Journal of
Transcatheter Interventions
e-ISSN e-2595-4350

Randomized comparison of hemostasis times after radial access for cardiac catheterization

Comparação randomizada de tempos de hemostasia após acesso radial para cateterismo cardíaco

Erlley Raquel Aragão Nobrega[1], Cristiane Maria Covello[1], Gabriela de Oliveira Buril[1], Priscila de Oliveira Carvalho[1], Pollyanna Dutra Sobral[1], Laécio Leitão Batista[1], Edgar Guimarães Victor[1]

[1] *Universidade Federal de Pernambuco, Recife, PE, Brazil.*

DOI: 10.31160/JOTCI2018;26(1)A0004

ABSTRACT – **Background:** Radial access has been widely used in percutaneous coronary procedures. Occlusion of the radial artery is the most important vascular complication related to the duration of compression time after radial access for cardiac catheterization. The objective of this study was to compare the efficacy and safety of hemostasis for 2 or 3 hours after diagnostic cardiac catheterization via radial approach. **Methods:** A prospective, randomized study with 206 patients recruited after cardiac catheterization using radial access, between November 2014 and November 2015. **Results:** There was no difference in vascular complications between the 2 and 3-Hour Groups. After the procedure, active bleeding during hemostasis occurred in 24 patients (9.7% vs. 13.6%; p=0.385). Clinical evaluation after 7 days found history of pain in 41 (19.9%), and hematoma in 48 patients (28.3 vs. 20.0; p=0.172), with higher frequency of hematomas smaller than 10cm (50.0% vs. 60.0%; p=0.679). Evaluation by ultrasound found flow reduction in 4 patients (2.0% vs. 2.0%; p=0.698), occlusion in 18 (7.7% vs. 11%; p=0.334), subcutaneous hematoma in 2 (2.0% vs. 0.0%; p=0.246), subcutaneous edema in 2 (1.0% vs. 1.0%; p>0.99), arterial dissection in 2 (1.0% vs. 1.0%; p>0.99), and pseudoaneurysm in 1 (0.0% vs. 1.0%; p>0.99). **Conclusions:** Reducing compression time of the radial artery to 2 hours during hemostasis in invasive diagnostic coronary procedures has been proved safe and effective. Compared to the 3-hour period, it demonstrated similar rates of vascular complications.

Keywords: Cardiac catheterization; Radial artery; Hemostasis

RESUMO – **Introdução:** A via de acesso radial tem sido amplamente empregada em procedimentos coronários percutâneos. A oclusão da artéria radial é a principal complicação vascular relacionada ao tempo de compressão após acesso radial para cateterização cardíaca. O objetivo do estudo foi comparar a eficácia e a segurança da hemostasia com compressão em 2 vs. 3 horas após cateterismo cardíaco diagnóstico radial. **Métodos:** Estudo prospectivo, randomizado, com recrutamento de 206 pacientes após cateterismo cardíaco radial entre novembro de 2014 e novembro de 2015. **Resultados:** Não houve diferença em complicações vasculares entre os Grupos 2 ou 3 Horas. Após o procedimento, o sangramento ativo durante a hemostasia ocorreu em 24 pacientes (9,7% vs. 13,6%; p=0,385). A avaliação clínica após 7 dias constatou relato de dor em 41 (19,9%) e hematoma em 48 (28,3 vs. 20,0; p=0,172), com maior frequência dos inferiores a 10cm (50,0% vs. 60,0%; p=0,679). A avaliação ultrassonográfica evidenciou redução do fluxo em 4 (2,0% vs. 2,0%; p=0,698) pacientes, oclusão em 18 (7,7% vs. 11%; p=0,334), hematoma subcutâneo em 2 (2,0% vs. 0,0%; p=0,246) edema subcutâneo em 2 (1,0% vs. 1,0%; p>0,99), dissecção arterial em 2 (1,0% vs. 1,0%; p>0,99) e pseudoaneurisma em 1 (0,0% vs. 1,0%; p>0,99). **Conclusões:** Reduzir o tempo de compressão da artéria radial para 2 horas durante a obtenção de hemostasia em procedimentos coronários invasivos diagnósticos mostrou-se estratégia segura e eficaz. Comparada ao período de 3 horas, a redução mostrou taxas similares de complicações vasculares.

Descritores: Cateterismo cardíaco; Artéria radial; Hemostasia

How to cite this article:
Nobrega ER, Covello CM, Buril GO, Carvalho PO, Sobral PD, Batista LL, et al. Randomized comparison of hemostasis times after radial access for cardiac catheterization. J Transcat Interven. 2018;26(1):1-6. https://doi.org/10.31160/JOTCI2018;26(1)A0004

Corresponding author:
Erlley Raquel Aragão Nobrega
Rua Professor Moraes Rego, S/N
Cidade Universitária
Zip code: 50670-900, Recife, PE, Brazil
E-mail: erlleyaragao@hotmail.com

Received on:
May 31, 2017

Accepted on:
Apr 9, 2018

INTRODUCTION

The radial access has been widely used for diagnostic and therapeutic percutaneous coronary procedures in Brazil and worldwide.[1-3] The use of this technique is more comfortable for the patient, reduces the risk of vascular complications and the length of stay, in addition to reducing costs, as compared to the femoral access.[4]

A complex series of biological phenomena is triggered to achieve hemostasis as an immediate response to blood vessel injury, aiming to maintain vascular integrity and blood fluidity.[5] The mechanical arterial compression technique with conventional dressing is often used for its effectiveness, easy handling and low cost, and facilitates the process of hemostasis by means of extrinsic pressure over the puncture site.[6,7] Although it represents a well-established technique, validated by previous research, there is a scarcity of data on the optimal duration of radial compression to achieve hemostasis and lower rates of vascular complications.

The objective of this study is to compare the efficacy of radial hemostasis for 2 or 3 hours, as well as the occurrence of vascular complications at 7 days, in patients undergoing invasive diagnostic coronary procedures.

METHODS

A prospective, randomized study recruited 206 patients with indication of coronary angiography using radial access between November 2014 and November 2015. Thirty-three patients were excluded for presenting vascular complications after puncture, prior to the compressive dressing, or for not consenting to participate.

The inclusion criteria were age above 18 years, use of 5 or 6Fr introducer, and unaltered Allen's test and pulse oximetry.

The parameters adopted to calculate the sampling size were 95% confidence interval, 80% power and 1:1 ratio between control group (3-Hour Group) and study group (2-Hour Group), estimating a rate of radial artery occlusion in the 3-Hour Group of 10%,[8] with 186 patients needed for the analysis. To compensate for possible losses or refusals, 10% were added and the final sample included 206 patients (103 in each group). Randomization was carried out in groups of ten patients. For random distribution of the two durations of arterial compression, sealed envelopes were presented to patients by draw, without identification, determining the period of mechanical compression as 2 or 3 hours.

The study was open label. Medical evaluation, both at hospital and the 7-day follow-up, was performed by trained nurses by means of clinical observation and palpation. Hematoma, if present, was measured with a tape featuring centimeters, taking into account the largest diameter. In the presence of vascular complications, a physician was called to evaluate the region and determine the management to be adopted. Ultrasound exams were performed by the same specialist, and the data was interpreted by the researchers.

After the interview and medical examination using the Allen's test and pulse oximetry to evaluate palmar arch patency, patients underwent coronary angiography according to the local medical practice. The selected patients were divided into 2-Hour and 3-Hour Groups, with compression duration of 2 or 3 hours, respectively. All patients were evaluated before and after radial artery compression and remained at rest in bed for one hour after removing the compressive dressing to assess bleeding and vascular complications.

During the procedure, 5,000IU of unfractionated heparin were administered through the radial introducer. At the end of coronary angiography, the puncture site was evaluated, checking for the presence of vascular complications after removal of the introducer.

A compressive dressing was applied with the gauze placed longitudinally over the puncture site, using three strips of plaster tape measuring 14-cm long by 5-cm wide (Figure 1). In case of inadequate hemostasis, the dressing was changed, with reevaluation every hour until complete hemostasis.

After 7 days, the arterial puncture site was reassessed clinically and by ultrasonography. The presence of blood

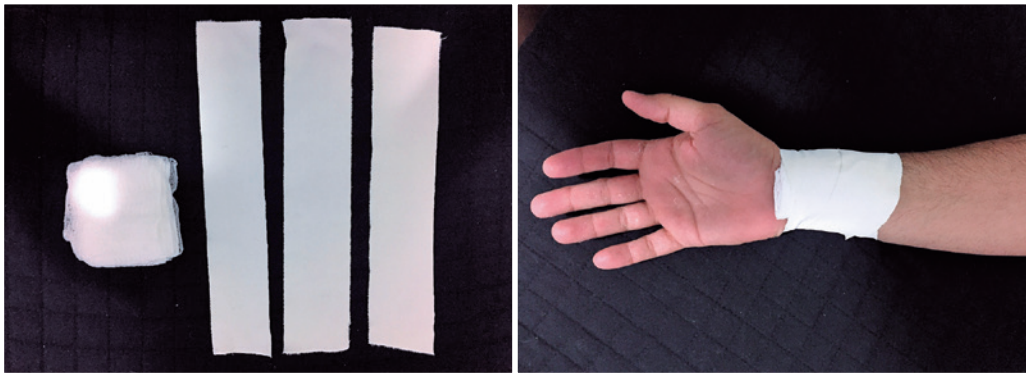

Figure 1. Compressive dressing on the radial artery using overlaying strips of plaster tape.

flow was verified by analyzing local flow rate, occurrence of arterial occlusion, arteriovenous fistula, pseudoaneurysm, stenosis or subcutaneous hematoma.

For statistical analysis, the software STATA/SE 12.0 and Excel 2010 were used. All tests were applied with 95% confidence interval and the results presented as tables with their respective absolute and relative frequencies. Numerical variables were represented by measures of central tendency and dispersion. The existence of association was verified using the Chi-squared test and Fisher's exact test for categorical variables; Kolmogorov-Smirnov normality test was used for quantitative variables; and Student's *t* test to compare both groups. All participants signed an Informed Consent Form. This study was approved by the Institutional Review Board of the Universidade de Pernambuco (CAAE 34767414.2.0000.5208).

RESULTS

The mean age of the 2-Hour and 3-Hour Groups was 63.8±11.0 and 62.5±10.2 years, respectively. There was no statistical difference regarding sex, body mass index or ethnicity. Table 1 depicts the comparative analysis of patient clinical characteristics with both groups being similar, except for a higher prevalence of stable angina in the 3-Hour Group (53.3% vs. 77.7%; p=0.001), and more extensive structural and/or valvular heart disease in the 2-Hour Group (30.1% vs. 11.7%; p=0.001). In relation to adjunctive pharmacotherapy, there were no differences between the groups - acetylsalicylic acid (ASA) (46.6% vs. 53.8%; p=0.265), other antiplatelet drugs (8.7% vs. 10.7%; p=0.638), and statin (48.5% vs. 61.2%; p=0.069).

Procedural characteristics did not differ between groups (Table 2). There was a predominance of 5F introducers (54.9%). Puncture was successful at the first attempt in 171 patients (83.0%), and the introducer was left in place for an average of 15 to 30 minutes in 126 patients (61.2%). A total of 57.8% of procedures were carried out within less than 30 minutes, and multivessel atherosclerotic coronary artery disease was the most frequent finding (58.3%).

The clinical evaluation made on the day of cardiac catheterization did not show significant difference between the 2-Hour and the 3-Hour Groups (Figure 2). Systemic blood pressure before removing the introducer was within normal range in 61.6% (58.2% vs. 65.0%; p=0.390). Pain was reported at the puncture site after compression of the radial artery by 16.9% of patients (19.4% vs. 14.6%; p=0.354), while arterial spasm during the removal of introducer occurred in 56 patients (27.2% vs. 27.2%; p>0.99). Post-compression ecchymosis was found in 34 patients (19.4% vs. 13.7%; p=0.273), mostly (97.1%) of small size (<5cm). Bleeding while attempting hemostasis was observed in 24 patients (9.7% vs. 13.6%; p=0.385), and edema at the compression site in six patients (2.9%). No cases of pseudoaneurysm, arteriovenous fistula or limb dysfunction were found. Compressive dressing had to be replaced once in 21 patients (8.7% vs. 11.6%; p=0.654), and twice or more in three patients (0.9% vs. 1.9%; p=0.654).

Three patients were lost to clinical and ultrasound-based follow-up (2.9%) in the 2-Hour Group, and four patients (3.8%) in the 3-Hour Group. At 7 days, pain reported in the punctured limb was similar in both groups (21.2% vs. 20.0%; p=0.839). Ecchymosis was more frequent in follow-up (28.3% vs. 20.0%; p=0.172), notably extensive ones (50.0% vs. 60.0%; p=0.679). Bleeding at the puncture site after discharge, signs of local infection, murmur, and pulsatile mass were not found (Figure 3).

Regarding the ultrasound findings, blood flow was reduced in two patients of each group (2.0% vs. 2.0%; p>0.99); higher (not significant) incidence of radial artery occlusion in the 3-Hour Group (7.1% vs. 11.0%; p=0.334); subcu-

Table 1. Clinical characteristics of patients

Variables	2-Hour Group (n=103) n (%)	3-Hour Group (n=103) n (%)	p-value
Body mass index			0.513
Low weight	1 (1.0)	2 (1.9)	
Normal weight	38 (36.9)	29 (28.2)	
Overweight	40 (38.8)	49 (47.6)	
Obesity	24 (23.3)	23 (22.3)	
Hypertension	94 (91.3)	100 (97.1)	0.074
Diabetes mellitus	28 (27.2)	29 (28.2)	0.876
Alcoholism	14 (13.6)	14 (13.6)	>0.99
Smoking	14 (13.6)	12 (11.7)	0.675
Dyslipidemia	59 (57.3)	59 (57.3)	>0.99
Stable coronary disease	57 (55.3)	80 (77.7)	0.001
Myocardial infarction	20 (19.4)	11 (10.7)	0.079
Structural/valvular heart disease	31 (30.1)	12 (11.7)	0.001

Table 2. Characteristics of procedures

Variables	2-Hour Group (n=103) n (%)	3-Hour Group (n=103) n (%)	p-value
Introducer diameter			0.069
5Fr	50 (48.5)	63 (61.2)	
6Fr	53 (51.5)	40 (38.8)	
Puncture attempts			0.337
1	84 (81.6)	87 (84.5)	
2	16 (15.5)	10 (9.7)	
≥3	3 (2.9)	6 (5.8)	
Duration of procedure, minutes			0.454
<30	63 (61.2)	56 (54.4)	
31-60	39 (37.9)	44 (42.7)	
>60	1 (1.0)	3 (2.9)	
How long the introducer was left in place after conclusion of procedure, minutes			0.224
<15	32 (31.1)	25 (24.3)	
15-30	63 (61.2)	63 (61.1)	
>30	8 (7.8)	15 (14.6)	
Severity of CAD			0.102
Absence of atheromatosis	34 (33.0)	21 (20.4)	
Single-vessel coronary disease	17 (16.5)	15 (14.6)	
Multivessel coronary disease	52 (50.4)	67 (65.0)	

CAD: coronary atherosclerotic disease.

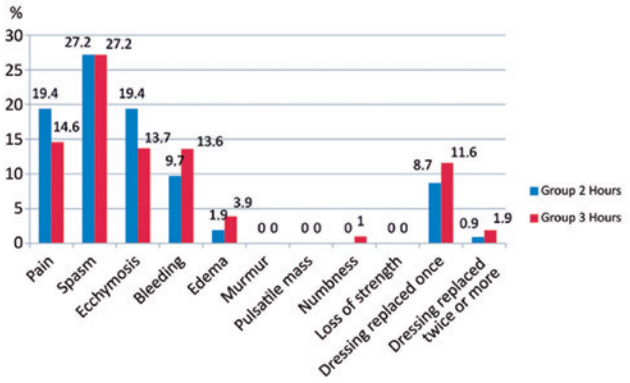

Figure 2. Clinical examination of arterial puncture site on the day of procedure.

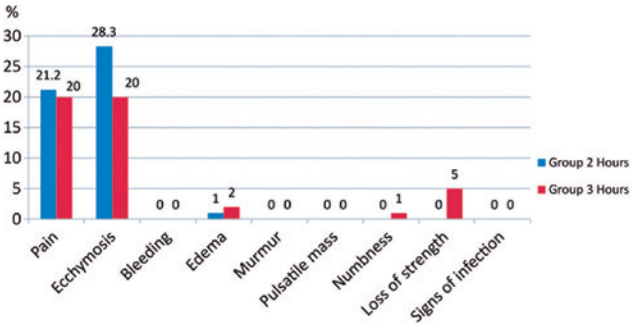

Figure 3. Clinical examination of arterial puncture site on return visit 7 days after procedure.

Table 3. Doppler ultrasound assessment after 7 days

Variables	2-Hour Group (n=103) n (%)	3-Hour Group (n=103) n (%)	p value
Patent flow	94 (91.3)	90 (87.4)	0.499
Reduced flow	2 (1.9)	2 (1.9)	>0.99
Occlusion	8 (7.8)	12 (11.6)	0.334
Hematoma	2 (1.9)	0	0.246
Pseudoaneurysm	0	1 (1.0)	>0.99
Arterial dissection	1 (1.0)	1 (1.0)	>0.99

taneous hematoma in two patients of the 2-Hour Group (2.0% vs. 0.0%; p=0.246); pseudoaneurysm in one patient of the 3-Hour Group (0% vs. 1%; p>0.99); and arterial dissection in one patient of each group (Table 3).

DISCUSSION

This study found no differences in the rates of vascular complications comparing the compression times of 2 and 3 hours, during radial artery hemostasis, after invasive diagnostic coronary procedures. Although we noted increased number and size of ecchymoses at 7-day follow-up, which may be related to difficult visualization and delimitation of

the area of blood leakage within a period of less than 12 hours, the incidence of subcutaneous hematoma at ultrasound was low and similar between groups, with spontaneous resolution and no need for intervention.

The benefits of the radial technique in reduction of vascular complications, as compared to the femoral technique, are widely known and reported in the literature. Welter et al.[9] demonstrated that using radial access presented lower risk of complications related to the puncture site, in addition to reducing the length of hospital stay, when compared to femoral access. After evaluating 3,000 procedures, Sanmartin et al.[10] demonstrated radial access offers greater safety, more predictable management of vascular complications, and infrequent need for surgical repair. Barbosa et al.[11] reported a low rate of bleeding, with predominantly small hematomas that did not require medical intervention and had spontaneous resolution, reinforcing radial access as the chosen approach. Similar findings were reported by Santos et al.[12] who studied 122 patients and found no severe vascular complications, such as pseudoaneurysm, arteriovenous fistula or compartment syndrome.

Radial artery occlusion is a frequent complication of this approach, and the incidence varies between 1.5 and 33%.[13,14] Up to 50% may present spontaneous recanalization within 30 days. The use of hemostasis techniques with maintenance of patent anterograde flow is the most effective strategy for its prevention.[15,16] Lisowska et al.[17] studied 220 patients who underwent diagnostic and therapeutic coronary procedures with 6Fr introducers and demonstrated, by ultrasonography, a radial artery occlusion rate of 15%. Sá et al .[18] reported rates of early and late radial occlusion of 10.5% and 9.1%, respectively. In the population of this study, the same type of occlusive compressive dressing was used for all patients, and the heparin dose was 5,000 units, the introducers being removed shortly after finishing the procedure. We noted by ultrasonography, the gold standard exam to detect vascular complications, that the incidence of radial artery occlusion at 7 days did not differ between groups and was consonant with the rates presented in previous studies.[12-14,16]

Regarding the perception of pain and discomfort referred by patients in invasive coronary procedures, Piva et al.,[19] in a cross-sectional study of 232 patients, observed that pain at the puncture site was more frequent among those undergoing radial access (26.8% vs. 52.2%; p=0.01). However, low back pain and general malaise were more common in the femoral group. In another series, 7.5% of patients reported mild discomfort; 0.8% moderate pain; 1.7% intolerable pain; and 90% denied any symptoms.[20] In our study, removal of introducer occurred most often between 15 and 30 minutes after the end of procedure. Although a routine of our institution, this may be related to a higher rate of arterial spasm and local pain. The duration of compression, however, was not a determining factor for reporting discomfort related to the procedure.

The study has limitations. In addition to the small number of patients and participation of a single center, we did not routinely evaluate patency of radial artery after placing compressive dressing, which is an important aspect in the prevention of occlusion of the artery. The absence of late follow-up, after 7 days, may underestimate the actual rate of complications at the access site and does not allow assessment of arterial recanalization.

CONCLUSIONS

Reducing duration of the radial artery compression to 2 hours during homeostasis of access in invasive diagnostic coronary procedures proved to be a safe and efficient strategy. When compared to 3-hour compression, the rate of vascular complications was similar. Shorter length of stay leads to cost reduction, greater bed availability, as well as time optimization for professionals directly involved in patient care.

FUNDING SOURCE

None.

CONFLICTS OF INTEREST

The authors have no disclosures.

REFERENCES

1. Aguiar Filho GB, Siqueira DA, Chaves AJ, Coelho FM, Costa Júnior R, Veloso M, et al. Intervenção coronária percutânea pela via radial: incorporação da técnica e resultados de um centro de formação em cardiologia intervencionista. Rev Bras Cardiol Invasiva. 2012;20(4):367-72.
2. Andrade PB, Tebet MA, Andrade MV, Labrunie A, Mattos LA. Acesso radial em intervenções coronarianas percutâneas: panorama atual brasileiro. Arq Bras Cardiol. 2011;96(4):312-6.
3. Abdelaal E, Molin P, Plourde G, Machaalany J, Bataille Y, Brousseau-Provencher C, et al. Successive transradial access for coronary procedures: experience of Quebec Heart-Lung Institute. Am Heart J. 2013;165(3):325-31.
4. Markovic S, Imhof A, Kunze M, Rottbauer W, Wöhrle J. Standardized radial approach reduces access site complications: a prospective observational registry. Coron Artery Dis. 2015(1):56-9.
5. Rodrigues ES, Castilho-Fernandes A, Fontes AM. Novos conceitos sobre a fisiologia da hemostasia. Rev Univ Vale do Rio Verde. 2012;10(1):218-33.
6. Argibay Pytlik V, Gómez Fernández M, Jiménez Pérez R, Santos Vélez S, Serrano Poyato C, editores. Manual de enfermería em cardiología intervencionista y hemodinâmica. Protocolos unificados [Internet]. Madrid: Asociación Española de Enfermería en Cardiología; 2007 [cited 2018 Apr 25]. Available from: https://www.enfermeriaencardiologia.com/publicaciones/manuales/manual-de-enfermeria-en-cardiologia-intervencionista-y-hemodinamica-protocolos-unificados
7. Gioppato S, Castello Júnior HJ, Conforti TB, Gonçalves SL, Morais FG, Cantarelli MJ. Análise da relação custo-efetividade do dispositivo

de oclusão vascular AngioSeal™ comparando à compressão manual e/ou mecânica após intervenções endovasculares. Rev Bras Cardiol Invasiva. 2011;19(2):189-93.
8. Pancholy S, Coppola J, Patel T, Roke-Thomas M. Prevention of radial artery occlusion-patent hemostasis evaluation trial (PROPHET study): a randomized comparison of traditional versus patency documented hemostasis after transradial catheterization. Catheter Cardiovasc Interv. 2008;72(3):355-40.
9. Welter DI, Leite RS, Cardoso CO, David RB, Raver MM, Sebben JC, et al. Intervenção coronária pelas vias radial ou femoral no infarto agudo do miocárdio com supradesnivelamento do segmento ST: uma visão da prática clínica contemporânea. Rev Bras Cardiol Invasiva. 2011;19(3):266-71.
10. Sanmartin M, Cuevas D, Goicolea J, Ruiz-Salmerón R, Gómez M, Argibay V. [Vascular complications associated with radial artery access for cardiac catheterization]. Rev Esp Cardiol. 2004; 57(6):581-4. Spanish.
11. Barbosa RR, Siqueira D, Coelho FM, Assaf Neto S, Costa Júnior JR, Costa R, et al. Crossover da terapia com heparina e risco de sangramento na intervenção coronária percutânea transradial na síndrome coronária aguda. Rev Bras Cardiol Invasiva. 2012; 20(4):392-7.
12. Santos MA, Borba RP, Moraes CV, Voltolini I, Azevedo EM, Cardoso CR, et al. Avaliação da patência da artéria radial após cateterismo transradial. Rev Bras Cardiol Invasiva. 2012;20(4):403-7.
13. Pancholy SB, Patel TM. Effect of duration of hemostatic compression on radial artery occlusion after transradial access. Catheter Cardiovasc Interv. 2012;79(1):78-81.
14. Uhlemann M, Möbius-Winkler S, Mende M, Eitel I, Fuernau G, Sandri M, et al. The Leipzig prospective vascular ultrasound registry in radial artery catheterization: impact of sheath size on vascular complications. J Am Coll Cardiol Intv. 2012;5(1): 36-43.
15. Andrade MV, Andrade PB, Barbosa RA, Tebet MA, Silva FS, Labrunie A, et al. Validação de protocolo para obtenção de hemostasia com dispositivo de compressão radial TR Band™ após intervenção coronária percutânea. Rev Bras Cardiol Invasiva. 2011;19(2):184-8.
16. Barbosa RA, Andrade MV, Andrade PB, Rinaldi FS, Bienert IR, Nogueira EF, et al. Utilização de pulseira compressora seletiva na prevenção da oclusão da artéria radial após procedimento coronário invasivo. Rev Bras Cardiol Invasiva. 2014;22(2):115-9.
17. Lisowska A, Knapp M, Tycińska A, Sielatycki P, Sawicki R, Kralisz P, et al. Radial access during percutaneous interventions in patients with acute coronary syndromes: should we routinely monitor radial artery patency by ultrasonography promptly after the procedure and in long-term observation? Int J Cardiovasc Imaging. 2015; 31(1):31-6.
18. Sá BJ, Barros LF, Brandão SC, Victor EG. Interferência de introdutores reprocessados na oclusão da artéria radial após cateterismo cardíaco. Rev Bras Cardiol Invasiva. 2013;21(3):270-5.
19. Piva CD, Vaz E, Moraes MA, Goldmeyer S, Linch GF, Souza EM. Desconfortos relacionados pelos pacientes após cateterismo cardíaco pelas vias femoral ou radial. Rev Bras Cardiol Invasiva. 2014;22(1):36-40.
20. Luis SF. Comparação entre coronariografia efetuada via artéria radial e via artéria femoral [tese] Lisboa: Faculdade de Medicina Universidade de Lisboa; 2011.