

# Effect of nitroglycerin on radial artery spasm and occlusion in transradial catheterizations performed in women

Efeito da nitroglicerina no espasmo e na oclusão da artéria radial em cateterismos transradiais realizados em mulheres

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**ABSTRACT - Background:** The benefit of transradial catheterization is well established in female patients. Women undergoing transradial catheterization exams present with unique challenges. The occurrence of radial artery spasm and occlusion after the procedure is higher in women. The objective of this study was to evaluate the benefit of nitroglycerin in reducing radial artery spasm and occlusion in women undergoing transradial catheterization. **Methods:** This was a 2x2 factorial randomized, multicenter, prospective, double-blinded study. Participants were randomized to nitroglycerin 500mcg or placebo at two time points: after placement of the hemostatic introducer and before its removal. The evaluation of the radial artery spasm was clinical, using a pain scale. The evaluation of the radial artery occlusion was performed with Doppler, in the first 12 hours. **Results:** A total of 2,040 patients were included, of which 774 (37.5%) were female. Mean age was similar between sexes (62.2 years *versus* 61.5 years;  $p=0.27$ ). The incidence of radial artery spasm was higher in women (21.2% *versus* 6.6%;  $p<0.01$ ), as well as the incidence of radial artery occlusion (3.4% *versus* 1.8%;  $p=0.03$ ). The use of nitroglycerin at the beginning of the procedure did not reduce the incidence of radial artery spasm in women when compared with placebo (19.7% *versus* 22.6%;  $p=0.34$ ), nor did the rates of radial artery occlusion (4.3% *versus* 2.5%;  $p=0.17$ ). The use of nitroglycerin at the end of the procedure did not reduce the incidence of artery occlusion in women (2.8% *versus* 3.9%;  $p=0.37$ ). **Conclusions:** Radial artery spasm and occlusion are more frequent in women undergoing transradial catheterization when compared to men. The use of nitroglycerin does not have a beneficial effect in reducing these incidences.

**Keywords:** Nitroglycerin; Vasodilator agent; Cardiac catheterization; Arterial occlusive diseases; Radial artery; Spasm

**RESUMO - Introdução:** O benefício do cateterismo transradial já foi confirmado em pacientes do sexo feminino. Mulheres submetidas a exames por cateterismo transradial apresentam desafios únicos. A ocorrência de espasmo e oclusão da artéria radial após o procedimento é maior em mulheres. Objetivamos avaliar o benefício da nitroglicerina na redução de espasmo e oclusão da artéria radial em mulheres submetidas a cateterismo transradial. **Métodos:** Estudo multicêntrico, prospectivo, randomizado 2x2 fatorial, duplo-cego. Participantes foram randomizados para nitroglicerina 500mcg ou placebo em dois momentos: após colocação do introdutor hemostático e antes da retirada. A avaliação de espasmo da artéria radial foi clínica, por meio de escala dor. A avaliação da oclusão da artéria radial foi realizada com Doppler, nas primeiras 12 horas. **Resultados:** Foram incluídos 2.040 pacientes, sendo 774 (37,5%) mulheres. A média de idade foi similar entre os sexos (62,2 anos *versus* 61,5 anos;  $p=0,27$ ). A incidência de espasmo da artéria radial foi maior nas mulheres (21,2% *versus* 6,6%;  $p<0,01$ ), bem como a incidência de oclusão da artéria radial (3,4% *versus* 1,8%;  $p=0,03$ ). O uso da nitroglicerina no início do procedimento não reduziu a incidência de espasmo da artéria radial em mulheres quando comparado com o placebo (19,7% *versus* 22,6%;  $p=0,34$ ), tampouco as taxas de oclusão da artéria radial (4,3% *versus* 2,5%;  $p=0,17$ ). O uso da nitroglicerina ao fim do procedimento não reduziu a incidência de oclusão da artéria em mulheres (2,8% *versus* 3,9%;  $p=0,37$ ). **Conclusões:** O espasmo e a oclusão da artéria radial são mais frequentes em mulheres submetidas a cateterismo transradial quando comparadas aos homens. O uso da nitroglicerina não apresenta efeito benéfico na redução dessas incidências.

**Descritores:** Nitroglicerina; Vasodilatadores; Cateterismo cardíaco; Arteriopatias oclusivas; Artéria radial; Espasmo

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## INTRODUCTION

The transradial access (TRA) is safe and effective, and is currently the preferred route for diagnostic and therapeutic procedures. Due to the superficial course of the radial artery, vascular complications are minimized, especially hemorrhagic ones.<sup>1</sup> The use of this access is associated with lower mortality in patients with acute coronary syndromes.<sup>2</sup> Women undergoing TRA cardiac catheterization have the same benefits as men, but there are characteristic difficulties in performing the procedure, associated with a smaller radial artery caliber and a greater tendency to spasm (radial artery spasm – RAS). Female sex is also an independent predictor of radial artery occlusion (RAO) after the procedure.<sup>3,4</sup>

Generally, vasodilatory medications are used to reduce the occurrence of RAS, aiming to increase patient comfort and the success rate of this access route.<sup>5</sup> As RAS may be associated with a higher rate of RAO, the impact of these medications in the incidence of RAO has also been evaluated. The use of nitroglycerin at the end of the procedure may reduce the incidence of RAO, facilitating patent hemostasis.<sup>6,7</sup>

A recent study evaluated the impact of nitroglycerin on RAO and RAS;<sup>8</sup> using data from this study, a gender analysis was conducted to assess the role of nitroglycerin in reducing RAS and RAO in women undergoing TRA procedures.

## METHODS

This study is a *post hoc* analysis of a 2x2 factorial, multicenter, prospective, randomized, double-blinded study. Details about the methodology were previously published.<sup>8</sup> In summary, a total of 2,040 participants were randomized to nitroglycerin 500mcg or placebo in two moments: after placement of the hemostatic introducer and before removal of the introducer for assessment of RAO, verified by Doppler ultrasonography within the first 12 hours after the procedure. In all cases, patent or minimum pressure hemostasis was applied. In all participants, clinical RAS was evaluated using a numeric pain scale (graded from zero to ten), and it was defined as present in cases with a score >6.

For this analysis, we included all patients undergoing cardiac catheterization in three high-volume centers, which primarily use TRA as the access route, in the period between August 2017 and October 2021. The inclusion criteria were age greater than 18 years, clinical indication for diagnostic or therapeutic cardiac catheterization, choice by the operator responsible for the TRA procedure, and use of 5F or 6F caliber sheaths.

The exclusion criteria were primary angioplasty in acute myocardial infarction, intubated patients, known allergy to nitrates, use of continuous nitrates by intravenous or any other route in the last hour before the procedure, use of 5-phosphodiesterase inhibitors in the last 24 hours before the procedure, and prior inclusion in the study.

## Randomization

Patients were randomized in a 1:1 ratio to receive nitroglycerin or placebo in two moments of cardiac catheterization: immediately after placement of the hemostatic introducer in the radial artery, and before removal of the hemostatic introducer and the application of a compressive dressing. For RAS evaluation, only the first randomization, at the beginning of the procedure, was performed.

Randomization was performed in blocks of 24 patients, following a plan generated by an online software. No stratification was performed. Medication and placebo were previously prepared in identical syringes by an independent investigator, who did not participate in the procedure or in the post-procedure evaluations.

## Procedure

Assessment of patency of the palmar arch was not mandatory before catheterization. After skin preparation with antiseptic solution, the puncture point, 1 to 2cm proximal to the styloid process, was anesthetized with 1% lidocaine. Radial access was obtained with a 21- or 20/22-Gauge Abo-cath needle, using the puncture or counterpuncture technique, followed by positioning of a 5F or 6F hydrophilic hemostatic introducer. All patients received heparin – 5,000IU in diagnostic cases or 100IU/kg in therapeutic cases. Additional medications, including sedatives, were left to the discretion of the responsible operator. All procedures were performed in accordance with current guidelines.

At the end of the procedure, the hemostatic dressing was performed using pneumatic bracelets, to achieve patent or minimal pressure hemostasis, following previously described protocol. Briefly, the bracelet was positioned with its position marker located at the puncture point. The balloon was then inflated with 15mL of air, with subsequent removal of air to the point of bleeding or a minimum volume of 7mL. With bleeding control, the bandage was kept for 1 hour in diagnostic cases or 2 hours in therapeutic cases, followed by progressive deflation, until the bracelet was removed and a simple bandage was applied.

## Definitions

Radial artery spasm was assessed using the pain reported by the patient during catheterization, which was quantified using a numerical scale at the end of the procedure by a nursing professional unaware of the randomization. The scale ranged from zero to ten, with zero corresponding to no pain and ten to the worst possible pain. A value >6, indicating severe pain, established the clinical diagnosis of RAS.<sup>9</sup>

Radial artery occlusion was evaluated using Doppler ultrasonography, within 12 hours after the procedures, by a professional unaware of the randomization, using a 6 to 13MHz linear transducer (Fujifilm SonoSite or Toshiba). The artery was assessed 1 to 2cm proximal to the radial styloid process, with patency measured using pulsed Doppler ultrasound. RAO was defined by the absence of antegrade flow.<sup>10</sup>

## Statistical analysis

Continuous variables were described as mean and standard deviation, compared using the Student's *t* test. Categorical variables were described as frequencies or percentages and compared by means of the Chi-squared test.

Multivariate linear regression was used to test significant predictors of RAS and RAO. For all variables with a *p*-value below 0.10, the univariate analysis was included in the multivariate analysis.

The level of significance was 0.05. The analyses were performed using the IBM software Statistical Package for the Social Sciences (SPSS), version 22.0.

## RESULTS

The PATENS study was conducted at three Brazilian centers, including 2,040 patients, of which 774 (37.9%) were women. The present analysis included all randomized patients.

### Comparison between sexes

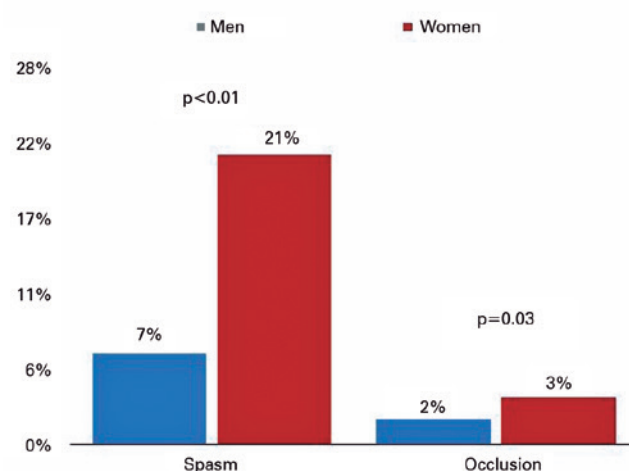
Mean age was similar between sexes (62.2 years *versus* 61.5 years; *p*=0.27), but women had a higher body mass index (BMI; 29.4 *versus* 28.1; *p*<0.01) and smaller radial arteries (2.33mm *versus* 2.74mm; *p*<0.01). In general, women undergoing catheterization in this study had a higher incidence of risk factors for coronary disease (Table 1). The incidence of RAS was higher in women (21.2% *versus* 6.6%; *p*<0.01), as well as the incidence of RAO (3.4% *versus* 1.8%; *p*=0.03) (Figure 1). In multivariate analysis, female sex was an independent predictor of RAS (OR 3.45; 95%CI 2.51-4.75; *p*<0.001), but not of RAS (OR 0.74; 95%CI 0.40-1.36; *p*=0.34).

**Table 1.** Baseline characteristics of patients

|                                          | Women<br>(n=774) | Men<br>(n=1,266) | Total<br>(n=2,040) |
|------------------------------------------|------------------|------------------|--------------------|
| Age, years                               | 62.25±10.08      | 61.51±10.46      | 61.79±10.32        |
| Height, cm*                              | 157.33±7.67      | 169.50±7.66      | 164.88±9.68        |
| Weight, kg*                              | 72.20±14.03      | 80.68±15.63      | 77.46±15.59        |
| Body mass index, kg/m <sup>2</sup> *     | 29.36±8.36       | 28.12±7.18       | 28.60±7.67         |
| Right-handed                             | 740 (95.6)       | 1,210 (95.6)     | 1,950 (95.6)       |
| Hypertension                             | 626 (80.9)       | 906 (71.6)       | 1,532 (75.1)       |
| Diabetes mellitus*                       | 331 (42.8)       | 416 (32.9)       | 747 (36.6)         |
| Dyslipidemia                             | 524 (67.7)       | 749 (59.2)       | 1,273 (62.4)       |
| Current smoking habit*                   | 153 (19.8)       | 301 (23.8)       | 454 (22.3)         |
| Previous transradial catheterization*    | 149 (19.3)       | 373 (29.5)       | 522 (25.6)         |
| Acute coronary syndrome*                 | 336 (43.4)       | 625 (49.4)       | 961 (47.1)         |
| Diameter of the right radial artery, mm* | 2.33±0.57        | 2.74±0.66        | 2.58±0.66          |

Results expressed as mean±standard deviation or n (%).

\* *p*<0.05.



**Figure 1.** Incidence of radial artery spasm and occlusion in men and women.

### Effect of nitroglycerin in women

The use of nitroglycerin at the beginning of the procedure did not reduce the incidence of RAS in women when compared with placebo (19.7% *versus* 22.6%; *p*=0.33), nor the rates of RAO (4.3% *versus* 2.5%; *p*=0.17). The use of nitroglycerin at the end of the procedure did not reduce the incidence of RAO in women (2.8% *versus* 3.9%; *p*=0.37) (Table 2).

## DISCUSSION

This study evaluated the effect of nitroglycerin in women undergoing TRA catheterization and showed no reduction in RAS and RAO rates with the use of the medication.

Radial artery spasm is still a major limiting factor for the adoption of TRA in many centers, and may occur in up to 24% of procedures.<sup>11</sup> The lack of a single definition of RAS contributes to the great variability in the incidence described in the literature. The only objective method for measuring RAS, the use of an automatic pull-back device to remove the introducer, showed a high correlation with the presence of severe pain described by the patient during catheterization.<sup>9</sup> Therefore, the adoption of a numerical scale of pain in this analysis is the best clinical alternative for defining RAS.

Evaluation of the size of the radial artery demonstrated that female sex is a predictor of arteries of smaller caliber.<sup>12,13</sup> The use of the pain criterion, despite being the most appropriate, may lead to a greater manifestation of pain in patients with arteries of caliber smaller than the material used, which may explain the higher incidence of RAS in women. The presence of circulating estrogen can also attenuate the effect of nitroglycerin, since estrogen has an important vasodilating role mediated by endogenous release of nitric oxide, normally maintaining a reduced vascular tone, with little response to the application of external nitrates.<sup>14</sup>

**Table 2.** Effect of nitroglycerin on the incidence of radial artery spasm and occlusion in women

|           | Start of procedure       |                    |         | End of procedure         |                    |         |
|-----------|--------------------------|--------------------|---------|--------------------------|--------------------|---------|
|           | Nitroglycerin<br>(n=374) | Placebo<br>(n=399) | p value | Nitroglycerin<br>(n=394) | Placebo<br>(n=380) | p value |
| Spasm     | 74 (19.7)                | 90 (22.6)          | 0.33    | -                        | -                  | -       |
| Occlusion | 16 (4.3)                 | 10 (2.5)           | 0.17    | 11 (2.8)                 | 15 (3.9)           | 0.37    |

Results expressed as n [%].

Nitroglycerin is the vasodilator drug most often used in Brazil, and the second worldwide is verapamil, a calcium channel blocker.<sup>11</sup> Both drugs have already been tested in previous studies. When evaluated more objectively, measuring the reduction in access route modifications, verapamil did not reduce conversion rates.<sup>15</sup> Since it is a rare event, the reduction in conversions to other accesses was not one of the objectives of this study, and it actually had a low occurrence not affected by the use of nitroglycerin.

The occurrence of RAO after the procedure is currently considered a thrombotic phenomenon, resulting from the activation of the coagulation cascade due to trauma to the endothelium during catheterization.<sup>16</sup> The presence of RAS could increase the endothelial damage caused by the introducer or the manipulation of the catheters.<sup>17</sup> The use of vasodilators can improve the caliber ratio between the material used and the artery, a well-established predictor of RAO.<sup>18</sup> The use of nitroglycerin at the end of the procedure was suggested to reduce RAO, for facilitating patent hemostasis.<sup>7</sup> In this analysis, the use of nitroglycerin was not beneficial in women. The application of a short hemostasis protocol with low compression pressure probably removed any additional benefit from using the medication.

Despite the large sample, some limitations must be acknowledged. This was a *post hoc* analysis of a randomized trial, which did not predict stratification by sex. Although the analysis of female patients is well balanced between the group that received the medication and the group that received the placebo, the conclusions of this analysis must be interpreted with caution, preferably as generators of hypotheses for new studies. Another important limitation is that the study was carried out in centers with a high volume of TRA catheterizations, with a well-established minimum-pressure hemostasis protocol. Different outcomes are possible in centers of varying expertise. Additionally, the application of TRA-related best practices has led to low incidences of RAS and RAO. However, considering the low difference among groups, it is unlikely that a larger sample would show difference in results. The choice of a clinical criterion for the definition of RAS may lead to an increased incidence of diagnosis, due to the confusion generated by anatomical alterations, but it is expected that these alterations have a homogeneous distribution, due to the randomization process.

## CONCLUSION

Radial artery spasm and occlusion are more frequent in women undergoing catheterization via transradial access. The use of nitroglycerin does not have a beneficial effect in reducing these incidences, regardless of the time of use. Based on the data from this analysis, the use of prophylactic nitroglycerin can be dispensed with, even in women.

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None.

## CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

## CONTRIBUTION OF AUTHORS

Conception and design of the study: RLS, TRWS, PBA and JRCJ; data collection: RLS, RMJ, PBA, TF, VCPJ and RZA; data interpretation: RLS and TRWS; text writing: RLS; approval of the final version to be published: RLS, TRWS, RMJ, PBA, TF, VCPJ, RZA, AGMS, FF and JRCJ.

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