (23.35)	0.89

Table 3. Overall complications, intervention times and radiation by femoral or radial approach

Variables	Radial approach (n = 159)		Femoral approach (n = 334)		p
Complications	11 (6.92)		7 (2.10)		0.00
Hematomas	3 (1.89)		4 (1.20)		0.54
Vasospasm	8 (5.03)		1 (0.30)		0.00
Ventricular fibrillation	0 (0)		2 (0.60)		0.32
Death	0 (0)		0 (0)		1
Crossover	9 (5.66)		0 (0)		0.00
Variables	n	Median (IQR) (minimum-maximum)	n	Median (IQR) (minimum-maximum)	p
Intervention time (hh: mm: ss)	143	1:20:00	315	1:20:00	0.85
Fluoroscopy time (hh: mm: ss)	143	00:12:00	315	00:09:01	0.05
Contrast media (ml)	77	140 (120-250) (80-700)	124	122.5 (100-180) (50-800)	0.00
Dose-product area ($\mu\text{G m}^2$)	143	2282 (1128.7-7290) (316.4-84,400)	315	2800 (1034-5600) (79-24,120)	0.04

IQR: interquartile range.

appeared 18 times, which represented 3.65% of the total population. The most frequent complication was vasospasm (n = 9), which occurred mainly in the radial approach, followed by hematoma (n = 7): 3 in the radial and 4 in the femoral access. Crossover from radial to femoral approach happened in 9 times and was always associated to complications in the original puncture site.

Complications were significantly higher in the radial approach – 6.92% versus 2.1% in the femoral approach. Intervention time between both techniques was similar;

nevertheless, fluoroscopy showed significant differences because the radial approach had 3 min more than the femoral. Finally, dose-area product was significantly higher in the femoral approach (Table 3).

In the logistic regression model, we found that intervention time longer than 60 min was associated with an increase in the overall occurrence of complications. Furthermore, we found certain tendencies toward risk increase for one-vessel disease, diagonal arteries disease, circumflex artery disease contrast media > 150 ml, dyslipidemia, left main artery disease,

Table 4. Logistic regression model for complications in angiographies and percutaneous coronary interventions

Variables	OR	SE	p	95% CI
1-vessel disease	6.19	7.69	0.14	0.54-70.76
Total intervention time > 60 min	5.49	4.59	0.04	1.06-28.32
Diagonal arteries	3.93	3.25	0.09	0.77-19.89
Circumflex artery disease	3.80	3.22	0.11	0.72-19.98
Dyslipidemia	2.75	1.93	0.15	0.69-10.92
Contrast media > 150 ml	1.62	1.41	0.57	0.29-8.94
Left main artery disease	1.54	1.49	0.65	0.23-10.28
Fluoroscopy time > 10 min	1.52	1.32	0.62	0.27-8.41
Female sex	1.28	0.91	0.72	0.31-5.22
Smoking	1.07	0.73	0.92	0.27-4.11
2-vessel disease	1.00	1.54	0.99	0.04-20.60
3-vessel disease	0.94	1.63	0.97	0.03-27.79
Right coronary artery disease	0.94	0.70	0.94	0.21-4.08
Previous myocardial infarction	0.91	0.56	0.87	0.26-3.10
Left anterior descending disease	0.80	0.58	0.76	0.19-3.30
Age < 50 years	0.75	0.71	0.76	0.11-4.88
Intermediate artery disease	0.52	0.65	0.60	0.04-3.96
Diabetes mellitus	0.47	0.33	0.28	0.12-1.85
Marginal arteries	0.40	0.47	0.43	0.04-3.96
Chronic kidney disease	0.28	0.32	0.26	0.03-2.57
Acute coronary syndrome	0.22	0.27	0.22	0.01-2.46

$R^2 = 0.3$. OR: odds ratio; SE: standard error; 95% CI: 95% confidence interval.

fluoroscopy > 10 min, female sex, and smoking, but without statistical significance (Table 4).

Temporal trends for the presence of complications showed that 14 events occurred in the first 6 months, and the 3rd month had the largest amount of events ($n = 5$). Figure 1 shows the frequency of complications per month and a decreasing tendency of these events toward the end of the study.

Discussion

To the best of our knowledge, this is the first study to compare outcomes by either radial or femoral approach in a Mexican population. Campeau described

radial access for the 1st time in 1989, and its use has been increasing since then¹⁻⁶. The main anatomical advantages offered for coronary interventions are the absence of large-size nerves or veins near the puncture site and double circulation to the rest of the hand which prevents ischemia and movement complications.⁷ Furthermore, it has become the most used technique due to high success and low complication rates, along with bleeding reduction in the puncture site. Nowadays, due to a more extended use, the radial access is not only applied in coronary interventions, but in peripheral interventions such as carotid artery, femoral, superficial, mesenteric, and renal artery disease³.

Our study found that the complication rate was higher among radial access patients compared to femoral approach; nevertheless, we have to clearly state that most of these events ($n = 14$) occurred during the first 6 months of the implementation of this technique. This phenomenon can be explained by the learning curve period, which is inherent to every recently acquired technique, in which the center has to perform certain amount of procedures to gain experience to accomplish a high success rate and low complication frequency as explained in other studies^{8,9}. On the other hand, it is important to recall that the study was made in an Interventional Cardiology Department that formerly was adapted to perform procedures using the femoral approach, and the operators had to adapt to the new radial-designed materials such as catheters, guide wires, and introducer sheaths.

As recently shown by the most recently published guidelines on ST-elevation myocardial infarction, radial approach has become the default access for coronary interventions in this context, due to its higher success, lower bleeding, and lower mortality rates¹. It is important to recall that our study included acute coronary syndromes as well as diagnostic angiographies and procedures for chronic stable angina. Furthermore, it is important to mention the great amount of multivascular disease (i.e., disease of more than one vessel) to state a more complex coronary anatomy in this population, which increases the intervention and fluoroscopy times, as well as the overall complication rates including bleeding and vasospasm, and prolongs the intervention time as well as the fluoroscopy time.

Vascular complications are the most prevalent and are mainly provoked by anatomical variants in the puncture site¹⁰⁻¹². After multiple punctures, radial artery tends to thicken its intimal media layer¹³; this generates higher complication and lower success rates. Unfortunately, we were not able to record which patients

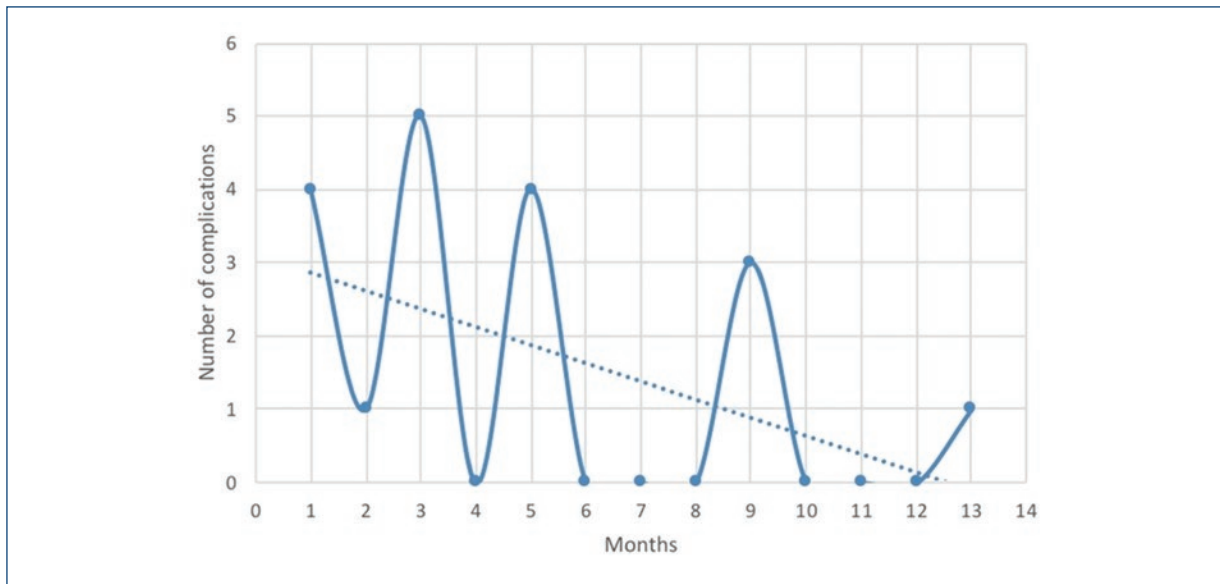


Figure 1. Temporal trends of complications in the femoral and radial approach.

underwent more than one puncture or have had a previous coronary intervention by the radial approach.

Vasospasm was the most commonly found complication in both types of approach. Meanwhile, crossover was done 9 times due to complication in the radial access. Radial access failure has been reported in up to 12.5%, and the most common factors are the lack of guide wire support, difficulty to cannulate the vessel and unfavorable anatomy¹⁴.

In our analysis, women made up to almost 30% of the population, and the gender did not explain the presence of complications. Other studies have demonstrated that women are more prone to require more than one radial puncture and that they have a higher risk for bleeding compared to men, which can be explained due to a less prominent diameter of the radial artery^{15,16}.

Radiation exposure is one of the main concerns for both the interventional cardiologist and the patient¹⁷. Radial access is associated to a higher radiation exposure, measured in $\mu\text{G m}^2$, in diagnostic and angioplasty procedures^{18,19}; however, in our study, radiation exposure was higher in the femoral access, suggesting that radial access can be both safe and effective. Regarding interventional and fluoroscopy time, the previous studies showed longer exposure times in radial access²⁰⁻²³. This fact can be explained because many of these studies were performed before 2010, a time in which a lower frequency of radial procedures was performed. On the other hand, our

study showed that there were differences in the fluoroscopy time, with lower times in the femoral approach; meanwhile, the logistic regression model that intervention times longer than 60 min was associated to more complications.

One of the most acclaimed advantages for the radial access is the reduction in hospitalization time due to a lower need of resting time and a faster time to the reintegration to the daily activities²⁴. In our study, we were able to demonstrate a 1-day reduction in hospitalization, which can lower the costs of health systems and help to a faster reintegration to the patients' life.

Finally, we have to make emphasis that both approaches are safe and that randomized controlled trials show that in high-volume centers, in which a greater amount of procedures are made, radial access procedures have shown better results²⁵.

The limitations of our study were the lack of randomization that could have made the groups more homogeneous, the high number of interventional cardiologist operators and being a single-center study.

Conclusions

This study showed that femoral approach had lower complication rates than the radial approach. Furthermore, the complications occurred more frequently in the first 6 months and the main predictor for complications was the intervention time > 60 min. More studies are

needed to identify earlier and prevent the potential complications associated to interventional procedures.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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