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Comparison between compression dressing and hemostatic wristband after cardiac procedures using the radial approach

Comparação entre curativo compressivo e pulseira hemostática após procedimentos cardiológicos por via radial

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ABSTRACT – **Background:** The radial approach for cardiac catheterization and coronary angioplasty is well established. The prevalence of radial artery occlusion and its determining factors still raises debate. The objective of this study was to analyze the incidence of radial artery occlusion after cardiac procedures using the radial approach, comparing hemostasis done by elastic compression dressing or hemostatic wristband. **Methods:** A randomized clinical trial comparing the incidence of radial artery occlusion as established by palpation and vascular Doppler, upon discharge and at 30-day follow-up, in patients submitted to cardiac procedures using the radial approach, assigned to hemostasis by elastic dressing or hemostatic wristband. **Results:** A total of 190 patients were included, 166 completed the 30-day follow-up. There were no differences in baseline characteristics between the groups. The incidence of radial occlusion at hospital discharge, with elastic bandage or hemostatic wristband as verified by palpation and arterial Doppler was, respectively, 9.7% vs. 12.4%, and 6.5% vs. 10.3%, with no difference between groups. At 30-day follow-up, it was 11.8% vs. 18.9% and 10.5% vs. 16.5%, with no difference between groups. No reduction in the incidence of arterial occlusion was noted with the use of high-dose heparin, although patients undergoing cardiac catheterization presented radial occlusion more frequently than those submitted to percutaneous coronary intervention. **Conclusion:** The radial artery patency of the compression dressing upon hospital discharge and at 30 days was similar to that of the hemostatic wristband.

Keywords: Cardiac catheterization; Radial artery; Hemostasis

RESUMO – **Introdução:** A abordagem radial para cateterismo cardíaco e angioplastia coronária está consolidada. A prevalência de oclusão da artéria radial e de seus fatores determinantes ainda suscita debate. O objetivo deste estudo foi comparar a incidência de oclusão da artéria radial após sua cateterização em procedimentos cardiológicos com hemostasia por pulseira hemostática ou curativo elástico compressivo. **Métodos:** Ensaio clínico randomizado, comparando a incidência de oclusão da artéria radial por palpação e Doppler vascular, na alta e no seguimento de 30 dias, em pacientes submetidos a procedimentos cardiológicos por via radial, alocados para hemostasia por curativo elástico ou pulseira hemostática. **Resultados:** Foram incluídos 190 pacientes, e 166 completaram o seguimento de 30 dias. Não se observaram diferenças nas características basais entre os grupos. A incidência de oclusão radial na alta hospitalar, verificada pela palpação e pelo Doppler arterial, em pacientes que receberam curativo elástico e pulseira hemostática foi, respectivamente, de 9,7% vs. 12,4% e 6,5% vs. 10,3%, sem diferença entre os grupos. No seguimento de 30 dias, foi de 11,8% vs. 18,9% e 10,5% vs. 16,5%, sem diferença entre os grupos. Não se observou redução na incidência de oclusão arterial com o uso de heparina em altas doses, apesar de os pacientes submetidos a cateterismo cardíaco apresentarem oclusão radial com maior frequência que aqueles submetidos à intervenção coronária percutânea. **Conclusão:** O curativo compressivo apresentou taxa de patência da artéria radial na alta hospitalar e no seguimento de 30 dias similar à da pulseira compressiva.

Descritores: Cateterismo cardíaco; Artéria radial; Hemostasia

INTRODUCTION

The radial technique in coronary diagnostic and therapeutic procedures is well established. Compared to the femoral technique, it has been proven to reduce bleeding

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and mortality rates, especially in patients at higher risk, such as in acute coronary syndromes.[1-4] It also decreases vascular complications related to puncture site, providing greater comfort to patients, early mobilization, and reduced hospital costs.[5-7]

The incidence of radial artery occlusion after catheterization or percutaneous coronary intervention (PCI) ranges from 3 to 12%, and it is an underrated complication for rarely causing hand ischemia that requires surgical intervention, due to the dual arterial supply.[8,9] Approximately half of interventional cardiologists do not systematically verify radial artery patency before discharge.[10] If the radial artery remains occluded, it can not be used for a new percutaneous procedure, arteriovenous fistula or surgical arterial graft.

Initially, there were no dedicated devices for radial artery hemostasis. Many types of dressings were adopted in different hospitals with no systematization. This raises doubts as to whether the dedicated devices have better results than dressings, regarding radial artery patency.

The primary objective of this study was to compare the effect of compression dressings and hemostatic wristband on patients submitted to cardiac procedures using the radial approach, regarding arterial patency.

METHODS

A randomized, single center, open-label clinical trial comparing hemostasis after radial approach in cardiac procedures. In one group the hemostatic wristband TR Band® (Terumo Corporation, Tokyo, Japan), with controlled compression was used (Figure 1), and in the other, compressive elastic dressing, standardized as six 21-thread gauzes overlapped, opened, longitudinally folded once and rolled, forming a 5-cm long cylinder, 3-cm in diameter, fixed with microporous adhesive tape (Figure 2).

The inclusion criteria were patients of both sexes, submitted to coronary angiography or PCI; intention to use the radial approach; and age ≥18 years. The exclusion criterion was failure to obtain radial access.

The study protocol was submitted to the Internal Review Board of the Universidade de Passo Fundo, on July 31, 2013 (CAAE 18477013.2.0000.5342) and was approved on August 2, 2013. Patients who consented to participate in the study signed an Informed Consent Form (ICF) before randomization.

The data collection form was completed, and randomization was conducted with the True Random Number Generator (www.random.org). Minimum and maximum values were defined as zero and 1, respectively, corresponding to the groups that received compression dressing with gauze and microporous adhesive tape, or radial artery compression device with controlled compression. After the end of the procedure, if there was no exclusion criterion, the hemostatic method was applied, according to the group for which the patient had been allocated.

Figure 1. Hemostatic wristband TR Band®.

Figure 2. Compressive elastic dressing.

Hemostasis devices were maintained for up to 240 minutes. The elastic dressings were loosened and removed entirely, after 120 minutes in diagnostic procedures, and after 240 minutes in PCI. If there were bleeding at the time of removal, the dressing was fixed again, and another attempt was conducted after 30 minutes. The procedure to remove the device was initiated after 60 minutes for diagnostic catheterization and 120 minutes for PCI, deflating half the air required for hemostasis and evaluating the presence of active bleeding. If present, the same volume of air was inflated and held for another 30 minutes. If not, the balloon with half the initial volume was kept in place for

another 30 minutes and then completely deflated. If there were bleeding at this stage, the device was inflated with half the air for an additional 30 minutes and, remaining free from bleeding, was completely removed. Subsequently, simple dressing was applied, with gauze and microporous tape, without compression.

Radial artery patency was verified upon hospital discharge and after 30 days, by means of palpation and vascular Doppler, with no associated imaging. At the time of hospital discharge, blood flow distal to the radial puncture and the presence of hematoma were evaluated, and each patient graded the discomfort caused by the dressing on a scale of zero to 10, respectively representing the absence of discomfort and the maximum discomfort imaginable. Hematomas were classified as type I if <5cm in diameter; type II, <10cm in diameter; type III, ≥10cm, without reaching the elbow; type IV, hematoma extending beyond the elbow; type V, any hematoma with ischemic injury at hand level. This information was inserted in the data collection form, as well as the need for intervention to manage complications related to the puncture site during hospital admission. At 30-day follow-up, the patients were reassessed at the Cardiology Outpatient Clinic, and the patency of the radial artery and the possible need for intervention to manage complications were reviewed.

Statistical analysis was conducted based on the principle of intention-to-treat. Data were initially collected in paper forms, manually entered in a Microsoft Excel spreadsheet, and analyzed using the Statistical Package for Social Science (SPSS) for Windows, version 17.0. Numerical variables were expressed as mean±standard deviation or median [25th percentile – 75th percentile], according to presence or absence of normal distribution. Categorical variables were expressed as absolute and relative frequency. The incidence of arterial occlusion and complications requiring intervention was compared between the groups using the Pearson's Chi-square test. The intensity of the discomfort was compared between the two groups using Mann-Whitney U-test. We considered statistically significant probability values of ≤0.05. The variables analyzed were sex, age, body mass index (BMI), heparin dose, puncture site, number of punctures, type of procedure, compression time, hemorrhagic complications, and radial artery patency as determined by palpation and vascular Doppler.

RESULTS

A total of 190 subjects were enrolled between September and December 2013, and the clinical characteristics and procedures are described in Table 1. The median number of punctures to catheterize the radial artery was 1.0 [1.0-2.0]; of the heparin dose was 2,500 U [2,500-10,000 U]; of the procedure time was 15.0 minutes [10.0-20.0 minutes]; of compression time, 167.5 minutes [120.0-210.0 minutes], being similar between the groups.

The incidence of radial occlusion upon hospital discharge, both at palpation and Doppler, did not differ between groups (Table 2). No severe bleeding was observed. Pain, measured by the Visual Analog Scale, was not different between the groups: 0 [0-3.0] for elastic dressing vs. 0 [0-2.5] among those who received the radial artery compression device. There were also no clinical risk factors related to a higher rate of radial artery occlusion, or to the heparin dose or type of procedure. The incidence of hematoma was significantly higher among the radial artery compression device group (p=0.047). All hematomas in both groups were type I.

Table 1. Clinical and procedure characteristics

Characteristics	Elastic dressing (n=93)	Hemostatic wristband (n=97)
Male	61 (65.6)	65 (68.0)
Age, years	64.7±10.8	63.5±9.9
Hypertension	77 (82.8)	80 (82.5)
Smoking	24 (25.8)	25 (25.8)
Dyslipidemia	50 (53.8)	51 (52.6)
Diabetes mellitus	31 (33.3)	26 (26.8)
Chronic kidney disease	6 (6.5)	3 (3.1)
Clinical presentation		
Stable CAD	63 (67.7)	72 (74.2)
Unstable angina	21 (22.6)	16 (16.5)
NSTEMI	7 (7.5)	5 (5.2)
STEMI	2 (2.2)	4 (4.1)
Diagnostic procedure	64 (50.3)	63 (49.4)
Therapeutic procedure	31 (49.2)	32 (50.8)
Mean compression time, minutes	178.4	186.1

Results expressed as n (%) or mean±standard deviation. p values are statistically non significant in all comparisions. CAD: coronary atherosclerotic disease; NSTEMI: non-ST elevation myocardial infarction; STEMI: ST-elevation myocardial infarction.

Table 2. Radial artery patency on clinical examination and vascular Doppler upon hospital discharge

	Arterial occlusion in follow-up			
	Pulse palpation	p value	Arterial Doppler	p value
Type of hemostasia		0.55		0.34
Elastic dresing, n=93	9 (9.7)		6 (6.5)	
Hemostatic wristband, n=97	12 (12.4)		10 (10.3)	
Heparin dose		0.64		0.47
≤5,000U, n=127	15 (11.8)		12 (9.4)	
>5.000U, n=63	6 (9.5)		4 (6.3)	
Type of coronary procedure		0.75		0.55
Diagnostic, n=127	15 (11.8)		12 (9.4)	
Therapeutic, n=63	6 (9.5)		4 (6.3)	

Results expressed as n (%).

Out of 190 patients included in the study, 166 (87.5%) completed the 30-day follow-up. The incidence of radial occlusion at 30 days, both by palpation and Doppler, was similar between groups (Table 3). When evaluating the association between heparin dose, divided into ≤5,000U and >5,000U, and incidence of radial occlusion, it was noted that radial occlusion was numerically higher among those who received lower doses of heparin, although not statistically significant. Diagnostic procedures were associated with a significant increase in the incidence of radial occlusion at 30 days as compared to PCI.

Table 3. Radial artery patency on clinical examination and vascular Doppler at 30-day follow-up

	Arterial occlusion in floow-up			
	Pulse palpation	p value	Arterial Doppler	p value
Type of hemostasia		0.21		0.25
Elastic dressing, n=76	9 (11.8)		8 (10.5)	
Hemostatic wristband, n=90	17 (18.9)		15 (16.7)	
Heparin dose		0.13		0.26
≤5.000U, n=115	21 (18.6)		18 (15.9)	
>5.000U, n=51	5 (9.4)		5 (9.4)	
Type of coronary procedure		0.02		0.048
Diagnostic, n=115	23 (20.0)		20 (17.4)	
Therapeutic, n=51	3 (5.9)		3 (5.9)	

Results expressed as n (%).

DISCUSSION

Radial artery occlusion is a subject of wide debate in Interventional Cardiology, especially because of the evidence that the use of radial access reduces mortality in acute coronary syndromes. Regarding the incidence of occlusion of the radial artery, however, the data in the literature are quite heterogeneous. There are several propositions regarding time of compression, whether occlusive or controlled, dose of heparin, and type of dressing, and all of them aim to maintain patency of radial artery.[7-9,11-13]

In our study, the incidence of radial artery occlusion after catheterization was slightly higher than that reported in the literature.[8,12,14,15] The hemostatic method used was not associated with different rates of radial artery occlusion; increased patency at discharge and 30-day follow-up was not attained with the use of the radial artery compression device as proposed. We had a sample loss of 12.5% in the 30-day follow-up, considered acceptable, since the limit adopted as good practice in clinical trials is <20%, and considering we are inserted in a large geographical area and the patients, most of them from economic classes D and E have logistic difficulties. We also believe that this loss did not impact on the result of the 30-day analysis, due to the linearity of endpoints.

Two studies examined the effectiveness of the TR Band® as compared to other forms of radial artery hemostasis. Pancholy et al. conducted a study with 500 patients and showed reduction of radial artery occlusion with the TR Band® as compared to HemoBand™ (4.4% vs. 11.2%).[11] Rathore et al. compared the devices RadiStop™ and TR Band® in 790 patients, and found no significant difference in the incidence of radial artery occlusion between them (5.6% vs. 8.0%; p=0.273).[12] Dharma et al. studied the duration of compression (>4 hours vs. <4 hours)[13] and reported it was a strong predictor of radial artery occlusion (odds ratio 3.11, 95% confidence interval - 95%CI: 1.62-5.82), reinforcing the hypothesis that reducing radial artery injury also impacts the occurrence of occlusion.

Although statistically non-significant, the decreased incidence of radial artery occlusion among patients receiving heparin doses >5,000U in our study is consonant with other models, which demonstrated that routine administration of 5,000U of heparin could reduce by up to tenfold the rate of radial artery occlusion.[16-19] A meta-analysis with 31,345 patients conducted by Mamas et al. concluded that the 5,000U dose of heparin was highly effective to maintain radial artery patency when compared to low doses, such as 2,000 to 3,000U (hazard ratio 0.36, 95%CI: 0.17-0.76), not increasing the risk of bleeding.[3,4] Pancholy et al. also demonstrated that maintaining anterograde blood flow during radial hemostasis (patent hemostasis) could contribute to reducing the occurrence of thrombosis of this artery.[8]

Likewise, it is corroborated by a meta-analysis of 66 clinical studies evaluating radial artery occlusion, in which the prevalence was higher in diagnostic procedures as compared to PCI (8.8% vs. 4.5%, p=0.001).[14] Our data demonstrated that the incidence of radial artery occlusion was approximately three to four times greater in those submitted only to diagnostic catheterization procedures. A national study with 528 patients conducted by Said et al. assessed radial artery occlusion after compressive dressing or hemostatic device in consecutive, non-randomized patients, also showing no difference between groups 7 days after the procedure (3.8% vs. 7.1%, p=0.20).[15]

This study reflects the care practice of our service. The institutional protocol recommended the use of 2,500U of heparin after radial artery puncture for diagnostic procedures, a group in which we had higher incidence of occlusion. Even with data demonstrating that the use of less than 5,000 U of heparin has an impact on higher rates of arterial occlusion, we chose to follow the protocol of the organization, since it would be a way to evaluate the actual data of our service. Although no statistical significance was demonstrated, the study findings led to a change in local regulations, with the purpose to reduce the prevalence of radial artery occlusion. We also noted that the incidence of hematoma was significantly higher among those who used the radial artery compression device (8.2% vs. 1.1%, p=0.047).

CONCLUSIONS

In patients undergoing invasive coronary procedures, the compression dressing had a patency rate of the radial artery at discharge and 30-day follow-up similar to the hemostatic wristband.

FUNDING SOURCES

Terumo Brazil donated 80 hemostatic wristbands TR Band® to the study.

CONFLICTS OF INTEREST

The authors have no conflicts to declare.

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