

ORIGINAL ARTICLE

Option for the Radial *versus* Femoral Access in Coronary Intervention in Acute Coronary Syndromes: A Risk-Treatment Paradox

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Abstract

Background: In coronary procedures, although the radial approach protects patients from hemorrhagic complications, it is technically more complex than the femoral approach.

Objectives: To test the hypothesis that the radial approach is the procedure of choice in ACS patients due to the high risk of bleeding; and to identify independent predictors of the choice for radial access.

Methods: Patients admitted for ACS who underwent invasive coronary procedure were included. We registered the type of access (femoral or radial) chosen by the physician for the first angiography; the investigators did not interfere with this choosing process. Student's t-test was used for comparisons between the CRUSADE and ACUITY scores. Predictors of radial access were compared between the groups. Statistical significance was defined by $p < 0,05$.

Results: Radial access was chosen in 67% of 347 consecutive patients. Patients who underwent radial approach had lower risk of bleeding determined by CRUSADE (30 ± 14 vs. 37 ± 15 ; $p < 0.001$) as compared with femoral access. In multivariate analysis, four variables were identified as independent predictors negatively associated with radial access – age (OR = 0.98; 95%CI = 0.96 – 0.99), creatinine (OR = 0.54; 95%CI = 0.3 – 0.98), signs of left ventricular failure (OR = 0.45; 95% CI = 0.22 – 0.92) and previous CABG (OR = 0.022; 95%CI = 0.003 – 0.166).

Conclusion: The propensity to choose radial over femoral access in coronary intervention was not primarily influenced by patients' bleeding risk. Predictors of this decision, identified in the study, indicated less complex patients, suggesting that the difficulty in performing the technique was a stronger determinant than its potential antihemorrhagic effect. (Int J Cardiovasc Sci. 2018;31(6):562-568)

Keywords: Angioplasty; Catheterism; Coronary Artery Disease; Percutaneous Coronary Intervention; Radial Artery; Femoral Artery; Stents.

Introduction

Percutaneous coronary intervention (PCI) is the main revascularization procedure performed in acute coronary syndromes (ACS) due to its efficacy in preventing recurrent coronary events and less invasiveness as compared with surgical procedures.¹ However, PCI is not free of complications, with access site bleeding as the most common adverse effect.²

Femoral access has been the predominant site for PCI for decades, due to its relative feasibility to perform.

Radial access, in turn, has shown to be efficient in preventing bleeding and therefore has become the preferred procedure in the last years.²⁻⁵ The radial approach, however, is a more complex technique, requiring greater technical ability and experience.⁶ Thus, considering the higher feasibility and reproducibility of the femoral access and the lower risk of bleeding of the radial access, both techniques are available for PCI.

Efficacy is the intrinsic property of the treatment, described in the ideal world of clinical trials, in which intervention occurs in a random fashion, excluding

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the effect of medical decision making. Effectiveness represents the performance of the therapy in the real world, in which allocation depends on the medical decision making. Effectiveness is then optimized when allocation of treatment prioritizes patients at high risk for the outcome expected to be prevented by the intervention in question. Radial access would be more effective for patients at higher risk of bleeding who are allocated to this intervention. In a recent study, Wimmer et al.,⁷ reported a risk-treatment paradox, in which the radial approach was less frequent in patients at higher bleeding risk than in those at lower risk.

The present study aimed to explore this phenomenon. Using the Prospective Registry of ACS, we tested whether the radial access was the first choice for PCI in patients at high risk of bleeding, which was evaluated by the CRUSADE⁸ and the ACUITY⁹ scores. Also, we identified predictors of radial access and developed a propensity score of representative, predicting factors of medical decision making.

Methods

Sample selection

We included in the study patients consecutively admitted to the coronary unit of a tertiary hospital between December 2011 and January 2016 with diagnosis of ACS (unstable angina or myocardial infarction) with previous diagnostic or therapeutic invasive cardiac procedures. ACS was defined as precordial discomfort in the 48 hours prior to admission, associated with at least one of the following criteria: 1) myocardial necrosis markers, defined as troponin T ≥ 0.01 $\mu\text{g/L}$ or troponin I > 0.034 $\mu\text{g/L}$, corresponding to values above the 99th percentile;¹⁰ 2) ischemic electrocardiographic changes, consisting of T-wave inversion (≥ 0.1 mV) or ST-segment changes (≥ 0.05 mV); 3) previous coronary artery disease, defined as previous Q-wave myocardial infarction or coronary obstruction $\geq 70\%$ confirmed by angiography. Patients who declined to participate were excluded from the study. The study protocol was in accordance with the Helsinki declaration and approved by the local ethics committee. All patients signed the informed consent form.

Study protocol

This is a registry of ACS, composed by collection of prospective data. Variables of these data were used for

calculation of bleeding scores. Access site for the first arterial puncture in the first (diagnostic or therapeutic) coronary procedure was systematically registered on data collection form. Major bleeding was defined as BARC (Bleeding Academic Research Consortium) type 3 or type 5.¹¹ The criteria for type 3 bleeding were as follow – decrease in hemoglobin of 3-5 g/dL or need for transfusion (type 3a); hemoglobin drop ≥ 5 g/dL, cardiac tamponade, requirement of surgical intervention or hemodynamic instability for control (type 3b); and intracranial or intraocular bleed (type 3c). Type 5 bleeding is a definite fatal bleeding (direct causal relationship, type 5a) or a probable fatal bleeding (indirect causal relationship, type 5b). Minor bleeding (type 1 or type 2) or cardiac surgery-related bleeding (type 4) were not included in the analysis.

Bleeding risk scores

The CRUSADE score was used to evaluate the baseline risk of bleeding. This instrument is composed of eight variables – four categorical variables (female sex, signs of heart failure, diabetes and peripheral arterial disease) and four numerical variables (baseline hematocrit, creatinine clearance, heart rate, and systolic blood pressure). The point scores were calculated based on the value of each variable; the sum of all variables indicated predetermined levels (low, intermediate and high).⁸ Bleeding risk was also confirmed by the ACUITY score, composed of seven variables – four categorical variables (female sex, anemia, bivalirudin therapy and type of ACS) and three numerical variables (age, creatinine clearance, white blood cell count).⁹

Statistical analysis

Although the collection of the variables included in the primary analysis was predetermined, the association between bleeding score and the access route was a posteriori exploratory analysis. Nevertheless, we estimated that a minimum of 100 patients with radial or femoral access would allow the insertion of 10 covariables into the propensity model, based on the logistic regression principle, which establishes the need of at least 10 patients with the outcome in question for each covariable.¹²

Numerical variables were described as mean and standard deviation or median and interquartile range, as appropriate. Normality of numerical variables was verified by the Shapiro-Wilk test. Categorical variables

were described as absolute and relative frequencies. The CRUSADE and ACUITY scores were compared between radial and femoral groups by the unpaired Student's t test. Predictors of the radial access were compared between both groups by the chi-square test or the unpaired Student's t test. Variables with $p < 0.10$ in the univariate analysis were inserted into the logistic regression, with radial access as dependent variable; the odds ratio of each predictor was determined. A $p < 0.05$ was set as statistically significant in all tests. The analysis was performed using the SPSS software version 21.

Results

Sample description

A total of 347 patients were included; mean age was 63 ± 14 years, 63% were men, 27% of them were hospitalized for ST-segment elevation myocardial infarction (the others had ASC with non-ST-segment elevation myocardial infarction). Invasive coronary angiography showed that 38% of patients had three-vessel disease or left coronary artery occlusion. Mean GRACE score was 119 ± 37 , compatible with an intermediate risk of cardiovascular events. Mean CRUSADE score was 32 ± 15 and mean ACUITY score was 14 ± 7 , both corresponding to moderate risk of bleeding according to validation studies.^{8,9} Bleeding occurred in 64 patients (18%) and major bleeding in 12 (3.5%). The CRUSADE score was higher in patients with major bleeding (47 ± 17 versus

32 ± 15 ; $p = 0.01$), confirming its predictive value. The same was observed with the ACUITY score (20 ± 9 versus 14 ± 7 ; $p = 0.02$). Patients treated with the radial approach showed a higher incidence of major bleeding as compared with those treated with femoral access (1% versus 8%; $p < 0.01$).

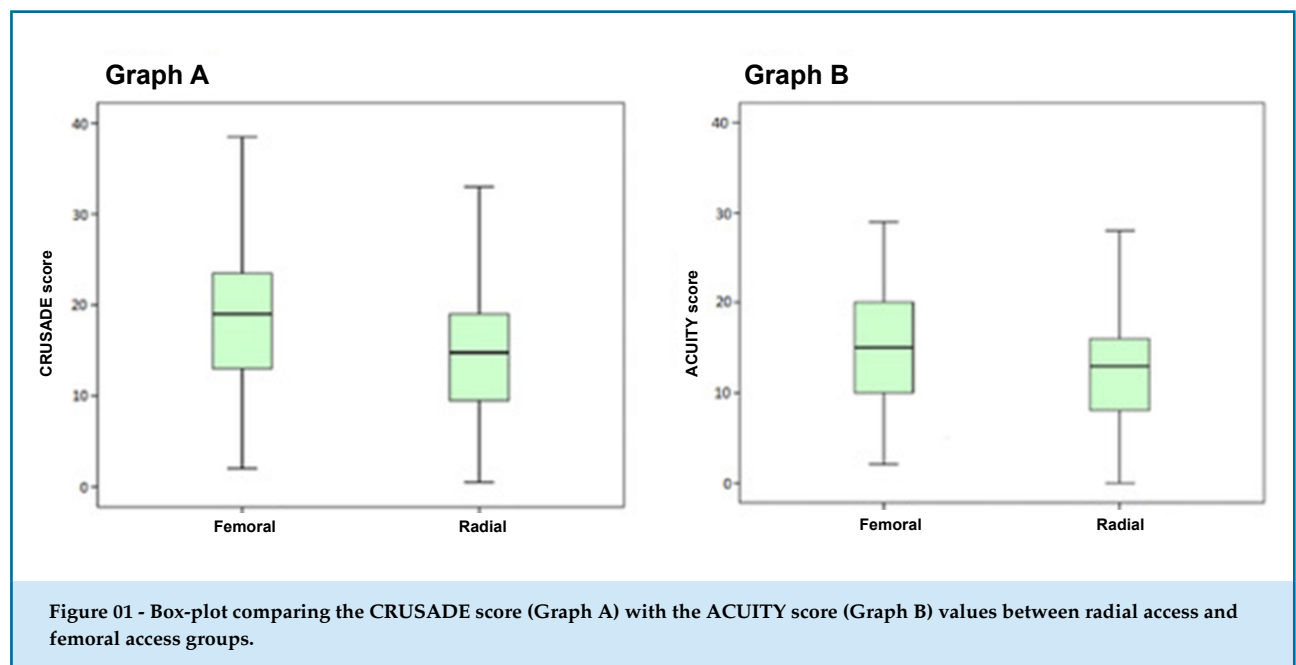
Risk of bleeding and the choice for the radial access

The radial artery was chosen as the primary vascular access in 64% of patients, whereas the femoral access was chosen for the others. The mean CRUSADE score showed that patients treated with the radial access showed a lower risk of bleeding (30 ± 14) compared with those treated with femoral access (37 ± 15 ; $p < 0.001$) (Figure 1). According to the literature, these values corresponded to a bleeding risk of 5.5% and 8.6%, respectively.⁸

Analysis of the ACUITY score corroborated the fact that patients treated with radial access had a higher risk of bleeding than patients treated with femoral access (13 ± 6 versus 15 ± 7 ; $p = 0.002$). These values correspond to a bleeding risk of 3.3% and 6.9%, respectively.⁹

Propensity to choose the radial access

With respect to general characteristics of patients, those with a radial access were younger (61 ± 13 years), compared with patients with femoral access (66 ± 14 years; $p < 0.001$). Sex, self-reported race, weight, height,



body mass index and body surface were not different between the groups (Table 1).

Regarding ACS presentation, compared with patients treated with femoral approach, patients with radial access had a lower mean GRACE score (114 ± 34 versus 128 ± 41 ; $p < 0,001$), better renal function according to creatinine levels (1.0 ± 0.3 versus 1.2 ± 1.1 ; $p < 0.001$) and lower prevalence of signs of left ventricular failure (Killip > 1 : 8% versus 19% ; $p < 0.003$). The type of ACS,

heart rate, systolic arterial pressure, positive troponin, electrocardiographic ischemia, three-vessel disease, coronary angiography showing involvement of the trunk and hemoglobin levels at admission were not different between the groups (Table 1).

Regarding comorbidities, there was a lower prevalence of previous coronary disease in patients treated with radial access (24% versus 46% , $p < 0.001$). Previous history of stroke (3% versus 9% ; $p < 0.021$) and myocardial

Table 1 - Comparison of clinical characteristics of the radial and femoral access groups

Variables	Radial (n = 223)	Femoral (n = 124)	p-value
Female sex	85 (38%)	38 (31%)	0.62 [†]
Age	61 ± 13	66 ± 14	0.001*
Weight	78 ± 13	76 ± 18	0.27*
Height	1.67 ± 0.1	1.65 ± 0.9	0.12*
Body mass index (kg/m ²)	27.9 ± 4.5	27.6 ± 5.9	0.57*
Body surface (m ²)	1.89 ± 0.2	1.86 ± 0.2	0.25*
Black/pardo race	132 (63%)	72 (62%)	0.88 [†]
ST-segment elevation myocardial infarction	63 (29%)	32 (26%)	0.62 [†]
Positive troponin	171 (77%)	95 (77%)	0.98 [†]
Ischemic electrocardiography	88 (40%)	50 (40%)	0.87 [†]
Three-vessel disease or left coronary trunk	42 (19%)	28 (23%)	0.1 [†]
Signs of left ventricular failure	18 (8%)	23 (19%)	0.003 [†]
Heart rate (bpm)	79 ± 16	82 ± 19	0.13*
Systolic arterial pressure (mmHg)	153 ± 30	154 ± 34	0.7*
Creatinine	1.0 ± 0.3	1.2 ± 1.1	0.001*
GRACE score	113.9 ± 33.5	128.1 ± 41	0.001*
Hemoglobin	14.0 ± 1.8	13.8 ± 1.9	0.29*
Diabetes mellitus	76 (34%)	48 (39%)	0.34 [†]
Peripheral arterial occlusive disease	9 (4%)	11 (9%)	0.1 [†]
Previous coronary disease	53 (24%)	57 (46%)	0.001 [†]
Previous revascularization	1 (0.5%)	24 (19.5%)	0.001 [†]
Stroke	7 (3%)	11 (9%)	0.021 [†]
Smoking	23 (10%)	8 (6.5%)	0.23 [†]
Previous heart failure	7 (3%)	7 (6%)	0.25 [†]
Previous bleeding	2 (5%)	1 (8%)	0.65 [†]

*Student's t-test; [†]chi-square test.

revascularization surgery (0.5% versus 19.5%; $p < 0.001$) was also different between the groups, whereas no difference was observed in the presence of diabetes mellitus, peripheral artery disease, smoking, previous history of heart failure or bleeding (Table 1).

The variables described above as significant in the univariate analysis were inserted into the logistic regression model, with radial access as dependent variable. In this analysis, the variables with independent association with radial access were age (OR = 0.98; 95%CI = 0.96 – 0.99), creatinine (OR = 0.54; 95%CI = 0.3 – 0.98), signs of left ventricular failure (OR = 0.45; 95%CI = 0.22 – 0.92) and previous myocardial revascularization surgery (OR = 0.022; 95%CI = 0.003 – 0.16), all with a discouraging effect on the use of the radial access (Table 2).

Discussion

In the present study, patients treated with radial approach for coronary procedures had lower baseline risk of bleeding as compared with the femoral access group. This finding contrasts with the logical expectation that the access related to lower incidence of bleeding is the one more commonly used in patients at higher risk for this complication, characterizing a risk-treatment paradox.

This paradoxical result raises the need for discussing potential causes of this phenomenon in a critical perspective of the cognitive process of the medical decision-making process. This, in turn, is presumedly influenced by several factors. One may expect that such decision is based on the main objective of the radial

approach, i.e. to prevent bleeding; however, other factors may be determinant in this process. Interventionists have a natural sense of achieving success with their techniques. By intuition, the chance of success is expected to be lower from procedures considered technically more difficult. Hence, the operator tends to avoid the access considered more difficult in attempt to reduce the challenge. Nevertheless, that would be a biased view, since the risk of failure in the radial approach is lower than the risk of increased bleeding in femoral approach (eight times greater in the present study). Besides, a migration from radial to femoral vascular access when needed is also possible. Although the results of this study were exploratory, they suggest that the physician's decision may be more strongly influenced by a sense of self-protection rather than a protection of the treated patients. This is quite possible, since while bleeding tends to be seen as a natural complication, failure in the intervention tends to be considered a medical failure. Further studies should explore these potential mechanisms.

Intuitive estimation of probabilities in conditions of uncertainties is influenced by cognitive biases.¹³⁻¹⁵ For example, when we opt to treat less complex patients, we are seeking cognitive comfort; and in search of this, we underestimate the risk of more complex patients, intuitively reducing the magnitude of the benefits that these patients could obtain from the procedure. In consequence, patients with more complex conditions receive less treatment than needed. This generates a risk-treatment paradox, typical of this intuitive process of decision making.

To understand the mechanisms of this paradox, we built a propensity model to identify potential determinants to the choice for the radial access. In this model, we identified variables that had a negative association with the radial access only, not including variables that may increase the chance for this choice. This propensity score allows us to make interpretations of the decision-making process. It is possible that our interventionist had the radial access as the first-choice option (in fact, this approach was the most frequent in the study) and then used other criteria for secondary options. These criteria were represented in our model by independent predictors of the radial access. Analysis of these predictors showed that all of them concerned more complex patients, with predictors representing each of the domains: patient's baseline constitution (age), comorbidities (creatinine), severity of ACS presentation (acute heart failure) and previous history (surgery). These observations suggest that the physician

Table 2 - Multivariate analysis that generated the propensity model of radial access

	Odds ratio	95% CI	p-value
Creatinine	0.54	0.3 – 0.98	0.041*
Age	0.98	0.96 – 0.99	0.037*
Killip class > 1	0.45	0.22 – 0.92	0.029
Previous revascularization	0.022	0.003 – 0.166	0.001
Stroke	0.366	0.13 – 1.07	0.066
Previous coronary disease	0.75	0.43 – 1.31	0.313
GRACE score	1.0	0.99 – 1.01	0.543*

*Numerical variables.

tends to avoid the radial access as the patient's condition gets more severe, disregarding patient's higher risk of bleeding. On the other hand, we should recognize that this is not a conscious choice.

The risk-treatment paradox has been described in situations in which the most effective approach is also the most complex. For example, in atrial fibrillation, anticoagulant therapy is more frequently provided to patients with a low risk of embolic events than patients at high risk.¹⁶ In the ACS scenario also, there has been no association between risk and the choice for an invasive strategy.^{17,18} In PCI, the prospective, observational, multicenter study by Wimmer et al.,⁷ also reported this phenomenon by showing that patients at higher risk of femoral access site complications were less susceptible of receiving the radial access approach. An additional contribution of our study is the identification of independent predictors involved in the generation of this paradox. Other previous studies^{19,20} evaluated the predictors involved in the choice for the radial access, however, in none of them a multivariate analysis was performed to minimize confounding bias.

Once the presence of the risk-treatment paradox is detected in certain situation, a possible adjustment strategy is the use of probabilistic models to estimate the risk.^{21,22} In other words, the use of scores for allocation of more complex resources induces the physician to make decisions based on probability. In case of bleeding in ACS, the best validated models are the CRUSADE⁸ and the ACUITY scores.⁹

Our findings were obtained in a single center, in which five interventional cardiologists were working during the study period. Thus, we must recognize the limited external validation of these findings. Nevertheless, the real aim of this study was not to describe interventionists' behavior, since in fact it may vary considerably among regions. Actually, the impact of the present study is not the inference of the prevalence of a phenomenon, but rather to call attention to a situation in which the decision-making process may suffer a risk-treatment paradox.

A natural thought would be to suggest an evaluation of medical practice variation, to verify the uniformity of this phenomenon. However, we avoided this analysis, since in the Registry design, the unit of analysis was the patient who was treated and not the physician himself, whose consent to be observed was not sought. We also believe that individual evaluation of each of the five interventionists involved in the study would not be accurate due to the sample size of the study.

Conclusion

In this exploratory study, we observed that the choice for the radial access was not primarily influenced by its potential benefit on bleeding prevention, since baseline bleeding risk was negatively associated with this access, characterizing a risk-treatment paradox. Determinants of the preference for the radial access were variables that connote patients' clinical status/severity, suggesting that in highly complex patients, the access is primarily chosen for its easiness and not for its antihemorrhagic effect.

Author contributions

Conception and design of the research: Lacerda YF, Sá NC, Suerdieck JG, Viana MS, Fonseca L, Lopes F, Rabelo MMN, Correia LCL. Acquisition of data: Lacerda YF, Sá NC, Suerdieck JG, Sodré GS. Analysis and interpretation of the data: Lacerda YF, Suerdieck JG, Viana MS, Sodré GS, Fonseca L, Rabelo MMN, Correia LCL. Statistical analysis: Suerdieck JG, Viana MS, Sodré GS, Fonseca L, Lopes F, Correia LCL. Obtaining financing: Lacerda YF. Writing of the manuscript: Lacerda YF, Suerdieck JG, Fonseca L. Critical revision of the manuscript for intellectual content: Lacerda YF, Sá NC, Lopes F, Rabelo MMN, Correia LCL. Supervision / as the major investigator: Lacerda YF, Sá NC, Rabelo MMN, Correia LCL.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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Ethics approval and consent to participate

This study was approved by the Ethics Committee of the *Hospital São Rafael* under the protocol number 35/11. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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