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Original Article

Failure of the Transradial Approach in a High-Volume Center

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ABSTRACT

Background: The mechanisms and predictors of failure of the transradial approach in centers dedicated to this technique are not well characterized and were the main objective of this analysis. **Methods:** 6,808 consecutive patients undergoing transradial coronary procedures by operators with utilization rate greater than 90% were included. Simple and multiple logistic regression models were used to identify the predictors of failed transradial approach. **Results:** Transradial failure rate was 1.7%. Vascular complications were observed in 5% of the sample, with a prevalence of asymptomatic arterial occlusion and subcutaneous hematomas. Predictors of failure were female gender (OR = 1.87; 95% CI: 1.29-2.71; p = 0.01), age > 70 years (OR = 1.78; 95% CI: 1.06-2.98; p = 0.03) and presence of chronic peripheral arterial disease (OR = 5.71; 95% CI: 2.40-13.54; p < 0.01). **Conclusions:** In a high-volume radial center, the failure rate was < 2% and variables associated with failure of the technique were female gender, advanced age and peripheral arterial disease.

DESCRIPTORS: Radial artery. Percutaneous coronary intervention. Hemorrhage. Ischemia.

RESUMO

Insucesso da Técnica Radial em Centro com Alto Volume de Procedimentos

Introdução: Os mecanismos e preditores de insucesso da técnica radial em centros que priorizam essa via não estão bem caracterizados, sendo tal caracterização o objetivo principal desta análise. **Métodos:** Foram incluídos 6.808 pacientes consecutivos submetidos a procedimentos coronários invasivos pelo acesso radial por operadores com taxa anual de utilização da via superior a 90%. Para a identificação dos fatores associados ao insucesso da técnica, foram ajustados modelos de regressão logística simples e múltipla. **Resultados:** A taxa de insucesso da técnica radial foi de 1,7%. Complicações vasculares ocorreram em 5% da amostra, com predomínio de oclusão arterial assintomática e hematomas subcutâneos. Os preditores de insucesso foram sexo feminino (OR = 1,87; IC 95% 1,29-2,71; p = 0,01), idade > 70 anos (OR = 1,78; IC 95% 1,06-2,98; p = 0,03) e presença de insuficiência arterial periférica crônica (OR = 5,71; IC 95% 2,40-13,54; p < 0,01). **Conclusões:** Em um centro caracterizado por alto volume de procedimentos realizados pelo acesso radial, a taxa de insucesso foi < 2%, sendo as variáveis associadas à falência da técnica sexo feminino, idade avançada e insuficiência arterial periférica.

DESCRITORES: Artéria radial. Intervenção coronária percutânea. Hemorragia. Isquemia.

The transradial approach has been established as a strategy for reducing vascular complications and episodes of severe bleeding in patients undergoing invasive coronary procedures, with potential impact on morbidity and mortality, especially in the case of acute coronary syndrome (ACS) with ST-segment elevation.[1,2] However, due to the smaller diameter of the radial artery, as well as the greater anatomical variability of its vascular bed, there is a learning curve, which results in increased radiological exposure, use of contrast, failure rates, and need for crossing to femoral access.[3-6]

Although described among surgeons with a low/moderate use of the radial access,[7] the mechanisms and technique failure predictors in centers that prioritize this route are not adequately characterized; this was the main objective of this analysis.

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METHODS

Study population

Consecutive patients undergoing diagnostic and/or therapeutic coronary procedures via the radial route in the period between May 2008 and January 2012 were included. All procedures were performed by operating physicians with an annual utilization rate of this technique of over 90%. The exclusion criteria were: presence of upper limb arteriovenous fistula, lymphedema, or prior coronary artery bypass graft (CABG) surgery with more than one internal mammary or left radial artery graft.

Definitions

Success of the technique was defined as a coronary angiography and left ventriculography and/or a percutaneous coronary intervention (PCI) without changing the access route. Vascular complications at the puncture site were: severe bleeding, hematoma > 5 cm, arteriovenous fistula, pseudoaneurysm, arterial occlusion, or the need for reconstructive vascular surgery. According to the definition of the Bleeding Academic Research Consortium,[7] bleedings of type 3 or 5 were considered as severe . Hematomas were graded as type I (≤ 5 cm diameter), type II (≤ 10 cm diameter), type III (> 10 cm, without reaching the elbow), type IV (hematoma extending beyond the elbow) or type V (any hematoma with ischemic injury to the hand).[8]

Radial technique

Upon hyperextension of the wrist and infiltration of 1-2 mL of 2% xylocaine, the radial artery was punctured 1 cm proximal to the styloid process of the radius by a 20 to 22 gauge polyethylene needle catheter , using the Seldinger (or modified Seldinger) technique. After the puncture, a 0.021-guide wire was introduced, followed by a small skin incision with a No. 11 scalpel blade and insertion of a short F5-or F6-hydrophilic sheath. A solution containing 5000-IU heparin sulfate and 10-mg isosorbide mononitrate was administered through the extension of the sheath. At the end of the procedure, the sheath was immediately removed; hemostasis was undertaken with a pressure dressing with porous elastic adhesive bandage in diagnostic examinations; or with a selective compressor bracelet in therapeutic interventions. At the time of hospital discharge, the patient underwent a clinical examination of the puncture site and radial pulse evaluation.

Statistical analysis

Quantitative data were summarized as means ± standard deviations, and qualitative data as absolute and relative frequencies (percentages). These characteristics have been described for all patients and according to the procedure result (success or failure of transradial technique). For comparison, Student's *t*-test was used for quantitative variables and chi-squared test for qualitative variables.

To identify the factors associated with failure of the procedure, simple (univariate approach) and multiple (multivariate analysis) logistic regression models were adjusted. These results were expressed as odds ratios and confidence intervals of 95% (95% CI). Variables with $p < 0.20$ in the univariate analysis were selected for the multivariate model. Based on the full multivariate model, the variables with no statistical significance were excluded with a stepwise approach, until a reduced model was obtained with only the variables that remained significant at the usual level of 0.05. For these calculations, SPSS for Windows, version 19.0, was used.

RESULTS

Out of a total of 7,449 invasive coronary procedures, 6,808 (91.4%) were performed via the radial, 392 (5.3%) via the femoral, and 244 (3.3%) via the ulnar access. The sample was mostly composed of diagnostic tests (77.6%). The failure rate of the transradial technique was 1.7% (114 cases).

Table 1 lists the patients' features in relation to the factors studied, as well as a comparison between those with success versus failure. It was noted that unsuccessful patients were, on average, 2.6 years older (63.9 ± 12.6 vs. 61.3 ± 11.1; $p = 0.01$). When the patients' age was categorically analyzed, in age groups, it was found that the frequency of failures was higher among the elderly. In the failure group, a higher proportion of women (55.3% vs. 39.8%; $p < 0.01$) and a higher prevalence of peripheral arterial disease (5.3% vs. 1.0%; $p < 0.01$) were observed.

Based on the initial analysis, the multiple logistic regression models (multivariate analysis) were adjusted considering the age quantitatively and by age group. The results were the same for both approaches (Table 2). The most important risk factor was chronic peripheral arterial disease (OR = 5.71; 95% CI: 2.40-13.54; $p < 0.01$), increasing the chance of failure of the procedure. Another factor that remained significant in the model was gender, with greater risk of failure among women (OR = 1.87; 95% CI: 1.29-2.71; $p = 0.01$). When quantitatively analyzing patient's age, a trend was observed ($p = 0.07$), indicating that the higher the age, the higher the chances of failure of the technique.

Based on full multivariate models (i.e., with the inclusion of all variables with $p < 0.20$ in the univariate analysis), all variables without statistical significance were excluded. Thus, a reduced model was created, containing only those variables that remained statistically significant (Table 3). Both in the analysis by age group and by age in years, the results were similar: gender and peripheral arterial disease remained in the model, and age (or age group) became statistically significant,

TABLE 1
Patient characteristics for the entire sample and according to the result of the procedure – comparisons between successes and failures

		Procedure result		
Variables	**Total (n = 6,808)**	**Successful (n = 6,694)**	**Failure (n = 114)**	***p value***
Female gender, n (%)	2,727 (40.0)	2,664 (39.8)	63 (55.3)	< 0.01
Age, years	61.4 ± 11.2	61.3 ± 11.1	63.9 ± 12.6	0.01
Age group (years), n (%)				0.08
< 40	174 (2.6)	171 (2.6)	3 (2.6)	
40-50	1,029 (15.1)	1,012 (15.1)	17 (14.9)	
51-60	1,951 (28.7)	1,926 (28.8)	25 (21.9)	
61-70	2,157 (31.7)	2,124 (31.7)	33 (28.9)	
71-80	1,255 (18.4)	1,228 (18.3)	27 (23.7)	
> 80	242 (3.6)	233 (3.5)	9 (7.9)	
BMI, kg/m^2	27.5 ± 4.9	27.5 ± 4.9	27.5 ± 5.2	0.88
BMI ranges (kg/m^2), n (%)				0.35
< 18.5	87 (1.3)	84 (1.3)	3 (2.6)	
18.5-24.9	2,154 (31.6)	2,121 (31.7)	33 (28.9)	
25.0-29.9	2,799 (41.1)	2,756 (41.2)	43 (37.7)	
≥ 30	1,768 (26.0)	1,733 (25.9)	35 (30.7)	
SH, n (%)	5,327 (78.2)	5,231 (78.1)	96 (84.2)	0.12
NIDDM, n (%)	1,691 (24.8)	1,661 (24.8)	30 (26.3)	0.71
IDDM, n (%)	290 (4.3)	285 (4.3)	5 (4.4)	0.82
Dyslipidemia, n (%)	3,192 (46.9)	3,136 (46.8)	56 (49.1)	0.63
Smoking, n (%)	1,861 (27.3)	1,837 (27.4)	24 (21.1)	0.13
CPAD, n (%)	73 (1.1)	67 (1.0)	6 (5.3)	< 0.01
Stroke, n (%)	233 (3.4)	229 (3.4)	4 (3.5)	0.80
CRF, n (%)	191 (2.8)	187 (2.8)	4 (3.5)	0.56
Previous AMI, n (%)	751 (11.0)	732 (10.9)	19 (16.7)	0.05
Previous coronariography, n (%)	2,213 (32.5)	2,168 (32.4)	45 (39.5)	0.11
Previous PCI, n (%)	782 (11.5)	769 (11.5)	13 (11.4)	0.98
Previous coronariography + PCI, n (%)	744 (10.9)	733 (11.0)	11 (9.6)	0.66
Catheter size (F), n (%)				0.55
5	4,724 (69.4)	4,642 (69.3)	82 (71.9)	
6 or 7	2,084 (30.6)	2,052 (30.7)	32 (28.1)	

BMI, body mass index; SH, systemic hypertension; NIDDM, non-insulin-dependent diabetes mellitus; IDDM, insulin-dependent diabetes mellitus; CPAD, chronic peripheral arterial disease; CRF, chronic renal failure; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention.

according to the usual level of 0.05. In the analysis that considered age groups, the significance emerged when comparing older patients (> 70 years) with those aged 51-60 years (OR = 1.78; 95% CI: 1.06-2.98; p = 0.03). The comparison between patients > 70 years and those aged 61-70 years was marginally significant (OR = 1.53; 95% CI: 0.95-2.46; p = 0.084).

The right radial artery was used in 94% of procedures. In the case of failure of the technique needing route crossing, the preferred alternative access was equally shared between radial and left femoral artery (36% each), followed by the ulnar artery (28%). The most common causes of failure were prior occlusion of the arterial bed (35.4%), predominantly of brachial artery after using the Sones technique; radial spasm (34.4%); radioulnar, innominate artery, or aortic arch tortuosity (26.0%); and arterial perforation or dissection (4.2%). The rate of vascular complications was 5%, with predominance of asymptomatic occlusion of radial artery and subcutaneous hematomata (Table 4).

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TABLE 2
Factors associated with failure. Results of simple (univariate analysis) and multiple (multivariate analysis) logistic regression model, considering age in age groups

	Univariate analysis			Multivariate analysis		
Factors	**OR**	**95% CI**	***p value***	**OR**	**95% CI**	***p value***
Female gender	1.869	1.288-2.712	0.01	1.838	1.253-2.697	0.01
Age group (years)						
≤ 50	1.302	0.720-2.355	0.38	1.423	0.782-2.590	0.25
51-60	1.000	–	–	1.000	–	–
61-70	1.197	0.709-2.020	0.50	1.130	0.665-1.919	0.65
> 70	1.898	1.135-3.176	0.02	1.685	0.986-2.878	0.06
SH	1.492	0.899-2.476	0.12	1.204	0.709-2.044	0.49
BMI ranges (kg/m^2)						
< 18.5	2.295	0.690-7.635	0.16	1.930	0.566-6.586	0.29
18.5-24.9	1.000	–	–	1.000	–	–
25.0-29.9	1.003	0.635-1.584	0.99	1.035	0.651-1.646	0.89
≥ 30	1.298	0.803-2.097	0.29	1.284	0.778-2.117	0.33
Smoking	0.705	0.448-1.110	0.13	0.800	0.496-1.290	0.36
Previous AMI	1.629	0.989-2.682	0.06	1.474	0.856-2.539	0.16
CPAD	5.495	2.333-12.941	< 0.01	5.096	2.101-12.359	< 0.01
Previous coronariography	1.362	0.932-1.989	0.11	1.207	0.801-1.820	0.37

OR, odds ratio; 95% CI, 95% confidence interval; SH, systemic hypertension; BMI, body mass index; AMI, acute myocardial infarct; CPAD, chronic peripheral arterial disease.

TABLE 3
Factors associated with failure. Results of the reduced multiple logistic regression model (considering only significant variables), with age in age groups

Factors	**OR**	**95% CI**	***P-value***
Female gender	1.863	1.281-2.710	0.01
Age group (years)			
≤ 50	1.351	0.746-2.447	0.32
51-60	1.000	–	–
61-70	1.163	0.689-1.966	0.57
> 70	1.776	1.059-2.978	0.03
CPAD	5.706	2.401-13.542	< 0.01

OR, odds ratio; 95% CI, 95% confidence interval; CPAD, chronic peripheral arterial disease.

TABLE 4
Vascular complications associated with the arterial puncture site

Variables	**n = 6,808**
Asymptomatic artery occlusion, No. (%)	272 (4.0)
Pseudoaneurysm, n (%)	1 (0.01)
Arteriovenous fistula, n (%)	2 (0.03)
Hematoma (type), n (%)	
I	170 (2.5)
II	102 (1.5)
III	31 (0.46)
IV	28 (0.41)
V	8 (0.12)
Severe bleeding, n (%)	1 (0.01)
Compartment syndrome, n (%)	4 (0.06)
Vascular surgery, n (%)	1 (0.01)

DISCUSSION

Lower rates of severe bleeding in the arterial puncture site and less need for transfusion are the mechanisms responsible for the reduced mortality observed in the radial access, when compared with the femoral access.[9] Thus, the most consistent benefits are demonstrated in patients undergoing primary PCI, commonly treated with aggressive antithrombotic pharmacotherapy and exposed to higher risks.[10,11] However, consensuses about this topic reinforce the importance of procedures performed by experienced operating physicians, with low percentage of failure of the technique (less than 4%), so that the technical difficulties do not result in a delayed reperfusion of the target vessel.[1,2]

While the learning curve is a limiting factor for a more universal acceptance of the radial technique, it is estimated that currently, with the advent of miniaturized dedicated devices with hydrophilic coating, the threshold for mastery of the technique is approximately 30-50 therapeutic procedures.[6] The gain in experience is reflected on the performance of more complex procedures, in patients with more severe conditions, with an impact on morbidity and mortality, as demonstrated in a London registry involving 10,095 patients with ACS without ST-segment elevation.[12] Data for the triennium 2005-2007, when the radial program started, did not indicate the technique as a predictor of mortality reduction. Since 2008, after the learning curve was transposed, the choice of the radial route has promoted a 35% reduction in mortality at 12 months (OR = 0.65; 95% CI: 0.46-0.92; p = 0.02). Similar findings were observed in the comparison between centers of low- and high-volume usage of this route, a hypothesis previously generated in the seminal study radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL).[13]

In the present series, the failure rate was 1.7%, comparable to the statistics of centers that use the radial route in over 90% of their procedures. In an Italian registry encompassing 10,676 procedures, the absolute rate of technical crossing was 4.9%.[14] However, operating physicians dedicated to the transradial approach exhibited a lower percentage of failure compared to others (2.1% vs. 6.6%; $p < 0.01$). Even among these, a progressive decrease in the failure rate throughout the evaluation period was observed (3.4% by 2006, 1.4% by 2008, and 1.0% by 2010; $p < 0.01$).

According to data analyzed in the present sample, failure predictors were restricted to: female gender, age > 70 years, and presence of chronic peripheral arterial disease. These findings are similar to those in the literature, which still show as predictors of failure, in addition to age > 70 years and female gender, previous CABG, and short stature.[14,15] The rate of vascular complications was low (close to 1%), when cases of arterial occlusion, whose demonstration was asymptomatic in its entirety, were not taken into consideration, which emphasizes the safety profile of this technique.

Limitations

A possible limitation of this study was the number of failures, which was small relative to the number of successes; this could undermine the comparative analysis. In order to minimize this bias, the data were re-analyzed considering a random sample of 114 patients from the success group, leading to two matched groups of the same size. The results were essentially the same, that is, female gender, age > 70 years, and chronic peripheral arterial disease was predictors of failure with the use of the radial technique.

CONCLUSIONS

In a center characterized by a high number of procedures performed via the radial route (over 90% of cases), the failure rate (and, thus, the need for crossing between routes) was 1.7%. The variables associated with failure of the technique were female gender, age > 70 years, and presence of chronic peripheral arterial disease.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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