Original Article

Comparing radial and femoral access for percutaneous coronary intervention in chronic total occlusions

Thalles O. Gomes[a], Júlio César Borges[b], Eduardo Kei M. Washizu[c], Igor Ferreira de Sales[c], Bruno R. Nascimento[c,*]

[a] *Hospital Nossa Senhora de Fátima, Patos de Minas, MG, Brazil.*
[b] *Hospital Medcenter, Patrocínio, MG, Brazil.*
[c] *Hospital das Clínicas, Universidade Federal de Minas Gerais, Belo Horizonte, MG, Brazil.*

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ABSTRACT

Background: Coronary chronic total occlusion (CTO) is present in approximately 15% of coronary angiographies, and the success rates of percutaneous coronary interventions (PCI) range from 55 to 80%. The radial access has been increasingly used, even in more complex scenarios, such as CTO. The objective was to compare the profile and results of CTO patients undergoing PCI by radial or femoral access, and evaluate the independent predictors of in-hospital mortality.
Methods: Data from the CENIC registry on patients submitted to CTO PCI from June 2006 to March 2016 were included and compared according to the access used. Death, reinfarction, and emergency revascularization during hospital stay were defined as major adverse cardiovascular events (MACE). A logistic regression model was adjusted for the evaluation of predictors of in-hospital mortality.
Results: A total of 3,768 patients (radial access: 905) and 3,799 procedures were included. Mean age was 60.4 ± 11.0 years, and 68.4% were males. Angiographic success was similar between the radial and femoral groups (96.9% *vs.* 96.6%, $p = 0.061$), as well as MACE rates (0.6% vs. 0.7%, $p = 0.71$) and their individual components. The radial access had no association with death (OR = 0.57; 95% CI: 0.13-2.50, $p = 0.46$). Age, female sex, extent of coronary disease, and use of glycoprotein IIb/IIIa inhibitors were independent predictors of in-hospital mortality.
Conclusions: Success rates in the treatment of coronary CTO were exceptionally high and similar in both groups. The rates of in-hospital MACE were low and similar, and the access chosen had no association with in-hospital mortality.

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Comparação das vias de acesso radial e femoral para intervenção coronária percutânea em oclusões crônicas

Palavras-chave:
Doença da artéria coronariana
Angioplastia coronária com balão
Oclusão coronária
Artéria radial
Artéria femoral

RESUMO

Introdução: As oclusões coronárias crônicas (OCC) estão presentes em aproximadamente 15% das coronariografias, com taxas de sucesso das intervenções coronarianas percutâneas (ICP) entre 55 e 80%. Tem-se observado um aumento da utilização da via radial, inclusive em contextos mais complexos, como nas OCC. Objetivamos comparar o perfil e os resultados de pacientes com OCC submetidos à ICP pela via radial vs. femoral, e avaliar os preditores independentes de mortalidade hospitalar.
Métodos: Foram incluídos dados do registro CENIC de junho de 2006 a março de 2016 de pacientes submetidos a tratamento de OCC, comparados de acordo com a via de acesso. Definiu-se a ocorrência de óbito, reinfarto ou revascularização de emergência na fase hospitalar como eventos cardiovasculares adversos maiores (ECAM). Um modelo de regressão logística foi ajustado para avaliação dos preditores de mortalidade hospitalar.
Resultados: Foram incluídos 3.768 pacientes (radial: 905), com idade de 60,4 ± 11,0 anos, 68,4% do sexo masculino, perfazendo 3.799 procedimentos. O sucesso angiográfico foi semelhante entre os grupos radial e femoral (96,9% vs. 96,6%; $p = 0,61$), assim como os índices de ECAM (0,6% vs. 0,7%; $p = 0,71$) e seus componentes individuais. A via de acesso radial não teve associação com óbito (OR = 0,57; IC 95% 0,13-2,50; $p = 0,46$), sendo idade, sexo feminino, extensão da doença coronariana e utilização de inibidores de glicoproteína IIb/IIIa os preditores independentes de mortalidade hospitalar.
Conclusões: Os índices de sucesso no tratamento de OCC foram excepcionalmente elevados e semelhantes entre os grupos. Os índices de ECAM hospitalares foram baixos e também similares, e a via de acesso não teve associação com a mortalidade hospitalar.

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* Corresponding author: Avenida Professor Alfredo Balena, 190, sala 246, CEP: 30130-100, Belo Horizonte, MG, Brazil.
E-mail: ramosnas@gmail.com (B.R.Nascimento).
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Introduction

Coronary chronic total occlusions (CTO) are morphologically characterized by variable percentages of atherosclerotic plaque, organized thrombus, neovascularization, negative vascular remodeling and calcification, resulting in complete interruption of the anterograde flow (Thrombolysis in Myocardial Infarction - TIMI - grade 0, no distal flow), presumably present for more than 3 months. The true prevalence of CTO remains uncertain due to the significant number of oligosymptomatic or asymptomatic patients. However, it is estimated these occlusions are present in approximately 15% of coronary angiographies, reaching 30% in patients with multivessel coronary artery disease (CAD) or left main coronary artery disease.[1-3] In addition to relief of ischemic symptoms, the benefits of revascularization may include improvement in ventricular function, reduced predisposition to ventricular arrhythmias, prevention of ventricular remodeling, and increased survival, in some series.[4] Attempts for percutaneous coronary intervention (PCI) in CTO occur in 12 to 15% of cases, with success rates ranging from 55 to 80% and related to some factors, such as the interventional cardiologist experience, availability of appropriate materials, and adequate case selection.[1,2]

Interventional Cardiology has observed increasing use of the transradial technique in PCI since they were described by Campeau.[5] Currently they are used in complex interventions, such as for CTO. Although the RIVAL study[6] has not demonstrated reduced mortality, it did find less bleeding and vascular complications with radial access as compared to femoral approach.

The objective of this study was to compare the profile and results of CTO patients submitted to PCI via radial or femoral access in our setting, as well as to evaluate the independent predictors of in-hospital mortality in this population.

Methods

Data extracted from the database of the *Central Nacional de Intervenções Cardiovasculares* (Brazilian National Registry of Cardiovascular Interventions; CENIC) of the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI),[7] in a 10-year period (June 2006 to March 2016) were included in this analysis. Data from patients who underwent PCI for CTO treatment, defined as a 100% luminal diameter obstruction not related to acute myocardial infarction or to recent acute coronary syndrome were included. Patients were divided according to the vascular access used for the procedure, either radial or femoral artery. Death, reinfarction or emergency revascularization were defined as in-hospital major adverse cardiovascular events (MACE), according to previously standardized definitions, and reported at the discretion of the attending medical team.[8]

Statistical analysis

A descriptive analysis of demographic and clinical variables, in addition to angiographic and PCI-related variables was performed. The distribution pattern of variables was evaluated using the Shapiro-Wilk test. Continuous variables were expressed as mean± standard deviation (SD), and categorical variables were expressed as absolute and percentage values. The Student's *t* test was used to compare continuous variables with normal distribution, and the Mann-Whitney U test was used for those with non-normal distribution. Discrete variables were compared using the Pearson's Chi-square test. Simple and multiple logistic regression models were adjusted to evaluate demographic, clinical, and procedure-related variables associated with in-hospital mortality. Significant variables ($p < 0.10$) in the univariate analysis were included in the multivariate model. Variables with large proportions of missing data were excluded from the models. A two-tailed test with a 0.05 significance level was considered statistically significant. Statistical analysis was conducted using the software Statistical Package for Social Science (SPSS), version 22.0 for Mac OSX (SPSS Inc., IBM®, Chicago, USA).

Results

The total sample consisted of 3,768 patients submitted to 3,799 procedures (1.01 procedure per patient) in 4066 vessels. Mean age of 60.4 ± 11.0 years, and 68.4% were male.

Clinical characteristics were relatively similar between the groups, with slightly higher rates of smoking, hypertension, and diabetes mellitus in the radial group. In this group, the proportion of symptomatic patients was also slightly higher (Table 1). The groups were similar in relation to angiographic characteristics, with a predominance of single vessel patients in both groups, making up 66.7% of sample. The left anterior descending artery territory had the highest proportion of interventions (41.0%). There was a slightly lower percentage of angiographic complexity markers in the radial group: calcified (18.1% vs. 22.4%; $p = 0.005$); thrombotic 14.1% *vs.* 22.1%; $p < 0.001$); > 20-mm (28.7% vs. 32.4%; $p = 0.03$); and bifurcated (16.2% vs. 27.4%; $p < 0.001$) lesions. Approximately 60% of patients in both groups presented with some degree of left ventricular dysfunction (Table 2).

Stents were used in 100% of PCI, totaling up 4,870 devices (1.3 stent per procedure); with 24.7% receiving drug-eluting stents.

The lesions were relatively long, the mean stent length was 24.0 ± 8.9 mm and 23.0 ± 8.1 mm ($p < 0.001$) in the radial and femoral groups, respectively. Thrombo-aspiration was performed in only 2.1% of procedures, with a lower proportion in the radial group, which also used less glycoprotein IIb/IIIa inhibitors. Angiographic success rates were high and similar in both groups (96.9% vs. 96.6%; $p = 0.61$) (Table 3).

The in-hospital incidence of MACE was low and similar in both groups (0.6% vs. 0.7%; $p = 0.71$). Death and reinfarction rates were similar, and there were no cases of emergency revascularization (Table 4).

In the logistic regression model, radial access was not associated with in-hospital death (odds ratio - OR = 0.57; 95% confidence interval - 95% CI: 0.13-2.50; $p = 0.46$). After adjusting for clinical, angiographic, and procedure-related variables, the independent predictors of mortality were age, female sex, extent of CAD, and use of glycoprotein IIb/IIIa inhibitors (Table 5).

Discussion

Data derived from the national registry CENIC demonstrated approximately a quarter of the PCI for CTO performed in Brazil used the radial access, with high angiographic success rates, similar to those conducted by the femoral approach. Despite the similar clinical profile, the radial group had less complex angiographic characteristics. The in-hospital incidence of MACE was low and similar in both radial and femoral groups, and no association of vascular access and mortality was observed

PCI in CTO is one of the frontiers of Interventional Cardiology. When conducted by radial access, the procedure may be even more challenging, considering the learning curve, safety and potential benefits of this technique. However, the femoral approach still prevails in Brazil,[9] as observed in data collected. Currently, the learning curve for the radial access is not long and requires approximately 50 to 70 cases for interventionists with experience in the femoral approach.[10] The development of radial technique has exceptionally advanced, and its use has been consolidated in increasingly complex procedures, such as CTO.

Table 1
Clinical characteristics

Characteristics	Access			p value
	Radial (n = 905)	Femoral (n = 2,863)	Total (n = 3,768)	
Age, years	60.1 ± 10.4	60.5 ± 11.2	60.4 ± 11.0	0.36
Male, n (%)	650 (71.8)	1,929 (67.4)	2,579 (68.4)	0.01
Smoking, n (%)	202 (22.3)	537 (18.8)	739 (19.6)	0.02
Hypertension, n (%)	720 (80.2)	2,002 (70.5)	2,722 (72.8)	< 0,0001
Dyslipidemia, n (%)	447 (49.4)	1,583 (56.6)	2,030 (55.3)	0.003
Diabetes, n (%)	145 (22.9)	424 (17.5)	569 (18.6)	0.002
Previous MI, n (%)	230 (36.4)	868 (35.8)	1,098 (35.9)	0.77
Previous PCI, n (%)	92 (10.7)	592 (21.4)	684 (18,9)	< 0,0001
Previous CABG, n (%)	25 (2.8)	107 (3.8)	132 (3.5)	0.17
Clinical presentation, n (%)				0.01
Stable angina	724 (80.0)	2,176 (76.0)	2,900 (77.0)	
Asymptomatic	181 (20.0)	687 (24.0)	868 (23.0)	

MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery.

Table 2
Angiographic characteristics

Characteristics	Access			p value
	Radial (n = 905 patients/ 911 procedures/970 vessels)	Femoral (n = 2,863 patients/ 2,888 procedures/3,096 vessels)	Total (n = 3,768 patients/ 3,799 procedures/4,066 vessels)	
Extension of coronary disease, n (%)				0.07
Single-vessel	477 (64)	1,841 (67.4)	2,318 (66.7)	
Two-vessel	186 (25)	589 (21.6)	775 (22.3)	
Three-vessel	77 (10.3)	295 (10.8)	372 (10.7)	
Multivessel + LMCA	5 (0.7)	6 (0.2)	11 (0.3)	
Treated vessels, n (%)				0.004
LAD	374 (38.6)	1,295 (41.8)	1,669 (41)	
RCA	355 (36.6)	1,134 (36.6)	1,489 (36.6)	
LCx	235 (24.2)	613 (19.8)	848 (20.9)	
Bypass graft	4 (0.4)	44 (1.4)	48 (1.2)	
LMCA	2 (0.2)	10 (0.3)	12 (0.3)	
Type B2/C lesions, n (%)	184 (98.9)	873 (95.5)	1,057 (96.1)	0.03
Calcified lesions, n (%)	176 (18.1)	692 (22.4)	868 (21.3)	0.005
Thrombotic lesions, n (%)	137 (14.1)	685 (22.1)	822 (20.2)	< 0.0001
Long lesions (> 20 mm), n (%)	278 (28.7)	1,003 (32.4)	1,281 (31.5)	0.03
Bifurcations, n (%)	157 (16.2)	847 (27.4)	1,004 (24.7)	< 0.0001
Left ventricular dysfunction* (<50%), n (%)	281 (59)	1,145 (60.2)	1,426 (60)	0.63
Collateral circulation, n (%)	186 (38.3)	735 (38.4)	921 (38.4)	0.95

* Left ventricular ejection fraction.

Table 3
Characteristics of procedures

Characteristics	Access			p value
	Radial (n = 905 patients/ 911 procedures/1,241 stents)	Femoral (n = 2,863 patients/ 2,888 procedures/3,629 stents)	Total (n = 3,768 patients/ 3,799 procedures/4,870 stents)	
Treated vessels/patients	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.42
Stent use, n (%)	905 (100)	2,863 (100)	3,768 (100)	NA
Stent/patient ratio	1.4 ± 0.6	1.3 ± 0.5	1.3 ± 0.6	< 0.0001
Drug-eluting stents, n (%)	323 (26.2)	875 (24.2)	1,198 (24.7)	0.09
Stent diameter, mm	2.93 ± 0.45	2.91 ± 0.45	2.92 ± 0.45	0.42
Stent length, mm	24.0 ± 8.9	23.0 ± 8.1	23.2 ± 8.3	0.0004
Glycoprotein IIb/IIa inhibitors, n (%)	20 (2.2)	127 (4.4)	147 (3.9)	0.003
Thrombo-aspiration, n (%)	5 (0.4)	96 (2.7)	101 (2.1)	< 0.0001
Diameter stenosis post, %	4.4 ± 14	6.1 ± 15	5.7 ± 15	0.0003
Successful procedure, n (%)	882 (96.9)	2,789 (96.6)	3,671 (96.7)	0.61

NA: not applicable.

The main findings of our study are the similarities between angiographic success rates and clinical outcomes of PCI for CTO when comparing radial and femoral accesses, demonstrating safety and feasibility of the former technique in selected cases.

Several angiographic variables were identified in previous studies as independent predictors of failure of PCI for CTO, such as long or ostial lesions; presence of calcification, tortuosity or large side branch with a takeoff adjacent to the occlusion; small reference diameter; no stump or multivessel disease.[2,11] In this study, some of these predictors of procedure failure, added to thrombotic lesions, were observed in a slightly lower percentage in the radial group. These suggest some limitations - although not representative - for choosing the radial approach in PCI for CTO. Therefore, there seems to be a group of lesions with specific characteristics, for which the interventional cardiologists prefer the femoral access, aiming to increase success of the procedure.

Previous randomized trials demonstrated greater benefit in favor of radial approach as compared to femoral access in other situations, such as in patients submitted to PCI after acute coronary syndromes.[6] Based on proven proficiency of the interventional cardiologist, the radial artery is the chosen access for invasive treatment of acute coronary syndromes, with significant reduction in mortality and in major bleeding.[6,9] Our study with patients treated predominantly by femoral approach, showed similar clinical outcomes using different accesses for intervention in CTO in stable patients, with no significant difference in the MACE rates. Important outcomes, however, were not evaluated, especially those related to bleeding, need for blood transfusion, and vascular complications related to the puncture site.

The decision to attempt PCI for CTO (instead of medical treatment or surgical revascularization) requires an individualized risk and benefit analysis that entails clinical, angiographic, and technical considerations.[2] The presence of 60% of patients with some degree of ventricular dysfunction, the predominance of single-vessel disease and the larger proportion of interventions in the left anterior descending artery (41%) - provided there is a favorable anatomy for PCI - were favorable conditions for percutaneous procedure in the study patients, with a greater probability of complete revascularization and improvement of ventricular function. In contrast, the recently published DECISION-CTO study, with more than 800 patients, questioned the clinical benefit of interventions in CTO. Arterial recanalization compared to optimized medical treatment in 3 years showed no reduction in major cardiovascular events or improvement in quality of life.[12]

The success rates above 90% found in the CENIC registry exceeded the data previously described in the literature, with maximum percentages ranging from 80 to 90%. This disagreement was probably caused by selection biases, as well as underreporting of complications and failures.

With the increased experience of interventional cardiologists in radial access, besides development and improvement of dedicated devices, further randomized studies, with greater reliability and larger and more diverse populations, can bring us more light and definitions about the success rates, complications of the procedure, and impacts on clinical outcomes in angioplasties for CTO when comparing radial and femoral approaches. The progressive increase in the number of transradial procedures in Brazil has certainly impacted on the learning curves of the professionals, contributing to the paradigm shift in high-complexity percutaneous procedures in the country, aligned with international trends.

Limitations

Our study has several limitations, most of them related to the characteristics of a PCI registry. The voluntary nature of the CENIC registry,

Table 4
In-hospital clinical outcomes

Outcome	Access			p value
	Radial (n = 905)	Femoral (n = 2,863)	Total (n = 3,768)	
Myocardial infarction, n (%)	3 (0.5)	7 (0.3)	10 (0.3)	0.46
Emergency CABG, n (%)	0	0	0	NA
Death, n (%)	2 (0.3)	13 (0.5)	15 (0.5)	0.45
MACE, n (%)	5 (0.6)	19 (0.7)	24 (0.6)	0.71

CABG: coronary artery bypass surgery; MACE: major adverse cardiovascular events.

Table 5
Variables associated to in-hospital mortality

Variable	Simple logistic regression			Multiple logistic regression		
	OR	95%CI	p value	OR	95%CI	p value
Radial access	0.57	0.13-2.50	0.46		-	
Age (years)	1.08	1.03-1.13	0.003	1.06	1.00-1.13	0.046
Female	4.37	1.49-12.82	0.007	4.80	1.21-19.01	0.03
Smoking	0.57	0.13-2.56	0.47		-	
Hypertension	2.68	0.6-11.91	0.19		-	
Dyslipidemia	1.51	0.52-4.44	0.45		-	
Diabetes mellitus	1.76	0.55-5.62	0.34		-	
Previous myocardial infarction	0.99	0.33-2.94	0.99		-	
Previous PCI	0.36	0.05-2.78	0.33		-	
Previous myocardial revascularization	2.00	0.26-15.35	0.51		-	
Angina symptoms	1.53	0.48-4.81	0.47		-	
Extension of CAD (two-vessel vs. single-vessel)	2.86	0.71-11.46	0.14		-	
Extension of CAD (three-vessel vs. single-vessel)	7.67	2.05-28.73	0.003	7.10	1.66-30.35	0.008
Left ventricular dysfunction	0.67	0.13-3.33	0.63		-	
Presence of collateral circulation	0.46	0.10-2.22	0.33		-	
Glycoprotein IIb/IIa inhibitors	7.70	2.42-24.50	< 0.001	13.97	3.61-54.05	< 0.001

OR: odds ratio; 95% CI: 95% confidence interval; PCI: percutaneous coronary intervention; DAC: coronary artery disease.

which is not linked to quality assessment systems or procedure reimbursement, makes it less representative of the reality of PCI performed in Brazil. In addition, there may be selection bias with greater inclusion of procedures with clinical and angiographic success, and underreporting of complications, thus explaining the remarkably high rates of angiographic success in unfavorable anatomical scenarios. Another possibility is that not all occlusions were chronic (> 3 months). In addition, the system does not yet have external audit of data quality or electronic adjudication of clinical events, which can also lead to inaccuracy and high percentage of incomplete or invalid data. Improving and expanding the registry can help minimize these limitations.

Regarding clinical outcomes, the database does not contemplate some important variables in the comparison of accesses, such as major and minor bleeding, red blood cell indices, and complications at the puncture site (hematoma, pseudoaneurysms, etc.). The benefit of the radial approach has already been demonstrated in relation to these surrogate outcomes, whose clinical relevance has already been mentioned.

Finally, the clinical follow-up of patients is limited to their hospital stay, there are no medium- and long-term data that could improve the validity of the findings.

Conclusions

Data from the CENIC registry showed that the radial approach has been used in a significant proportion of coronary interventions to treat chronic total occlusions. The angiographic success rates were exceptionally high and similar in the radial and femoral groups. The rates of in-hospital adverse events were low and similar, and the vascular access was not associated to in-hospital mortality.

The expansion of the number of organizations participating in CENIC registry, as well as the improvement of its methods and its linkage to quality of care criteria, can lead to more robust conclusions about the use of radial access in the interventional practice and its impact on results, primarily in unfavorable clinical and angiographic situations.

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