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ORIGINAL ARTICLE

12-Month Clinical Follow-Up of Patients Undergoing Early Invasive Strategy by the Transradial or Transfemoral Approach with Vascular Closure Device

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Abstract

Background: The radial approach reduces the prevalence of vascular complications, major bleeding and mortality when compared to the femoral approach. However, the last still prevails as the preferred approach for the performance of invasive coronary procedures, requiring the adoption of strategies to minimize complications.

Objectives: To compare the survival free of major adverse cardiovascular events at 12 months in patients undergoing early intervention strategy by the radial or femoral access with vascular closure device.

Methods: Randomized non inferiority trial involving 240 non-ST-segment elevation acute coronary syndrome patients. The survival free of death, myocardial infarction or stroke was estimated by the Kaplan-Meier method and compared using the log rank test.

Results: The 30-day rate of vascular complications in the arterial puncture site was 12.5% in the Angio-Seal group and 13.3% in the radial group (p = 1.000). The 12-month incidence of major bleeding or blood transfusion did not differ between groups (2.5% vs. 1.7%, p = 1.000). There was no difference in survival free of major adverse cardiovascular events (90.8% versus 94.2%, p = 0.328).

Conclusions: There was no distinction between the techniques in survival free of major adverse cardiovascular events at 12 months of follow-up. Clinical trials with greater statistical power are needed to validate these findings. (Int J Cardiovasc Sci. 2017;30(4):299-306)

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Keywords: Myocardial Ischemia; Percutaneous Coronary Percutaneous; Radial Artery; Hemostasis.

Introduction

The early interventionist strategy represents an important step in the treatment of non-ST segment elevation myocardial infarction (NSTEMI), due to its superiority in reducing death and reinfarction when compared to the conservative strategy.[1] Since the completion of invasive coronary procedures undergoing therapy Intense antithrombotic therapy predisposes to the occurrence of severe bleeding, with a potential prognostic impact, strategies aimed at preventing this complication guide the contemporary management of this patient profile.[2]

In this context, the option for radial access, in detriment to the femoral one, has been shown to reduce mortality and severe bleeding rates, especially after obtaining proficiency with the technique.[3] In turn, the efficacy and safety resulting from the adoption of vascular occlusion devices (VOD) in the prevention of complications in procedures carried out through the

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lower limb is still a matter of debate.[4] In the randomized clinical trial *Angio-Seal* versus the *Radial approach in acute coronary syndrome* (ARISE) the systematic use of a VOD in patients undergoing invasive stratification by femoral access was shown to be not inferior to radial access with respect of the incidence of vascular complications related to the arterial puncture site at 30 days.[5]

The objective of the present pre-specified analysis of the ARISE study was to compare the incidence of serious adverse cardiovascular events in clinical follow-up of 12 months, according to the access route adopted.

Methods

The design and rationale of the ARISE pilot study has been previously published.[6] In summary, from July 2012 to March 2015, 240 patients with a diagnosis of NSTEMI who underwent invasive stratification were randomized to perform the procedure by radial access or femoral vein with VOD Angio-Seal (St. Jude Medical, St. Paul, Minnesota, US). The choice of Angio-Seal relied on the ease of handling, lower cost and greater casuistry published in the literature in its favor. Patients should present at least two of three markers of greatest clinical severity: ischemic changing in 12-lead electrocardiogram, positivity of biomarkers of myocardial necrosis or more than 60 years age. The objective of this analysis was to compare the techniques for free survival of serious adverse cardiovascular events at 12 months, defined as general mortality, acute myocardial infarction (AMI) or cerebrovascular accident (CVA).

Study procedures

For the randomization process an aleatory sequence was obtained through computational algorithms and maintained in individual envelopes, allowing allocation concealment. The coronarography, by both, radial and femoral accesses, was performed using the Judkins technique, using arterial introducers with 6 French diameter. Percutaneous coronary intervention (PCI) was indicated when a lesion was determined as a culprit lesion of the clinical event, with a severity of stenosis diameter ≥ 70%, showing a high probability of angiographic success, being performed immediately after the end of coronary angiography and left ventriculography (ad hoc) . Anticoagulation in the hemodynamic laboratory was obtained with intravenous 85-100 U / kg unfractionated heparin, suited to prior subcutaneous administration of enoxaparin or fondaparinux. In order to obtain haemostasis in the radial technique, the TR BAND radial compression device (*Terumo Corporation*, Tokyo, Japan) was applied, according to a protocol previously validated by our center, aiming at maintenance of patent anterograde flow.[7] In the femoral technique, The VOD Angio-Seal, preceded by the systematic accomplishment of femoral angiography and maintaining absolute rest in the bed for 60 minutes after achieving adequate hemostasis. The success of the device was defined as the obtaining the adequate hemostasis at the end of the procedure, without the need to apply other compression methods.

Markers of myocardial necrosis, hemoglobin and hematocrit were measured pre-procedure and between 12 and 24 hours after its completion. Electrocardiogram was performed soon after the procedure or before the suspicion of a new ischemic event. Vascular complications related to arterial access were evaluated during hospitalization and on-site visit in 30 days after the procedure. The late assessment of the occurrence of cardiovascular events was obtained through telephone contact at six and twelve months, as well as by electronic chart review.

Statistical analysis

Absolute and relative frequencies were presented for the categorical and numerical variables, summary-measures (mean and standard deviation). The existence of associations between two categorical variables was verified using the chi-square test, or alternatively in cases of small samples, Fisher's exact test. The comparison of means between two groups was performed using Student's t-test for independent samples. The survival function free of serious adverse cardiovascular events (death, AMI or CVA) was estimated by the Kaplan-Meier model and compared using the log rank test (Mantel-Cox). A significance level of 5% was used for all statistical tests. Statistical analyzes were performed using the statistical software SPSS 20.0.

The study was approved by the local research ethics committee and a free and informed consent form was obtained from every participant. There was no source of external funding and the authors are entirely responsible for the design, conduction, data analysis and final drafting of the manuscript.

Results

Figure 1 illustrates the inclusion and randomization flowchart of the study. The mean age was 63 years, 30.8% were diabetic, troponin positive was detected in 84.2% of the sample and, except for the greater prevalence of women in the radial group, no differences were observed between the groups (Table 1). 65% of the evaluated sample was classified as low or very low risk for bleeding from the CRUSADE score. PCI was performed in 86.7% of the cases and the characteristics of the procedures are expressed in Table 2. Stents were implanted in 97.6% of the cases, with predominance of non-pharmacological stents due to public health system reimbursement policies.

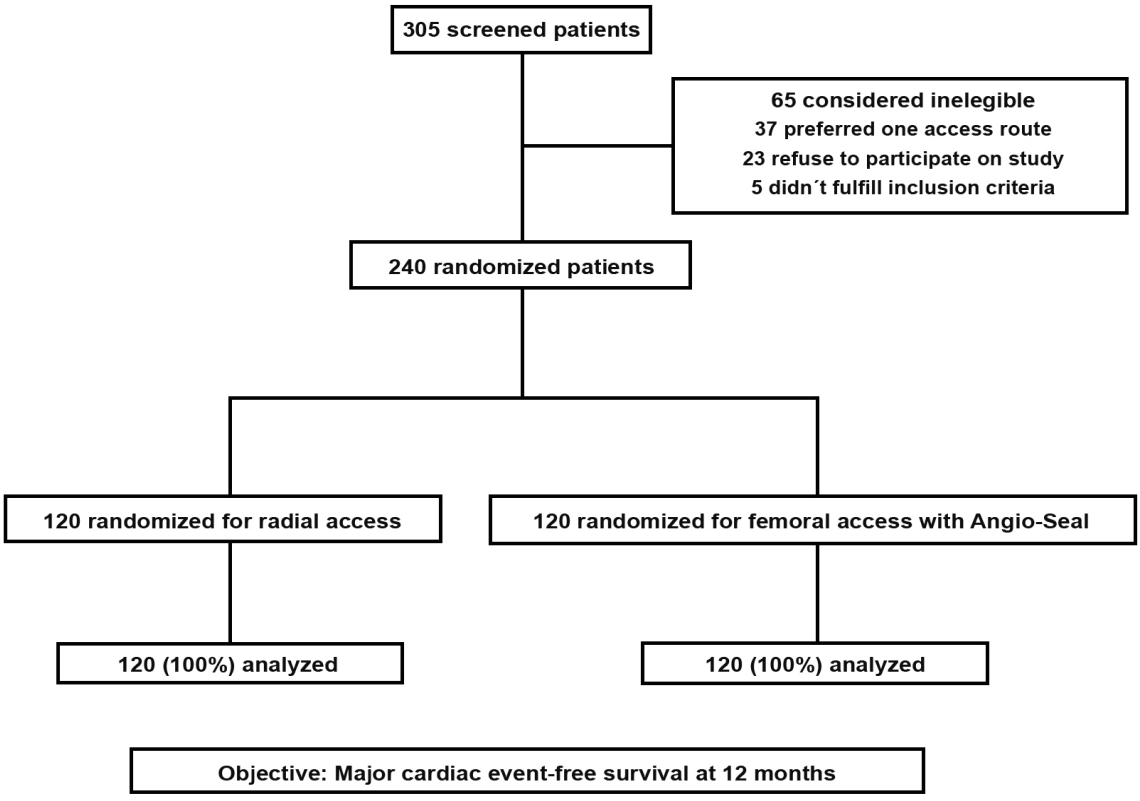

Figure 1 – *Inclusion and randomization flowchart of the ARISE study.*

Angiographic and procedural success rates were high (97.6% and 95.2%, respectively). Hemostasis with TR BAND was obtained in 100% of the procedures by radial access, with anterograde flow demonstrated by the oximetric curve in 102 patients (85%). In six (5%) patients in the femoral group, the Angio-Seal device was not sufficient to obtain hemostasis, requiring additional manual compression for a period longer than 10 minutes. The rate of vascular complications at the 30-day arterial puncture site was 12.5% in the Angio-Seal group, at the cost of hematomas > 5 cm, and 13.3% in the radial group, at hematomas > 5 cm (6.7%) and asymptomatic occlusion of the radial artery (5.8%), with no significant difference. There were no cases of arteriovenous fistula, retroperitoneal hematoma, compartment syndrome, limb ischemia, nerve damage or the need for repairing vascular surgery.

Table 1 – Clinical characteristics of patients

Variable	General (n=240)	Angio-Seal (n=120)	Radial (n=120)	p
Age, years (mean(standard deviation SD))	63.0 ± 10.7	63.6 ± 10.2	62.5 ± 11.2	0.438
Female gender, n (%)	64 (26.7%)	24 (20.0%)	40 (33.3%)	0.020
Diabetes mellitus, n (%)	74 (30.8%)	41 (34.2%)	33 (27.5%)	0.263
Hypertensionl, n (%)	179 (74.6%)	93 (77.5%)	86 (71.7%)	0.299
Dyslipidemia, n (%)	104 (43.3%)	52 (43.3%)	52 (43.3%)	1.000
Positive family history, n (%)	72 (30.0%)	35 (29.2%)	37 (30.8%)	0.778
Smoking, n (%)	82 (34.2%)	41 (34.2%)	41 (34.2%)	1.000
Previous myocardial infarction, n (%)	13 (5.4%)	5 (4.2%)	8 (6.7%)	0.392
Previous coronary angioplasty, n (%)	11 (4.6%)	4 (3.3%)	7 (5.8%)	0.354
Previous revascularization surgery, n (%)	2 (0.8%)	1 (0.8%)	1 (0.8%)	1.000
Previous stroke, n (%)	16 (6.7%)	11 (9.2%)	5 (4.2%)	0.121
Creatinine clearance < 60 mL/min, n (%)	50 (20.8%)	20 (16.7%)	30 (25.0%)	0.112
Peripheral arterial disease, n (%)	8 (3.3%)	5 (4.2%)	3 (2.5%)	0.472
GRACE score ≥ 140, n (%)	119 (49.6%)	58 (48.3%)	61 (50.8%)	0.699

The ischemic endpoints after 1 year according to the used access via are expressed on Table 3. The rate of severe bleeding or blood transfusion was 2.5% in the Angio-Seal group and 1.7% in the radial group (p = 1,000). Figure 2 illustrates the free survival curve of serious adverse cardiovascular events compound at 12 months, with no distinction being made between techniques (90.8% versus 94.2%, p = 0.328).

Discussion

The approach of NSTEMI contemplates invasive risk stratification risk and potent antithrombotic pharmacotherapy, a strategy that promotes the reduction of ischemic adverse events at the expense of increased bleeding risk. In this scenario, the adoption of the radial technique as an alternative to the femoral technique was shown to be superior in the reduction of vascular complications related to the arterial puncture site and consequently of clinical outcomes.[8] Encouraging results from unicentric studies with modest sampling were corroborated by large randomized meta-analyzes. Reviewing the data from patients with acute coronary syndrome conducted in a meta-analysis of 17 studies and 19,328 procedures, radial access promoted a significant reduction of 27% in mortality and 40% in severe bleeding.[9] Including all spectra of the atherosclerotic coronary disease, meta-analysis with 22,843 participants maintained the observed benefit with reduction of 29% in total mortality and 47% reduction in severe bleeding.[10]

However, femoral access still prevails as a preferential route for the accomplishment of invasive coronary procedures. In Brazil, it is estimated that the use of the radial technique in PCI make up currently about 30% of the cases.[11,12] Thus, it is imperative to adopt measures able to provide greater safety to the procedure, such as reducing the diameter of the devices endovascular, early removal of the arterial introducer, fluoroscopy or ultrasound guided femoral puncture. On the other hand, the use of DOV in obtaining haemostasis by the femoral technique shows conflicting data about its efficacy, supported mainly by negative studies involving first generation devices, many of which are no longer commercialized.[13,14] However, contemporary analyzes indicate superiority Strategy against manual compression. Among 85,048 ICPs performed between 2007 and 2009, registered in a multicenter registry in the state of Michigan, of which 28,528 used a DOV, they promoted a significant reduction of vascular

Table 2 – Angiographic characteristics and procedures

Variable	General (n=240)	Angio-Seal (n=120)	Radial (n=120)	P
Ad hoc angioplasty, n (%)	208 (86.7%)	107 (89.2%)	101 (84.2%)	0.255
Volume of contrast, ml (mean(standard deviation SD))	163.6 ± 46.9	168.1 ± 47.8	159.1 ± 45.7	0.140
Fluoroscopy time, min (mean(standard deviation SD))	8.5 ± 5.5	8.6 ± 6.0	8.5 ± 4.9	0.879
Enoxaparin, n (%)	114 (47.5%)	53 (44.2%)	61 (50.8%)	0.301
Fondaparinux, n (%)	117 (48.7%)	63 (52.5%)	54 (45.0%)	0.245
Glycoprothein Inhibitor, n (%)	17 (7.1%)	7 (5.8%)	10 (8.3%)	0.450
AAS, n (%)	240 (100%)	120 (100%)	120 (100%)	–
Clopidogrel, n (%)	195 (81.2%)	99 (82.5%)	96 (80.0%)	0.620
Ticagrelor, n (%)	45 (18.7%)	21 (17.5%)	24 (20.0%)	0.620
Treatment time, days (mean(standard deviation SD))	3.7 ± 2.5	3.9 ± 2.7	3.6 ± 2.3	0.413
Atherosclerotic Disease, n (%)				0.316
No lesion	26 (10.8%)	9 (7.5%)	17 (14.2%)	
Uniarterial	112 (46.7%)	57 (47.5%)	55 (45.8%)	
Biarterial	70 (29.2%)	39 (32.5%)	31 (25.8%)	
Triarterial	32 (13.3%)	15 (12.5%)	17 (14.2%)	
Ejection fraction, n (%)				0.433
Normal	157 (65.4%)	79 (65.8%)	78 (65.0%)	
Discrete disfunction	42 (17.5%)	17 (14.2%)	25 (20.8%)	
Moderate disfunction	26 (18.8%)	15 (12.5%)	11 (9.2%)	
Severe disfunction	15 (6.2%)	9 (7.5%)	6 (5.0%)	
Culprit artery, n (%)				0.562
Left coronary artery trunk	2 (0.9%)	2 (1.8%)	0 (0.0%)	
Anterior descending	106 (50.2%)	53 (48.6%)	53 (52.0%)	
Circumflex	36 (17.1%)	17 (15.6%)	19 (18.6%)	
Right coronary	65 (30.8%)	36 (33.0%)	29 (28.4%)	
Ramus intermedius	2 (1.0%)	1 (1.0%)	1 (1.0%)	
Stent, n (%)	203 (97.6%)	105 (98.1%)	98 (97.0%)	0.676
Ballon, n (%)	5 (2.1%)	2 (1.7%)	3 (2.5%)	1.000
Number of stents, (mean(standard deviation SD))	1.1 ± 0.4	1.2 ± 0.4	1.1 ± 0.4	0.406
Number of lesions, (mean(standard deviation SD))	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.3	0.629
Stent diameter, (mean(standard deviation SD))	3.1 ± 0.6	3.1 ± 0.6	3.1 ± 0.6	0.724
Extension of stent, (mean(standard deviation SD))	23.4 ± 7.5	23.4 ± 7.8	23.4 ± 7.3	0.948
Non-drug-eluting stent n (%)	200 (98.5%)	103 (98.1%)	97 (99.0%)	1.000
Drug-eluting stent, n (%)	3 (1.5%)	2 (1.9%)	1 (1.0%)	1.000
Crossover techniques, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	–
Angiographic success, n (%)	203 (97.6%)	105 (98.1%)	98 (97.0%)	0.676
Procedure Success, n (%)	198 (95.2%)	102 (95.3%)	96 (95.0%)	1.000
Device success, n (%)	234 (97.5%)	114 (95.0%)	120 (100.0%)	0.029
Time to discharge, days (mean(standard deviation SD))	1,4 ± 1.4	1.5 ± 1.8	1.3 ± 0.8	0.311

Table 3 – Ischemic adverse cardiovascular events in 12 months

Variable	General (n=240)	Angio-Seal (n=120)	Radial (n=120)	p
Cardiovascular death, n (%)	10 (4.2%)	6 (5.0%)	4 (3.3%)	0.769
Death, n (%)	12 (5.0%)	7 (5.8%)	5 (4.2%)	0.749
Acute myocardial infarction, n (%)	6 (2.5%)	1 (0.8%)	5 (4.2%)	0.213
Stent thrombosis, n (%)	4 (1.7%)	1 (0.8%)	3 (2.5%)	0.622
Stroke, n (%)	1 (0.4%)	1 (0.8%)	0 (0.0%)	1.000
Major adverse cardiac events, n (%)	18 (7.5%)	11 (9.2%)	7 (5.8%)	0.463

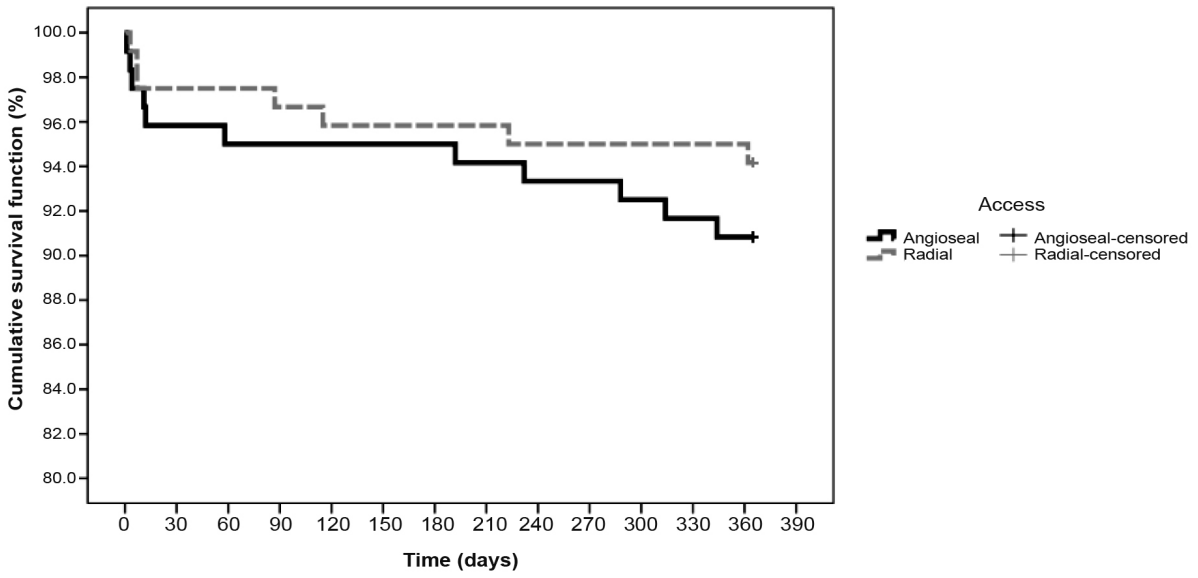

Figure 2 – *Probability of death, acute myocardial infarction or stroke-free survival at 12 months according to the access route adopted.*

complications and the need for transfusion.[15] The British national real-world registry encompassing 271,485 therapeutic procedures performed between 2006 to 2011 showed a lower 30-day DOV-favorable mortality rate, especially among women, acute coronary syndrome as a form of clinical presentation and recent thrombolysis.[16]

The main question still open is whether the DOV present the same effectiveness of the radial technique in the reduction of vascular complications and bleeds related to the access route. The ARISE study adds data to this questioning, since it is the first randomized clinical trial comparing the two strategies in a population of patients with SIMISSST. No differences were observed between the techniques regarding the incidence of vascular complications at 30 days and serious adverse cardiovascular events at 12 months. In fact, it is postulated that the benefits derived from the radial technique are mainly due to the reduction in the prevalence of severe bleeding and the need for blood transfusion,[17] which was not observed in our study. Our findings differ from the few publications comparing the radial access to VOD, where the first is associated with a significant reduction of vascular complications, as the main difference

between these cases and our study being the non-random nature of them.[18,19]

The study has limitations, the main one being its small sample size and statistical nature of hypothesis generating. In addition, in all procedures performed by femoral access, the diameter of the devices used was 6 French, and it was not possible to extend the findings to cases where larger diameter devices were used. Since the study population covered predominantly low-risk bleeding patients, the results can not be expanded to situations characterized by a higher risk of bleeding, especially for patients with ST-segment elevation myocardial infarction who underwent primary PCI. The Angio-Seal cost-effectiveness analysis, although attested in previous publications,[20,21] was not the scope of this analysis and requires the evaluation of different variables, such as work process in the interventional cardiology laboratory, nature of the procedure, patient risk profile and reimbursement policies.

Conclusions

In patients submitted to the early interventional strategy in the ARISE pilot study, randomized to the radial or femoral technique with a vascular occlusion device, no distinction was observed in survival free of serious adverse cardiovascular events at 12 months of follow-up. Clinical trials with greater statistical power are necessary for the validation of these findings.

Author contributions

Conception and design of the research: Andrade PB, Mattos LAP, Labrunie A, Sousa AGMR. Acquisition of data: Andrade PB, Rinaldi FS, Bienert IRC, Barbosa RA, Labrunie A. Analysis and interpretation of the data: Andrade PB. Statistical analysis: Andrade PB. Obtaining financing: Andrade PB. Writing of the manuscript: Andrade PB. Critical revision of the manuscript for intellectual content: Andrade PB, Mattos LAP, Kreimer S, Esteves VC, Tebet MA, Labrunie A, Sousa AGMR.

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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