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Peripheral Arterial Occlusive Disease

Comparison of Ultrasound Guidance and Conventional Method for Common Femoral Artery Cannulation: A Prospective Study of 939 Patients

Mahmut Tuna Katırcıbaşı, Hakan Güneş, Ahmet Çağrı Aykan, Ekrem Aksu and Sami Özgül

Background: Many techniques, methods and closure devices have been developed in order to reduce vascular complications that occur after coronary and peripheral interventions. The aim of the present study was to identify which method i.e. ultrasound (US) guidance or traditional access technique, is better for common femoral artery cannulation.

Methods: The study included 939 patients, who were assigned to either the US-guided cannulation group (n = 449) or manual technique group (n = 490). The procedure time, first pass success rate, inadvertent venous puncture rate and complications developing within the first 7 days of the procedure were compared between the two groups.

Results: No differences were found between the two groups regarding basic characteristics and antiplatelet and anticoagulant therapy administered during and up to 24 hours before the procedure. Arterial puncture attempts ($p < 0.001$), inadvertent venous entry ($p = 0.02$), and total procedure time ($p = 0.012$) were significantly lower in the US-guided group compared to the manual technique group. Furthermore, the first pass success rate was significantly higher in the US-guided group compared to the manual technique group ($p < 0.001$). The US-guided group had significantly lower pain levels ($p < 0.001$), hematomas ($p < 0.001$) and arteriovenous fistulas ($p = 0.011$) than the manual technique group.

Conclusions: US-guided common femoral artery cannulation yields both higher access rates at first attempt and a shorter access time, and lower pain and complication rates.

Key Words: Common femoral artery cannulation • Traditional palpation • Ultrasound guidance

INTRODUCTION

The common femoral artery (CFA) is the most frequently used vascular access site for diagnostic and therapeutic vascular interventions in coronary and peripheral arterial disease.[1,2] In addition, the femoral artery is currently also used as a first access site for complex procedures such as transaortic aortic valve implantation (TAVI) as well as for the treatment of congenital heart diseases such as patent ductus arteriosus.[3,4] Common complications include local hematoma, retroperitoneal hemorrhage, pseudoaneurysm, arterio-venous fistula, infection, and injury of other local structures.[5,6] These complications are more frequent in women, extremely underweight or overweight individuals, patients with renal insufficiency, and in those receiving anticoagulant or glycoprotein IIb/IIIa inhibitor treatment.[1,6] The access technique and the method used for localization of the entry site both play an important role in the development of these complications. Pseudoaneurysm and arteriovenous fistula formation are more common when the entry site is below the inguinal ligament, whereas the risk of retroperitoneal hemorrhage is higher when

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Department of Cardiology, Medicine Faculty of Sütçü İmam Üniversity, Kahramanmaraş, Turkey.
Corresponding author: Dr. Mahmut Tuna Katırcıbaşı, Department of Cardiology, Medicine Faculty of Sütçü İmam Üniversity, Kahramanmaraş, Turkey. Tel: +90344-300-3338; E-mail: doktortuna@gmail.com

the entry site is above the inguinal ligament.[7,8]

Ultrasound (US) guidance is commonly used for arterial and venous access procedures. Real-time US guidance for central venous cannulation has been shown to reduce complications, the number of attempts, and time to access.[9,10] However, few studies have investigated complications in the 'arterial' diagnostic and therapeutic interventions performed under US guidance. The aim of this prospective study was to evaluate the effectiveness and safety of two-dimensional US versus traditional palpation and fluoroscopy methods for CFA puncture during coronary or peripheral interventions. We assessed whether there were differences in complication rate, number of attempts for arterial cannulation, first pass success rate, inadvertent venous puncture rate, and pain scores between traditional landmark-guided and US-guided CFA puncture.

MATERIAL AND METHODS

The present study was designed as a randomized controlled study. Patients transferred to the catheterization laboratory for diagnostic or therapeutic interventions were consecutively enrolled and successively assigned to the manual entry group or US-guided entry group for femoral arterial cannulation. Manual access and US-guided access was performed by operators with 10 years of experience and who treated > 1000 patients per year for manual or US-guided access.

Study population

A total of 939 patients older than 21 years of age and scheduled to undergo a diagnostic or interventional coronary or peripheral procedure via retrograde femoral arterial with a 6 Fr sheath were enrolled in the study. All enrolled patients gave written informed consent.

A Venue 40 US system (Antares, Siemens Erlangen Germany) with a 9-13-MHz linear transducer was used (Figure 1). The modified Seldinger technique was used for vascular access. All patients received local anesthesia around the femoral artery (usg-2-10). In the manual guided cannulation group, the femoral head was marked under fluoroscopy guidance using a clamp. Similarly, in the US-guided cannulation group, the operators held the US probe in their left hand and an 18-gauge needle in their right hand, so that they could simultaneously manipulate both the US probe and needle (Figure 2).

The number of arterial puncture attempts to place the sheath, time to access and inadvertent venous punctures were recorded by an independent observer. A failed attempt was defined as the need to withdraw the needle and repeat the puncture again. Time to access was defined as the first movement of the table for fluoroscopy or the first application of the US probe until the sheath was successfully inserted. The time spent to prepare the US probe was not included. A 6 Fr sheath was used in all of the patients as vascular sheath size I. Antiplatelet and anticoagulant drug use during or within 24 hours of the procedure was recorded.

A visual analog scale (VAS) was used to assess pain level during the procedure. The VAS was a 10-point scale with 0 indicating no pain and 10 the worst pain imaginable. A nurse or technician (not the operator) recorded the VAS in the catheter laboratory. Manual compression and weight placement were applied upon withdrawal of the sheath. Sheath withdrawal was performed once the

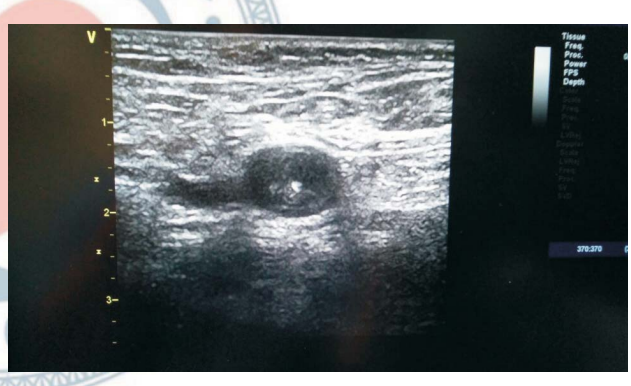

Figure 1. *Ultrasonographic view of common femoral artery.*

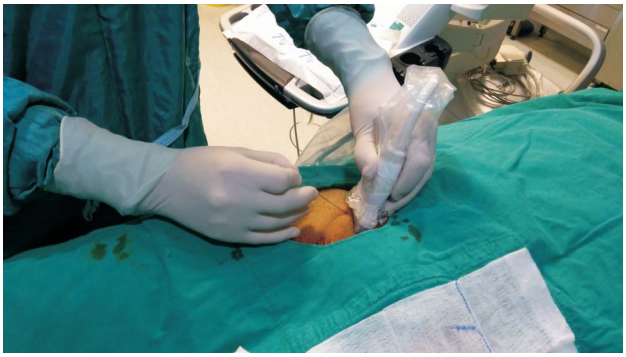

Figure 2. *Demonstration of operation in US group: the operator held the US probe in the left hand and the needle in right hand to cannulation of common femoral artery.*

activated clotted time (ACT) dropped below 180 seconds for those who received fractionated heparin during the coronary or peripheral therapeutic intervention, or within 15 minutes of the procedure for those who only underwent a diagnostic procedure. All of the patients were examined before discharge from the hospital. A follow-up visit (7 days after discharge) with the same operator that performed the procedure was scheduled to identify possible complications. The formation of a pseudoaneurysm, retroperitoneal hemorrhage, arterio-venous fistula, or hematoma larger than 5 cm were recorded as complications.

Statistical analysis

Statistics were performed using SPSS version 15.0. Parametric data are presented as mean and standard deviation, and nonparametric data are presented as frequencies. The parametric demographic parameters were evaluated using the Student's t-test, and the nonparametric parameters were evaluated using the chi-square test. A p-value of 0.05 or less was considered to be statistically significant.

RESULTS

The patients' basic characteristics and antiplatelet and anticoagulant drug use up to 24 hours before or during the procedure were similar in both groups (Table 1). The number of puncture attempts (1.06 ± 0.26 vs. 1.32 ± 0.74; p < 0.001), number of inadvertent venous punctures [8 (1.7%) vs. 26 (5.3%); p = 0.02], and total procedure time (33.3 ± 28.2 seconds vs. 41.3 ± 64.7 seconds; p = 0.012) was significantly lower in the US-guided group compared to the manual group (Table 2). In addition, the first pass success rate was significantly higher in the US-guided group compared to the manual group (success rate N: 402 (84%) vs. 346 (70%); p < 0.001) whereas the number of attempts was significantly lower in the US-guided group (p < 0.001) (Table 3). Interestingly, the VAS score was significantly lower in the US-guided group compared to the manual group (3.27 ± 2.64 vs. 5.60 ± 2.87; p < 0.001).

Hematomas and arterio-venous fistula complications were significantly less frequent in the US-guided group compared to the manual group. One case in each group developed a pseudoaneurysm (Table 2).

DISCUSSION

In this prospective study, we found that femoral access via US guidance during femoral artery cannulation led to fewer venous punctures, shorter access time, fewer attempts, higher first pass success rate and reduced risk of complications such as hematoma and arterio-venous fistula. Furthermore, the pain level was also significantly lower when the procedure was performed under US guidance.

In vascular interventions, the first reports of US gui-

Table 1. Comparisons of USG and manual patients of baseline characteristics

	US (n = 449)	Manual (n = 490)	p
Age (years)	60.3 ± 11.4	59.8 ± 10.6	0.410
Weight (kg)	82.4 ± 14.9	82.2 ± 14.4	0.826
Height (cm)	166.1 ± 8.0	167.0 ± 7.9	0.939
BMI (kg/m^2)	29.2 ± 5.0	29.5 ± 4.8	0.710
Female/male (n)	216/233	233/257	0.801
Hypertension (n, %)	259 (57.6)	278 (56.6)	0.534
Diabetes mellitus (n, %)	175 (38.9)	190 (38.7)	0.574
Hyperlipidemia (n, %)	189 (42.1)	203 (41.3)	0.430
Smoking (n, %)	141 (31.4)	144 (29.3)	0.240
Acetylsalicylic acid (n, %)	121 (26.1)	110 (22.4)	0.05
Clopidogrel (n, %)	90 (20.0)	99 (20.2)	0.645
Unfractionated heparin (n, %)	99 (22.4)	98 (20.0)	0.993
Enoxaparin (n, %)	1 (0.42)	4 (0.8)	0.192
Tirofiban (n, %)	2 (0.4)	7 (1.4)	0.105
Interventional procedure (n, %)	105 (23.5)	90 (18.3)	0.120

Table 2. Comparisons of USG and manual patients of procedural characteristics

	US (n = 449)	Manual (n = 490)	p
Vein puncture (n, %)	8 (1.7)	26 (5.3)	0.002
Number of attempts (n)	1.06 ± 0.26	1.32 ± 0.74	< 0.001
Mean time of insertion (sec)	33.3 ± 28.2	41.3 ± 64.7	0.012
First pass success rate (n, %)	396(84%)	346 (70%)	0.001
VAS pain score	3.27 ± 2.64	5.6 ± 2.87	< 0.001
Complications			
Hematoma (n, %)	6 (1.3)	25 (5.1)	0.001
Arterio-venous fistula (n, %)	1 (0.2)	10 (2.0)	0.011
Pseudoaneurysm (n, %)	1 (0.2)	1 (0.2)	1.000

Table 3. Distribution of the number of attempts

Number of Attempts	1	2	3	4	5
US group (n = 449)	377 (84%)	27 6%	13 (3%)	22 (5%)	9 (2%)
Manual group (n = 490)	343 (70%)	107 (22%)	10 (2%)	10 (2%)	20 (4%)

dance were for central vein catheter insertion. However over the last decade,[10-17] central catheter administration guidelines have changed to recommend US-guidance.[18] Arterial interventions are different from venous access. First, most arteries are palpable in patients leading to withdrawal from US-guided interventions because of the time required and sterilization of the equipment. In addition, there is a natural learning process for US-guided interventions. Nevertheless, due to patient volume and high variability in angiography teams, US-guided arterial interventions are attractive, especially in patients without palpable arteries, since it reduces the duration of the procedure, increases initial success rate, and reduces interference-related complications. Very few randomized trials have compared US-guided arterial cannulation to conventional methods.[18-21] Dudeck et al.[20] reported that femoral artery cannulation with US guidance is simple and easy to learn, and may be useful in obese patients and patients who cannot receive femoral pulses. The Femoral Arterial Access with Ultrasound Trial (FAUST), the largest randomized study to date, did not find a significant difference between fluoroscopy guidance and US guidance for CFA interventions (86.4% vs. 83.3%; p = 0.17).[16] However, the rate of CFA cannulation was higher with US guidance in the patients with high CFA bifurcation. The lack of significant difference in CFA cannulation success was thought to be due to limited training of the operators for US guidance.[16] On the other hand, in the present study, we found a higher initial intervention success rate (83% vs. 46%; p > 0.0001) (first pass success), lower number of attempts (1.3 vs. 3; p < 0.001), fewer false vein interventions (2.4% vs. 15.8%; p < 0.0001) and lower complication rate (3.4% vs. 1.4%; p = 0.04) with US guidance. Taken together, these findings suggest that US might be considered for patients at high risk of intervention problems and possible inguinal complications.

Our study confirmed the results published by Gedikoğlu et al.[22] However, our study included information on antiplatelet and anticoagulant drug use. The low complication rates in Gedikoğlu et al.'s study (no complications in the US-guided group, and 4 patients in the palpation-guided group) could be due to low enrollment (n = 208).

A previous meta-analysis on radial artery cannulation included 4 prospective, randomized controlled trials[18-21] comparing real-time US-guided cannulation with a traditional palpation technique.[23] The use of US to guide radial artery cannulation was associated with a 71% increased likelihood of successful cannulation on the first attempt. However, VAS pain score analysis was not performed in any of these studies. To the best of our knowledge, this study is the first to show a significantly lower VAS pain score in patients who underwent US-guided access. This may be due to the fact that the US guidance group had a higher first pass success rate.

Many physicians may be hesitant to use US guidance during arterial interventions because of the training period and the equipment preparation time. However this study and previous published studies show that arterial interventions with US guidance can be very beneficial to both the operator and the patient, by shortening the time of entry and reducing complications. Moreover, this study also demonstrated that arterial interventions with US guidance led to less pain and therefore may provide higher patient comfort.

This study has several limitations. First, blinding of the operators was only possible for the US examination of the CFA before the puncture and not for other measurements. Therefore, we cannot exclude bias in the measurements of the number of attempts and time to successful vascular access. Second, the duration of US probe preparation was not included in the average intervention time. If the operator rather than a nurse did the preparation, the advantage of the shorter intervention time in the US group in our study might be lost.

CONCLUSIONS

This study showed that US-guided CFA cannulation yielded a significantly higher success rate at the first attempt and also a shorter access time. Based on these

findings, we suggest that both radiologists and other branch specialists who perform arterial cannulation should be trained for vascular imaging with two-dimensional US.

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