# Comparision of pain levels of transradial versus transfemoral coronary catheterization: a prospective and randomized study

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## Abstract

**Objective:** The aim of the present study was to assess access site pain levels of patients undergoing coronary catheterization via transradial route.
**Methods:** We performed a prospective and randomized study in which 408 patients underwent coronary angiography (CAG) and/or percutaneous coronary intervention (PCI) via transradial approach (TRA) and 428 patients underwent CAG and/or PCI via transfemoral approach (TFA). Pain levels of patients were assessed with Visual Analog Scale (VAS) after catheterization and at 30 days. Student-t, Mann-Whitney U and chi-square tests were used for statistical analysis.
**Results:** Patients in the TRA group showed higher VAS scores than those in TFA group after catheterization [CAG alone, 3 (2-5) vs. 1 (1-3), p<0.0001; PCI, 4 (2-6) vs. 2 (1-3), p<0.0001, respectively]. One month later, patients in TRA group also showed higher VAS scores than those in TFA group [CAG alone, 1 (0-1) vs. 0 (0-1), p<0.0001; PCI, 1 (0-2) vs. 0 (0-1), p<0.0001, respectively]. By the ROC analysis in TRA group, a level of BMI <24.3 kg/m$^2$ predicted unacceptable pain with a 87.3% sensitivity and 91.6% specificity [area under curve (AUC): 0.875, 95% CI: 0.839-0.906, p<0.0001], while a wrist circumference <16.7 cm predicted unacceptable pain with 84.6% sensitivity and 89.8% specificity (AUC: 0.900, 95% CI: 0.867-0.928, p<0.0001).
**Conclusion:** The current study suggests that a radial approach for CAG and PCI in patients with a low BMI and small wrist circumference may cause more access site pain as compared with a femoral approach. *(Anadolu Kardiyol Derg 2014; 14: 140-6)*
**Key words:** Transradial approach, body mass index, wrist circumference, pain

## Introduction

Coronary angiography and angioplasty are usually performed via the transfemoral approach (TFA). This approach is widely used and a convenient method for the operator in many ways (1). Because of patient discomfort, bleeding complications at the vascular access site and the necessity for prolonged follow-up and bed rest in the TFA (2-4), other approaches to reduce complications and improve quality of life for patients in the diagnostic and interventional procedures were searched. The radial approach appears as a safe method and multiple randomized clinical trials and reports have confirmed its applicability and potential advantages over the TFA in elective (5, 6) and acute (7-11) procedures with excellent success rates and very low complication rates of transradial approach (TRA). In addition, TRA is associated with reduced procedural discomfort of the patients mostly due to prolonged bed rest and vascular compression (12, 13). However, there is much less data regarding the pain at the vascular access site associated with TRA and TFA. Thus, the purpose of this prospective and randomized study was to evaluate pain level with the use of visual analog scale (VAS) at the vascular access site during and after cardiac catheterization in a single center with extensive and well-established experience in both TRA and TFA.

## Methods

### Study design

This study was based on a single-centered prospective randomized study design.

***Summary of the study were presented as posters at the 8th cardiology and cardiovascular surgery news congress.***
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**Study population**

This study was carried out in the cardiology department of our hospital between March 2011 and November 2011. 987 consecutive patients admitted to the coronary angiography laboratory at our institution for coronary angiography with the suspicion of coronary artery disease (CAD) were screened and 873 eligible patients were randomized either to TRA or to TFA. Cardiogenic shock, acute ST-elevation myocardial infarction, history of coronary artery bypass surgery, previous ipsilateral transradial approach, Raynaud's syndrome, simultaneous right heart catheterization, necessity for a preprocedural implantation of a transient pacemaker, chronic renal insufficiency (creatinine >2.0 mg/dL) with the potential necessity of using the radial artery as a native fistula in the future, hemodialysis patients with an arteriovenous fistula, absence of an experienced operator, patient refusal and patients age over 75 years were considered as exclusion criteria. Because there may be some difficulties with the use of VAS among the elderly, we excluded patients over 75 years (14). The protocol was approved by the Local Research Ethics Committe and written informed consent was obtained from each patient.

**Study protocol**

Of all 873 eligible patients, 436 patients were randomized to TRA group and 437 patients were randomized to TFA group. Randomization was carried out using a concealed computer-generated random sequence on an intention-to-treat basis. The randomization list was managed by the nursing staff who informed the interventional cardiologist of the assigned approach just before the procedure. The person responsible for patient registration and randomization was not in any way involved in the treatment of the patient. 28 patients from TRA group and 9 patients from TFA group were excluded after randomization. The most common reasons for exclusion were patient withdrawal (25 patients in TRA group and 6 patients in TFA group) and both unfavorable radial artery anatomy and Leriche sydrome (3 patients in both groups), which were later completed via right brachical artery. All of the transradial or transfemoral crossovers were subsequently completed via other approach during the same procedure.

Baseline clinical, demographic and procedural data of the study population was collected prospectively by well-trained nursing personel. Patients' levels of pain were assessed by VAS scale. VAS assessments were performed before discharge in patients who only underwent coronary angiography and 24 hour later in those who underwent PCI. All patients were asked to come back one month later for the reevaluation of pain level according to the same scale.

**Study variables**

**Baseline clinical, demographic and procedural variables**

Clinical data of the study population was collected prospectively by in 2 main categories: (1) patients demographics including age, gender, height, weight, body mass index (BMI), risk factors for coronary artery disease such as diabetes mellitus (DM), hypertension (HT), smoking, hyperlipidemia and family history of coronary artery disease, previous myocardial infarction and/or percutaneous coronary intervention (PCI) and right wrist circumference. BMI was calculated as weight in kilograms divided by the square of height in meters. Right wrist circumference was measured 2 cm above the processus styloideus (2). Procedural parameters including level of pain (measured by VAS score), sheath introduction time, total procedural time, total amount of contrast used, mobilization time, hospital length of stay, use of fractional flow reserve (FFR) or intravascular ultrasound (IVUS), procedural failure of coronary angiography or PCI, use of aspirin, clopidogrel, tirofiban and complications such as catheter induced spasm, hematoma, pseudoaneurysm, bleeding, arteriovenous fistula, transient ischemic attack, cerebrovascular event and mortality. Patients' levels of pain were measured by VAS. Bleeding was defined according to the criteria of the thrombolysis in myocardial infarction trial (TIMI); major bleeding was defined as a decrease in the hemoglobin basal level of 5 g/dL, intracranial hemorrhage or cardiac tamponade. Hematoma was defined as >5 cm (15).

**Radial coronary angiography and coronary intervention**

All transradial procedures were performed by 2 interventional cardiologists who have performed at least 400 transradial catheterizations per year before participation and to have extensive experience performing transfemoral procedures. Any low volume interventional cardiologist (<400 transradial catheterizations per year and/or in a learning curve) was not allowed to take part in the study. All patients were sedated with an oral dose of 7.5 mg diazepam one hour before the procedure.

Allen test was performed before catheterization of the right radial artery. If normal, the right radial artery was accessed after local administration of 1-2 mL of lidocaine with a 21 g needle over which a hydrophilic 0.025" wire (Terumo, Japan) was advanced. Upon removal of the needle, a non-hydrophilic 5-F sheath with a length of 10 cm (Terumo, Japan) was placed over the guidewire and 3-4 mg of verapamil, 5000 iu of UFH and 250 µg of nitroglycerine were injected directly into the radial artery through the sheath in the absence of contrandications. Normally, a single 5-F Tiger catheter (Terumo) dedicated for cannulation of both left and right coronary arteries was used for diagnostic angiography. If coronary angioplasty was indicated, it was performed immediately after the diagnostic procedure and the 5-F sheath was replaced by a non-hydrophilic 6-F sheath with a length of 10 cm. We used 6-F Judkins left or right guiding catheter (Boston Scientfic) for PCI. We also used the same 6-F catheter for bifurcational lesions as suggested by Lim et al. (16). After completion of the procedure, the sheath was immediately removed and hemostasis was achieved with a Band (Terumo, transradial Band) for one hour. All of the transradial or transfemoral failures were subsequently completed via other approach during the same procedure.

**Femoral coronary angiography and coronary intervention**

The right femoral artery was punctured with the Seldinger technique using a 18 g needle after local administration of 15-20 cc of lidocaine. A J-wire was advanced up into the aorta and a 6-F sheath with a length of 18 cm (Cordis) was introduced in all cases; however, in case of a true bifurcational lesion, it was replaced with a 7-F sheath with a length of 18 cm (Cordis), allowing the use of a 7-F guiding catheter for ''kissing technique''. We used 6-F Judkins right and left catheters (Boston Scientific) for diagnositic angiography and 7-F Judkins (Boston Scientific), EBU (Medtronic) or Amplatz (Boston Scientific) guiding catheters for bifurcational lesions. After the procedure, sheath was removed and hemostasis was obtained by manual compression for approximately 15 minutes. Patients were asked to lie flat for 2 hours and then sit up at 30° for 4 hours before walking.

**Visual analog scale**

Pain levels of the patients were evaluated by VAS. This is a 10 cm vertical line with 'no pain' at the bottom and 'worst pain imaginable' at the top. All patients were asked to rate their pain by using a VAS scale. The far-left end of the line represents total absence of pain, while the extreme right represents unbearable pain or 'the worst pain imaginable'. The patient marks on this line the point which best represents his or her perception of the pain level during. The score is determined by the distance in centimeters from the starting point on the left end of the line up to the point marked by the patient. Operators reported the presence of spasm on the basis of a questionnaire addressing the following five signs: persistent forearm pain, pain only during catheter manipulation, pain response to introducer insertion or retrieval, difficult catheter manipulation after being "trapped" by the radial artery and augmented resistance to sheath retrieval. Radial artery spasm (RAS) was considered to be indicated by the presence of at least 2 of these 5 signs.

**Statistical analysis**

Statistical analysis was performed using SPSS version 17 (SPSS, USA) and MedCalc version 12 softwares (MedCalc software, Belgium). The Kolmogorov-Smirnov test was used to evaluate whether the variables were normally distributed. Continuous variables were presented as means±SD or median with interquartile range (IQR) and categorical variables as frequency and percentage. Categorical data were analysed using chi-square test or Fisher's exact test where appropriate. Continuous data were analysed by Student's t-test for normally distributed variables and Mann-Whitney U test for non-normally distributed variables. The cutoff value of BMI and wrist circumference for predicting unacceptable pain (>5 score according to VAS) with corresponding sensitivity and specificity was estimated through the receiver operating characteristic (ROC) curve analysis. All p values were two-tailed, and values of less than 0.05 were considered to indicate statistical significance.

## Results

**Baseline characteristics of the study population**

Baseline demographic and clinical characterisitcs of the study groups are shown in Table 1. A total of 836 patients included in the study. TFA was performed in 428 patients and TRA was performed in 408 patients. PCI was carried out in 134 patients in TFA group, while it was carried out in 124 patients in TRA group. The mean age of the study population was 60.1 years and 54.3% were men. Patient age, gender, height, weight, BMI, wrist circumference, HT, DM, hypercholesterolemia, smoking, history of PCI and/or myocardial infarction, use of aspirin, clopidogrel, and tirofiban were similar between groups.

**Visual analog scale**

VAS scores of the study population are demonstrated in Figure 1. Patients who underwent coronary angiography alone in TRA group showed higher VAS scores than those in TFA group [3 (2-5) vs. 1 (1-3), p<0.0001]. The VAS scores after PCI alone were also higher in TRA group compared with TFA group [4 (2-6) vs. 2 (1-3), p<0.0001]. One month later, although there was not any patient having VAS score above moderate level, patients who underwent coronary angiography alone in TRA group showed higher VAS scores than those in TFA group [1 (0-1) vs. 0 (0-1), p<0.0001]. In addition, patients who underwent PCI alone in TRA group had also higher VAS scores than those in TFA group at 30 days [1 (0-2) vs. 0 (0-1), p<0.0001]. By the ROC analysis, a level of BMI <24.3 kg/m$^2$ predicted unacceptable pain with a 87.3% sensitivity and 91.6% specificity [(area under curve (AUC): 0.875, 95% CI: 0.839-0.906, p<0.0001)], while a wrist circumference <16.7 cm predicted unacceptable pain with 84.6% sensitivity and 89.8% specificity (AUC: 0.900, 95% CI: 0.867-0.928, p<0.0001) in TRA group after coronary angiography or PCI (Fig. 2). In contrast, it was found that patients who had a BMI higher than 37 kg/m$^2$ in TFA group had higher VAS scores in comparision to those in TRA group (4.6±2 vs. 1.6±1.9 p=0.002).

**Procedural characteristics and complications**

Data for procedural characteristics and complications of the study population are presented in Table 2. Sheath introduction time, total procedural time and contrast amount used were higher in TRA group compared to TFA group. Whereas, TRA were associated a shorter mobilization time and length of hospital stay compared to TFA. There were 87 catheter induced spasms in the TRA group. Here were negative correlations between wrist circumference and RAS; and between BMI and RAS (r=-0.732, p<0.0001 and r=-0.685, p<0.0001, respectively).

The rate of access site crossover was tended to be higher with TRA in comparision to TFA. There were 21 cross-over patients in TRA group (4 patients with inability to puncture radial artery, 9 patients with radial artery loop or tortuosity, 3 patients with difficulty to advance the guiding catheter to ascending aorta, 2 patients with subclavian artery tortuosity, 3 patients with

**Table 1. Baseline characteristics of the study population**

| Variables | TRA group (n=408) | TFA group (n=428) | *P |
|---|---|---|---|
| Age, years | 59.6±8.4 | 60.3±8.4 | 0.24 |
| Women/men | 222/186 | 234/194 | 0.94 |
| Height, cm | 168.7±7.3 | 167.4±6.7 | 0.42 |
| Weight, kg | 79.5±13.0 | 78.3±14.0 | 0.20 |
| BMI, kg/m$^2$ | 28.3±1.5 | 28±5 | 0.27 |
| Wrist diameter, cm | 18.9±2.6 | 19.0±2.1 | 0.51 |
| Diabetes, n (%) | 74 (18.1) | 82 (19.2) | 0.70 |
| Hypertension, n (%) | 142 (33.2) | 164 (40.2) | 0.29 |
| Smoking, n (%) | 140 (34.3) | 124 (29) | 0.09 |
| History of CAD, n (%) | 90 (22) | 96 (22.4) | 0.89 |
| History of PCI, n (%) | 62 (15.2) | 68 (16) | 0.78 |
| ASA use, n (%) | 80 (19.6) | 86 (20) | 0.86 |
| Clopidogrel use, n (%) | 18 (4.4) | 20 (4.7) | 0.98 |
| Tirofiban use, n (%) | 22 (5.4) | 20 (4.7) | 0.87 |

Data are presented as mean±SD and number (percentage)
*Student's t-test and chi-square test
ASA - acetyl-salicylic acid; BMI - body mass index; CAD - coronary artery disease; PCI - percutaneous coronary intervention; TFA - transfemoral approach; TRA - transradial approach

**Table 2. Procedural characteristics and complications of the study groups**

| Variables | TRA group (n=408) | TFA group (n=428) | *P |
|---|---|---|---|
| PCI, n (%) | 124 (30.4) | 134 (31.3) | 0.77 |
| FFR and IVUS use, n (%) | 10 (2.5) | 12 (2.8) | 0.91 |
| Sheath introduction time, min | 2.6±2.0 | 1.5±0.4 | <0.0001 |
| Total procedural time, min | 42±15 | 39.4±16.0 | 0.01 |
| Contrast amount, mL | 127±12 | 122±17 | <0.0001 |
| Mobilization time, hours | 4.1±2.6 | 12.0±2.4 | <0.0001 |
| Hospital length of stay, hours | 8.3±4.5 | 24.4±7.0 | <0.0001 |
| Access site crossovers, n (%) | 21 (5.1) | 10 (2.3) | 0.04 |
| Catheter induced spasm, n (%) | 87 (21.3) | - | - |
| Hematoma, n (%) | 5 (1.2) | 16 (3.7) | 0.03 |
| Pseudoaneurysm, n (%) | 1 (0.2) | 8 (1.9) | 0.03 |
| Major bleeding, n (%) | 0 (0) | 1 (0.2) | 0.33 |
| Arteriovenous fistula, n (%) | 1 (0.2) | 7 (1.6) | 0.04 |
| TIA, n (%) | 3 (0.7) | 2 (0.5) | 0.61 |
| CVE, n (%) | 0 (0) | 1 (0.2) | 0.33 |
| Mortality, n (%) | 0 (0) | 1 (0.2) | 0.33 |

Data are presented as mean±SD and number (percentage)
*Student's t-test and chi-square test
ASA - acetyl-salicylic acid; BMI - body mass index; CAD - coronary artery disease; CAG - coronary angiography; CVE - cerebrovascular event; FFR - fractional flow reserve; IVUS - intravascular ultrasound; PCI - percutaneous coronary intervention; TFA - transfemoral approach; TIA - transient ischemic attack; TRA - transradial approach

bifurcation lesion requiring 7F sheath) and 10 patients in TFA group (4 patients with Leriche sydrome and 6 patients with bilateral severe peripheral artery disease).

There was a higher incidence of access site complications in patients randomized to TFA group. The development of hematomas, pseudoaneurysms and arteriovenous fistula were less likely in the TRA group compared with the TFA group. Transient ischemic attack, cerebrovascular event and mortality were similar between groups.

## Discussion

In the present study, we evaluated the level of pain patients experienced after coronary catheterization and again at 30 days by VAS, which is a well-validated and the most widely-used pain measurement tool, and found that the intensity of pain measured by VAS at both assessments were higher in the TRA group. Moreover, the results of the VAS scores were more meaningful when BMI and wrist circumference of the patients were considered. The perception of pain was above moderate level in patients with a BMI lower than 24.3 kg/m$^2$ and a wrist circumference less than 16.7 cm in the TRA group. In addition, the perception of pain in patients with a higher BMI was also different. We found that those with a BMI greater than 37 kg/m$^2$ in TFA group had a higher level of pain as compared to those in TRA group. We think that the reasons which caused those results might be that patients with a higher BMI in TFA group are more likely to have hematomas in the area of procedure and consequently more pain due to more bleeding into soft tissue. On the other hand, patients with a lower BMI in TRA group are more likely to have radial artery spasm and consequently more pain due to the fact that the smaller the BMI and wrist circumference, the smaller the radial artery.

Previous studies showed that the TRA for coronary procedures is a highly safe, effective and comparable technique for both transcatheter diagnostic and therapeutic procedures that yields clinical results similar to transfemoral access (3, 5, 6, 17). Moreover, TRA has several advantages over TFA such as reduced bed rest, shortened hospital length of stay and a reduction in vascular access site complications. In a previous study by Cooper et al. (12), it was showed that TRA leads to impoved quality of life after the catheterization. In that study, back pain was more intense in patients undergoing TFA, but access site pain was not different between two approaches, which is inconsistent with our findings. This may be due to relatively small number of patients included in that study. In an another study evaluating quality of life between TRA and TFA (13), TRA has been shown to be associated with better patient tolerability. In that study, pain level during manual compression was found to be higher in patients undergoing TFA. This may be seem to conflicting with our findings at first, but they assessed pain resulting from manual compression.

RAS is one of the most common access site complications of TRA and it occurs in 10-25% of all cases undergoing transra-

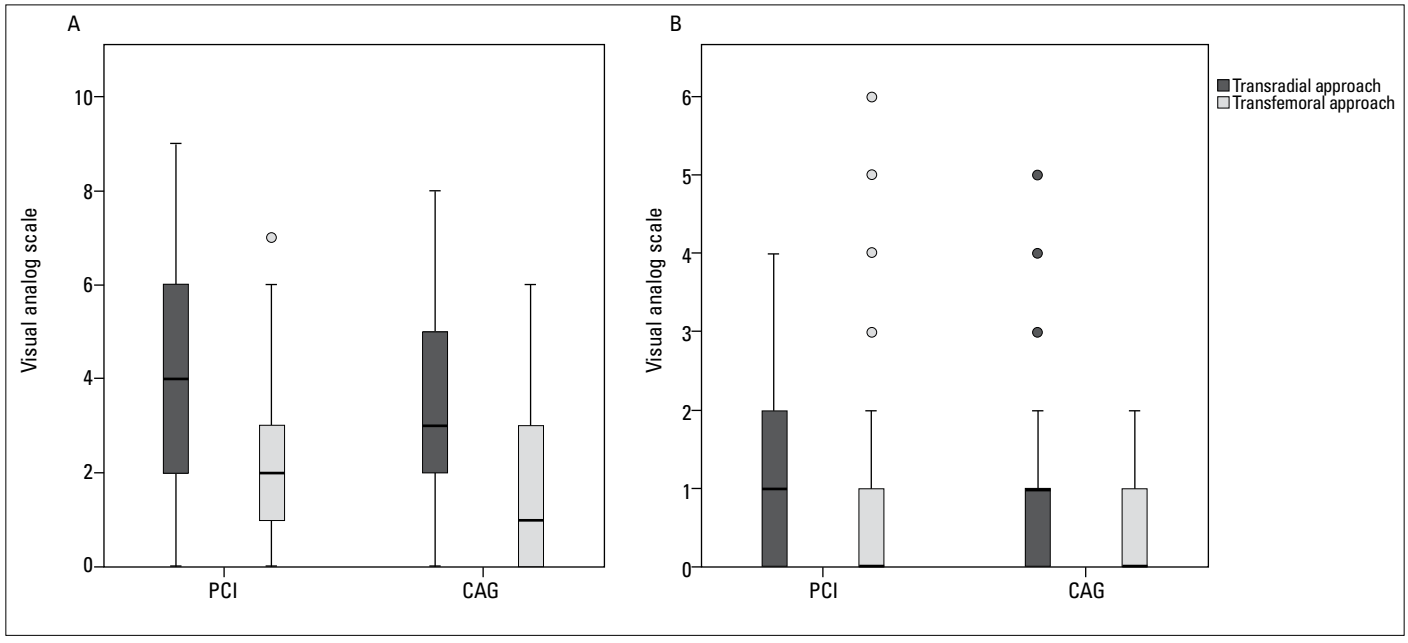


**Figure 1. Box plots of VAS scores of the study groups during catheterization (A) and at 30 days (B)**
CAG - coronary angiograph;, PCI - percutaneous coronary intervention

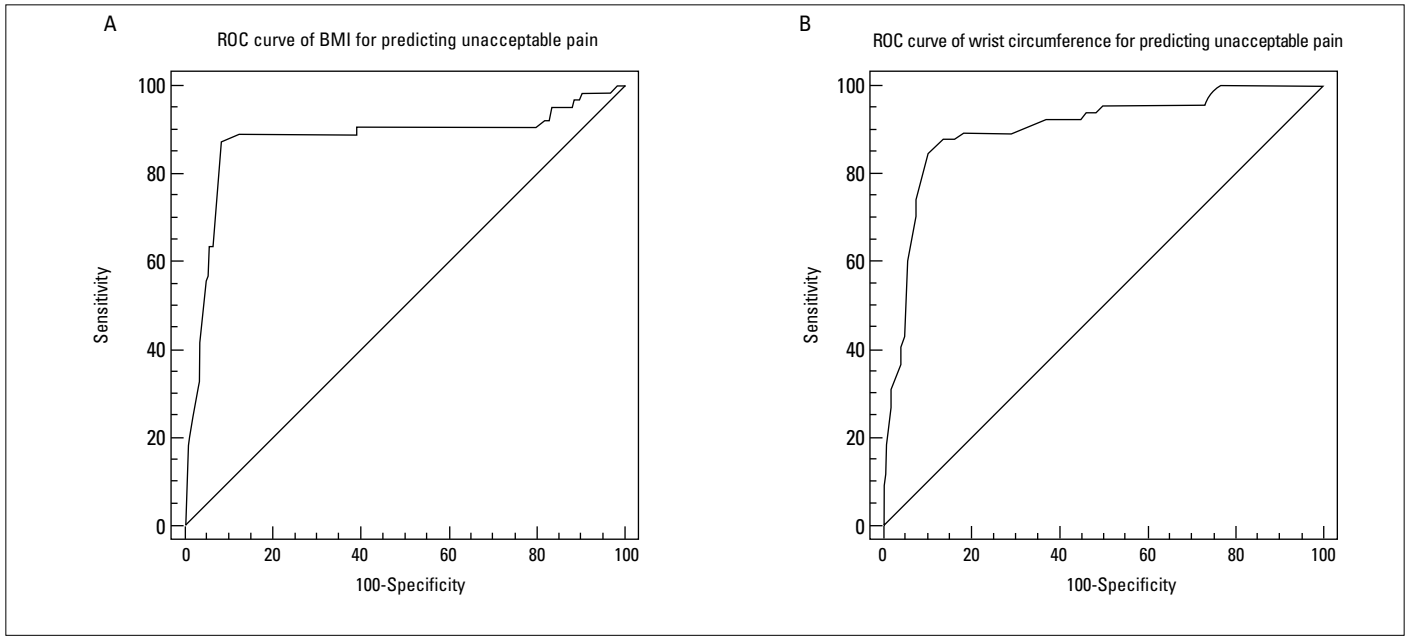


**Figure 2. ROC curve analysis of BMI (AUC: 0.875, 95% CI: 0.839-0.906, p<0.0001) and wrist circumference (AUC: 0.900, 95% CI: 0.867-0.928, p<0.0001) for predicting unacceptable pain**

dial coronary procedures (18, 19). Female sex, diabetes, smoking, sheath to radial artery mismatch and low BMI are considered predisposing factors for radial artery spasm (20). It will be prudent that spasm prevention is more efficient than spasm treatment. Thus, in patients considered high risk for excessive pain and/or RAS such as those who have a lower BMI and small wrist circumference, some further precautions may be needed to prevent excessive pain and/or RAS such as using long hydrophilic sheaths (21), hydrophilic or nonhydrophilic sheatless catheters (22), administering more potent analgesics and sedatives.

TRA nearly abolishes entry site complications in comparison with significantly higher rates in patients undergoing transfemoral catheterization (23). In our study, hematoma, pseudoaneurysm and arteriovenous fistula were more frequent in the TFA group. This finding is not surprising as previous studies and meta-analyses have demonstrated that TRA reduces access site complications compared to TFA (24, 25). Because the radial

artery, in contrast to femoral artery, courses superficially and there are no important venous structures or nerves in its vicinity, access site complications related to femoral approach will be, not very suprisingly, encountered more frequently (26).

**Study limitations**

We recognize that the present study has several limitations. Firstly, neither systematic ultrasound examination of post-procedural radial artery patency in subjects with high VAS scores nor radial artery diameter were not assesed. However, it should have been done even in subjects with a good radial pulse. Longer and hydrophylic radial sheaths were not used in the present study. Diagnosis of RAS was made according to subjective criteria. Lastly, this study is a single center observational study and differences in the radial artery diameter between the races were not considered.

## Conclusion

The current study suggests that TRA for coronary angiography and PCI in patients with a low BMI and small wrist circumference may cause more access-site pain as compared with a TFA. Appropriate precautions to reduce pain is needed to maximize potential benefits offered by TRA.

**Conflict of interest:** None declared.

**Peer-review:** Externally peer-reviewed.

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