



Post-procedural/pre-hemostasis intra-arterial nitroglycerin after transradial catheterization: A gender based analysis ^{☆,☆☆,★}



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ABSTRACT

Background: We analyzed the effect of nitroglycerin on radial artery occlusion (RAO) in women undergoing transradial catheterization.

Methods: A total of 1706 patients undergoing transradial catheterization were randomized to receive either 500 µg intra-arterial nitroglycerin or placebo at the end of the radial procedure. We explored the gender-based analysis between women (n = 539) and men (n = 1167). The primary outcome was the incidence of RAO as confirmed by absence of antegrade flow at one day after the transradial procedure evaluated by duplex ultrasound of the radial artery.

Results: The use of nitroglycerin, as compared with placebo, did not significantly reduce the risk of RAO in women patients [odds ratio, 0.69; 95% confidence interval (CI), 0.38 to 1.26; P = 0.147]. The risk of RAO was higher in women age <60 years as compared with women age ≥60 years [5.6% vs. 3.5%; odds ratio, 2.16; 95% CI, 1.18 to 3.94; P = 0.008]. In women age <60 years (n = 237), both counter puncture technique and a duration of hemostasis ≥4 h were associated with a similar enhanced risk of developing RAO (odds ratio, 3.51; 95% CI, 1.59 to 7.72; P < 0.001).

Conclusions: The administration of nitroglycerin at the end of a transradial catheterization in women did not reduce the risk of RAO as determined by ultrasound one day after the radial procedure. Age <60 years was associated with a higher risk of RAO compared with age ≥60 years in women. Further strategies to reduce RAO in women are needed.

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1. Introduction

The benefit of transradial approach (TRA) compared with transfemoral approach has recently been confirmed in women undergoing cardiac catheterization or percutaneous coronary intervention (PCI) [1]. Women undergoing a transradial catheterization potentially present some unique challenges compared to men and it may be due to smaller radial artery diameters [2], and different vasodilation response of the endothelium associated with different hormonal states in women [3]; therefore, the risk-treatment paradox seen with respect to the underuse of TRA in women [4] may be explained by the higher rates of radial artery spasm and occlusion leading to procedural failure.

Currently, there are no data reporting the incidence of radial artery occlusion (RAO) specifically in women while RAO itself is one of the

remaining major challenges in TRA that can occur in up to 9.9% of patients undergoing transradial catheterization [5]. Our recent study suggested a protective effect against RAO from the addition of nitroglycerin to the artery just prior to sheath removal in patients undergoing transradial catheterization [5]. Using the data from this study, a gender-based analysis of the patients was undertaken. We hypothesized that women would be especially benefited from this approach but that this benefit would be attenuated by age as a reflection of changing influences of female hormonal state.

2. Methods

2.1. Patient selection and study design

The design of the original study has been previously reported [5]. In brief, the previous study was a multicenter, prospective, randomized, placebo-controlled trial in which 1706 patients who underwent transradial catheterization in three experienced radial centers were randomized to receive either 500 µg nitroglycerin (n = 853) or placebo/

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Table 1
Baseline clinical characteristics of the two individual subgroups.

Variables	Female Subgroup (N = 539)	Male Subgroup (N = 1167)	P Value
Age, years	60.61 ± 9.75	58.64 ± 10.59	<0.001
Age ≥60 years, N (%)	302 (56%)	558 (48%)	0.002
Body mass index, kg/m ²	26.35 (15–45)	25.64 (16–50)	<0.001
Diabetes mellitus, N (%)	153 (28%)	260 (22%)	0.006
Acute coronary syndrome, N (%)	127 (23%)	359 (31%)	0.002
Glycoprotein IIb/IIIa inhibitor use, N (%)	1 (0.1%)	2 (0.1%)	1.000
Procedure, N (%)			
Coronary angiography	357 (66.2%)	668 (57.2%)	0.002
PCI	181 (33.5%)	496 (42.5%)	
Others	1 (0.18%)	3 (0.25%)	

Continuous data are presented as mean ± standard deviation or median (minimum–maximum). PCI = percutaneous coronary intervention.

saline (n = 853), given intra-arterially through the sheath at the end of the transradial procedure. The sheath was then removed and a hemostatic compression device applied immediately after total sheath removal with patent hemostasis attempted in all patients per protocol. Patent hemostasis techniques were used by titrating the pressure applied by the hemostatic device used. Each center used its standard protocol for patent hemostasis that varied by commercial device used while maintaining the ideal goal of preserving perfusion down the radial artery during the hemostasis process. There are three devices used for hemostasis including TR-Band (Terumo Corporation, Japan) in 77% patients, with SteptyTMP (Nichiban Company, Japan) and Finale (Merit Medical EMEA, Maastricht, The Netherlands) used in the remaining.

One day after the transradial catheterization, all patients underwent color duplex ultrasound studies of the access forearm by dedicated vascular ultrasonographers who were blinded to the treatment assignment. The absence or presence of an antegrade flow in radial artery was recorded while compressing the ulnar artery. The diameter of radial artery of the access forearm was recorded. All patients received 50–100 IU/kg of unfractionated heparin, administered intravenously or intra-arterially after sheath insertion. All sheaths used were hydrophilic coated.

The gender-based analysis was performed by comparing the clinical and procedural characteristics between female and male patients, as well as the diameter of radial artery. An age-subgroup analysis for women was performed and classified into <60 and ≥60 years. We used 60 years as a cut-off for the age sub-group because at this age the estrogen has begun to reach its plateau level in women (3). The study was approved by the institutional review committee of all participating hospitals and each patient provided a written informed consent.

2.2. Study end-points and definitions

The primary outcome of the study was the incidence of RAO in women at one day after the procedure as confirmed by absence of antegrade flow of the radial artery in vascular high-resolution ultrasound.

Demographic data including age, body mass index, history of diabetes mellitus, and acute coronary syndrome (ACS) were compared between women and men. Procedural data including technique of puncture, number of puncture attempts, procedural time, occurrence of RAS, and duration of hemostasis were also compared.

Procedural time was calculated from local anesthetic injection to last catheter removal. Multiple puncture was defined as multiple skin puncture attempt with positive blood return. Repeated radial procedure was defined as repeated transradial catheterization using the same access. Severe RAS was defined as severe local pain and discomfort during catheter movement compelling the operator to stop the procedure and crossover to the other route [6]. Hematoma formation was assessed using the EASY bleeding scale [7].

2.3. Statistical analysis

Continuous variables are presented as mean ± standard deviation (normally distributed) or median (range) for continuous variables not fitting a normal distribution. Comparisons between groups were performed using Pearson chi-square test or Fisher's exact test for categorical variables and the un-paired two-tailed *t*-test or Mann–Whitney *U*-test for numerical variables. Due to the low rate of events, odds ratios (OR) assessing the association between gender and RAO were not adjusted; therefore, the ORs measured were used to determine the odds of several variables in women patient whom are at risk for having RAO. A 2-sided P value <0.05 was used for statistical significant. All statistic computations were performed using PASW SPSS 18.

3. Results

3.1. Baseline clinical and procedural characteristics

Compared with men, women patients were older, and had higher incidence of diabetes mellitus and lower incidence of ACS. The median body mass index was higher in women compared to men ($P < 0.001$). Baseline characteristics are seen in Table 1.

Most of women patients had their first radial procedure (84%), received anterior puncture technique (74.7%) and intravenous heparin administration (93%). Earlier hemostasis (≤4 h) was achieved more in women than men ($P < 0.001$). Procedural characteristics are shown in Table 2.

3.2. Study outcomes

The incidence of the primary outcome examined one day after the procedure by Doppler ultrasound was similar between women and men (8.7% vs. 9.8%, $P = 0.457$), whereas women had smaller radial artery diameter than men (Table 3). Compared with placebo, the administration of nitroglycerin in women reduced the primary outcome by 31%, which did not reach statistical significance (Fig. 1).

Furthermore, in women, both counter puncture technique and duration of hemostasis >4 h were associated with a similarly increased risk of having RAO (OR 3.90; 95% CI, 2.14 to 7.11; $P < 0.001$). When examined by age, women aged <60 years, as compared with age ≥60 years, received more counter puncture technique, longer duration of hemostasis, lower heparin dose and shorter procedural time (Table 4). Moreover, the incidence of the primary outcome in women age <60 years was significantly higher than women age ≥60 years (5.6% vs. 3.5%; OR 2.16; 95% CI, 1.18 to 3.94; $P = 0.008$) (Figs. 1 and 2). In women age <60 years, both counter puncture technique and duration of hemostasis ≥4 h were associated with an increased risk of RAO (OR 3.51; 95% CI, 1.59 to 7.72; $P < 0.001$) (Fig. 3).

4. Discussion

This is the first study investigating the effect of post-procedural nitroglycerin on RAO in women undergoing transradial catheterization.

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