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Ultrasound Guidance versus Traditional Approach for Femoral Artery Access in Coronary Angiography

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ABSTRACT

Background: Optimal femoral artery access plays an important role in minimizing complications associated with cardiac catheterization. Suboptimal access can occur with traditional method. Ultrasound guided femoral access can minimize the vascular complications by reducing the attempts to catheterize the artery.

Aim of the Study: This study is conducted to compare the procedural and clinical outcomes of femoral arterial access with ultrasound (US) guidance versus traditional approach.

Patients and Methods: We investigated a total of 50 patients undergoing elective coronary angiography via the femoral artery in Mansoura cardiology department between January 2020 to January 2022 as prospective comparative cross-sectional study.

Results: Successful CFA cannulation occurred in 92.0% of US guided procedures compared with 56% of traditional approach (P <0.05). Time of sheath/ seconds was higher in traditional approach group, median = 120, ranged from 2 to 360 as compared to median=60, ranged from 5 to 300 with statistically significant difference (p value ≤0.05). First pass was higher among ultrasound guidance group, representing 72% as compared to 40% among traditional approach group. Venipuncture was higher among traditional approach group (52%) as compared to 12% among ultrasound guidance group with statistically significant difference (p value ≤0.05). Vascular complications were higher among traditional approach group, representing 40% as compared to only 4% among ultrasound guidance group with statistically significant difference (p value ≤0.05).



Conclusion: Ultrasound guided femoral access reduced time to access, risk of venipunctures, and vascular complications.

Key Words: femoral access, ultrasound, coronary angiography

INTRODUCTION

Procedural and outcomes for patients undergoing coronary angiography and percutaneous coronary intervention (PCI) depend on obtaining safe and adequate vascular access. (1).

Femoral access is used in most cases of mechanical circulatory support, high-risk and coronary chronic total occlusion PCI (2).

Traditional femoral access during coronary angiography has been obtained using anatomic

landmarks along with pulsation and fluoroscopic guidance (3).

Ultrasound-guidance for femoral access has been examined in several studies. FAUST (Femoral Arterial Access with Ultrasound Trial) was the largest prospective, multicenter study that randomized 1,004 patients to ultrasound or fluoroscopic-guided femoral access (4).

The rate of common femoral artery cannulation (primary endpoint) was similar with ultrasound and fluoroscopy; however, ultrasound

guidance significantly increased common femoral artery sheath placements in patients with high common femoral artery bifurcations. Moreover, ultrasound significantly reduced the number of attempts, venipuncture, time to insertion and increased first-pass success. Similarly, ultrasound guidance reduced clinical access complications, a significant decrease in hematomas >5 cm (5). Inadvertent sheath insertion beyond the common FA (CFA) boundaries increases rates of FA access complications (6).

PATIENTS AND METHODS

Patients:

The present study was prospective randomized controlled study was conducted on 50 patients recruited from Cardiac Catheterization Unit-Mansoura Cardiovascular Medicine Department-Specialized Medical Hospital from 2020 to 2022. Subjects of the study were classified into 2 groups; group (1) comprises 25 patients undergoing US-guided femoral approach for coronary angiography and group (2) comprises 25 patients undergoing traditional femoral approach for coronary angiography. Patients underwent 1:1 randomization to either the US-guided approach or the traditional approach. Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Mansoura University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Clinical outcomes were assessed in accordance with the standard protocol, all the included cases in our study were followed up clinically and by US at 1st day ,2nd day & 7th day after the index procedure. a

Inclusion and exclusion criteria:

The inclusion criteria were patients aged ≥ 18 years undergoing elective coronary angiography via the femoral artery. The Exclusion criteria were patients with bleeding diathesis, low platelet count ($< 50\ 000/\text{mm}^3$), international normalized ratio > 1.5 , Cr $> 3.0\text{mg/dl}$ (unless already receiving dialysis), non-palpable femoral pulse, pregnant women and emergent procedure (acute ST-elevation myocardial infarction).

METHODS

- Comparative analysis between two groups of US approach and traditional approach with full history regarding age, gender, occupation, hypertension,

diabetes mellitus, obesity, smoking, CKD, peripheral arterial disease (PAD), drugs (Clopidogrel, Ticagrelor & Heparin) and with full clinical examination focusing on body mass index (BMI), blood pressure and pulse.

- All patients received manual palpation of the anatomic landmarks, anterior superior iliac spine and symphysis pubis.
- For traditional technique, needle insertion was guided under direct palpation of the strongest femoral pulse.
- US-guided femoral arterial puncture with direct visualization was performed using TOSHIBA PLG-805S vascular, Linear, Ultrasound with frequency range 6.0MHz-10.0MHz under complete aseptic technique.
- Femoral angiography in ipsilateral oblique view without cranial or caudal angulation was performed to confirm sheath entry location and assess for any complication.

Outcomes:

The primary end point was successful common femoral artery (CFA) cannulation by femoral angiography. Secondary end points were time to sheath insertion, total number of attempts required for success, first pass success and rate of accidental venipunctures. Secondary safety end points were vascular access complications at 1st, 2nd and 7th day (hematoma ≥ 5 cm, pseudoaneurysm formation, retroperitoneal haematoma, arterial dissection, vessel thrombosis, hemoglobin drop $> 4\text{g/dl}$ or access bleeding requiring blood transfusion).

Statistical analysis and data analysis:

Data were analyzed using the Statistical Package of Social Science (SPSS) program for Windows (Standard version 26). The normality of data was first tested with one-sample Kolmogorov-Smirnov test.

Qualitative data were described using number and percent. Association between categorical variables was tested using Chi-square test while Fisher exact test and Monte Carlo test were used when expected cell count less than 5.

Continuous variables were presented as mean \pm SD (standard deviation) for normally distributed data and median (min-max) for non-normal data. The two groups were compared with Student t test for parametric data and Mann Whitney test for non-parametric data.

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level. The results was considered significant when $p \leq 0.05$. The

smaller the p-value obtained, the more significant are the results.

RESULTS

The present study included 50 patients: 25 patients undergoing US-guided approach for coronary angiography and 25 patients undergoing traditional approach for coronary angiography.

1. Patients’ characteristics:

The mean (SD) age of ultrasound guidance group was 58.12 (8.95) ranged from 34 to 76 years as compared to 61.04 (8.57) ranged from 41 to 77 years among traditional approach group with no statistically significant difference (p value >0.05). Male versus females were 96% versus 4% as compared to 84% versus 16% among ultrasound guidance and traditional approach groups, respectively. Mean (SD) BMI was 23.76(3.88) among ultrasound guidance as compared to 22.12 (2.83) among traditional approach group. There were 68% smokers in ultrasound guidance group as compared to 60% in traditional approach group with no statistically significant difference as observed in table (1).

Regarding medical history, only one case of ultrasound guidance group had renal impairment, 2 cases had peripheral vascular disease and 18 cases had suffered from dyslipidaemia as compared to (0, 5 and 12 cases) traditional approach group, respectively with no statistically significant difference. 40% vs. 24% had history of medications before procedure as observed in table (2).

2- Angiogram analysis:

Successful CFA cannulation occurred in 92.0% of US guided procedures compared with 56% of traditional approach (P <0.05). Femoral dissection occurred cur in 4.0% of traditional approach (P<0.094) as shown in figure (1).

3- Intraprocedural outcomes:

No statistically significant difference was observed between studied groups regarding number of punctures. 76% had one puncture as compared to

64%, 20% for both had 2 punctures and 4% as compared to 12% had 3 punctures among ultrasound guidance and traditional approach groups, respectively. Only 1 case had 4 punctures among traditional approach group. Number of inward needle advancement was higher in traditional approach group, median = 3 ranged from 1 to 12 as compared to median=1 ranged from 1 to 6 with statistically significant difference p value ≤0.05 as observed in table (3).

Time of sheath/ seconds was higher in traditional approach group, median = 120, ranged from 2 to 360 as compared to median=60, ranged from 5 to 300 with statistically significant difference p value ≤0.05.

First pass was higher among ultrasound guidance group, representing 72% as compared to 40% among traditional approach group. Venipuncture was higher among traditional approach group (52%) as compared to 12% among ultrasound guidance group with statistically significant difference, p value ≤0.05 as shown in figure (2).

4- Clinical outcomes:

Vascular complications at 1st & 2nd day were higher among traditional approach group, representing 40% as compared to only 4% among ultrasound guidance group with statistically significant difference, p value ≤0.05. Only one case had evacuated hematoma in ultrasound guidance group as compared to 5 cases in traditional approach group. 4 cases suffered from retroperitoneal hematoma and 1 case with pseudoaneurysm in traditional approach as observed in table (4).

Abnormal findings at 7th day were statistically higher among traditional approach group (P value ≤0.05); 3 cases with hematoma, 8 cases with skin discoloration, 2 cases died and 1 case had hypotension-blood transfusion. Among Ultrasound guidance group, 1 case had hematoma and 3 cases had skin discoloration as observed in table (5).

Table (1): Sociodemographic data among studied groups

Sociodemographic data	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	Test of significance	P value
Age (Years)			t=1.18	0.245
Mean ± SD	58.12± 8.95	61.04± 8.57		
Min-Max	34-76	41-77		
Sex			FET	0.349
Male	24 (96.0%)	21 (84.0%)		
Female	1 (4.0%)	4 (16.0%)		

Sociodemographic data	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	Test of significance	P value
BMI	23.76±3.88	22.12±2.83	t=1.71	0.095
Smoking	17 (68.0%)	15 (60.0%)	$\chi^2=0.347$	0.556

t: Independent t test, χ^2 : Chi square test, FET: Fisher exact test

Table (2): Medical history among studied groups

Medical history	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	Test of significance	P value
Degree of renal impairment	1 (4.0%)	0 (0%)	FET	1.0
Ipsilateral peripheral vascular disease	2 (8.0%)	5 (20.0%)	FET	0.417
Dyslipidaemia	18 (72.0%)	12 (48.0%)	$\chi^2=3.0$	0.083
Type of drugs			MC	0.036*
Clopidogrel	10 (100%)	3 (50.0%)		
Ticagrelor	0 (0%)	2 (33.3%)		
Heparin	0 (0%)	1 (16.7%)		

MC: monte Carlo test

Table (3): Number of puncture and number of inward needle advancement among ultrasound guidance and traditional approach groups

Variables	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	Test of significance	P value
Number of Attempts			Monte Carlo test	0.641
1	19 (76.0%)	16 (64.0%)		
2	5 (20.0%)	5 (20.0%)		
3	1 (4.0%)	3 (12.0%)		
4	0 (0%)	1 (4.0%)		
Number of inward needle advancement Median (Min-Max)	1 (1-6)	3 (1-12)	Z=2.93	0.003*

Z: Mann Whitney test, *significant $p \leq 0.05$

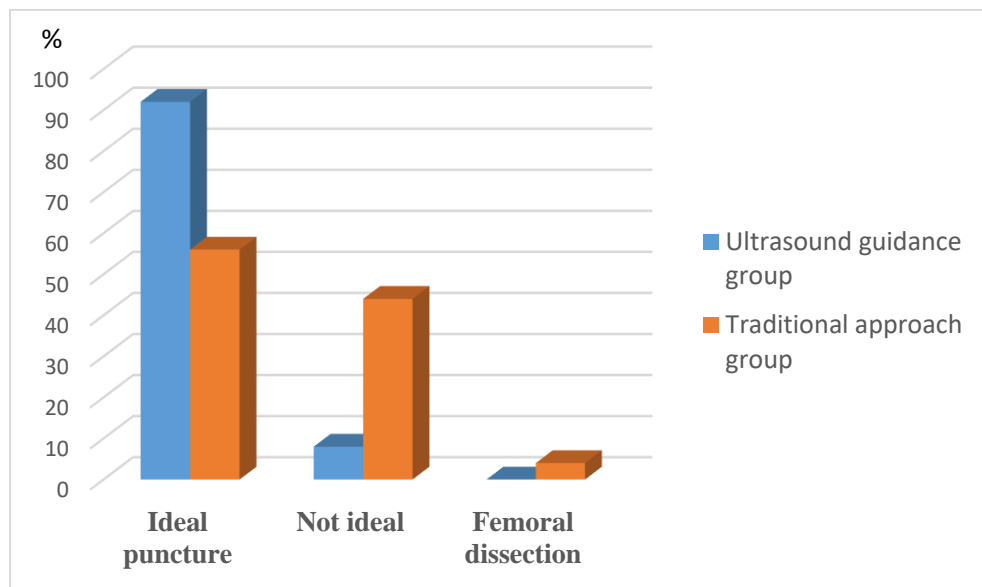
Table (4): Vascular complications at 1st & 2nd day among ultrasound guidance and traditional approach groups

Vascular complications at 1 st & 2 nd day	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	Test of significance	P value
Complications	1 (4.0%)	10 (40.0%)	$\chi^2=9.44$	0.002*
No Complications	24 (96.0%)	15 (60.0%)		
Hematoma \geq 5 cm	1 (4.0%)	5 (12.0%)	Monte Carlo test	0.008*
Retroperitoneal	0 (0%)	4 (16.0%)		
Pseudoaneurysm	0 (0%)	1 (4.0%)		

Table (5): Follow up findings at 7th day among ultrasound guidance and traditional approach groups

Follow up findings at 7th day	Ultrasound guidance group (n=25)	Traditional approach group(n=25)	P value
Normal	21 (84.0%)	11 (44.0%)	$\chi^2=8.68$ P=0.003*
Abnormal	4 (16.0%)	14 (56.0%)	
Hematoma	1 (4.0%)	3 (12.0%)	0.094
Skin discoloration	3 (12.0%)	8 (32.0%)	
Died	0 (0%)	2 (8.0%)	
Hypotension-blood transfusion	0 (0%)	1 (4.0%)	

Abnormal findings= hematoma, discoloration, death , hypotension - blood transfusion



Ideal puncture= successful common femoral artery (CFA) cannulation by femoral angiography

Figure (1): Angiographic result among ultrasound guidance and traditional approach groups.

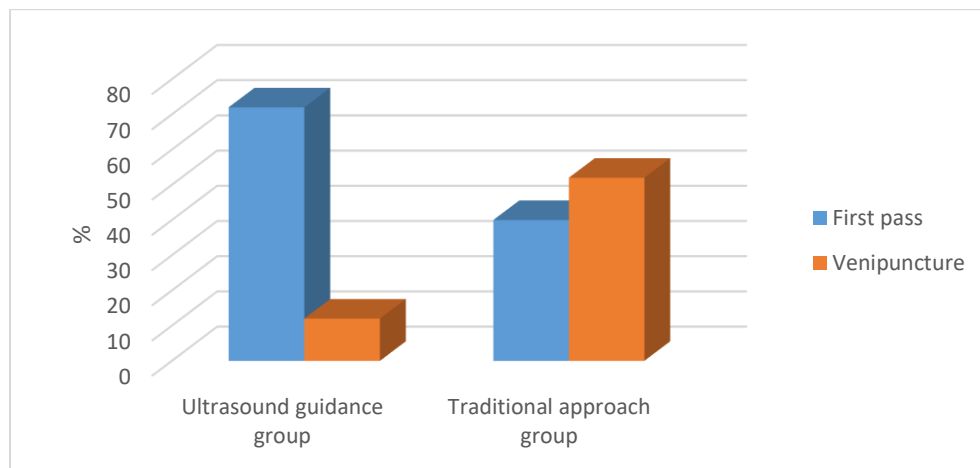


Figure (2): First pass & venipuncture among ultrasound guidance and traditional approach groups.

Femoral artery access site complications are not uncommon after coronary angiography. While radial is the access of choice, femoral artery access is used for high-risk patients (7). Therefore, the magnitude of ultrasound guided approach benefits may potentially be greater in patients undergoing such high-risk interventions (8). Ultrasound-guidance for femoral access has been examined in several studies. FAUST (Femoral Arterial Access with Ultrasound Trial) was the largest prospective, multicenter study that randomized 1,004 patients to ultrasound or fluoroscopic-guided femoral access (4).

Therefore, the aim of the present study was to compare the procedural and clinical outcomes of femoral arterial access with ultrasound (US) guidance versus traditional approach.

The present study was prospective randomized controlled study conducted on patients aged ≥ 18 years undergoing elective coronary angiography study comparing the efficacy of US-guided versus the traditional approach for coronary angiography with or without percutaneous intervention (PCI). All patients were matched in sociodemographic and indication for Coronary Angiography.

Our study showed that the clinical benefit of US guidance is reduction in tissue and vessel trauma from multiple attempts and venipunctures. Ultrasound guidance group was associated with significant decrease in number of inward needle advancement and time of sheath/ seconds, significant increase in first pass and ideal puncture when compared to traditional group ($p= 0.003$).

US guidance is also more likely to achieve a true anterior wall puncture. Also, with US guidance, entrance to unhealthy part of femoral artery can be

avoided. Manual pressure applied to the artery during standard cannulation might reduce its caliber increasing the risk of posterior or anterior wall puncture. On the other hand, with US guidance, any compression of the artery is both minimized and made visible during procedural potential reducing the risk of posterior wall puncture (5).

In agreement with our results, Sorrentino et al (9) found that the first attempts success rate was significantly higher with ultrasound approach than traditional approach. Likewise, time to access in patients undergoing ultrasound approach was significantly lower compared to traditional approach.

In a large, randomized trial published by Katircibaşı and colleagues, including 939 patients, the ultrasound group had a significant risk reduction for hematomas, and arteriovenous fistulas compared to the conventional group (10).

Likewise, Seto and colleagues, randomizing 1004 patients for fluoroscopic versus ultrasound cannulation of the femoral artery, showed a slightly lower rate of vascular complications in ultrasound access patients compared to fluoroscopic access (5).

Following data pooling, bleeding events, venipuncture, and multiple puncture attempts were significantly improved with US-guidance, but not successful common FA cannulation (11).

In our study clopidogrel was used for 40% of patients undergoing ultrasound guidance coronary angiography. However, it didn't cause any increase in vascular complication in this group when compared to the other group.

In line with our finding, Patti et al (12) demonstrated that pretreatment with a 600-mg loading dose of clopidogrel 4 to 8 hours before the procedure is safe.

Venipuncture showed significant increase in traditional approach group when compared to ultrasound guidance group. Furthermore, vascular complications at 2nd day showed significant increase in traditional approach group when compared to ultrasound guidance group. hematoma retroperitoneal, discoloration and pseudoaneurysm showed increase in traditional approach group when compared to ultrasound guidance group. During follow up abnormal finding were more common in traditional approach group when compared to ultrasound guidance group (p=0.003).

In line with our findings, routine use of ultrasound may decrease the risk for hematoma formation. Encouraging routine ultrasound is a feasible quality improvement opportunity to decrease patient morbidity (13). The use of real-time 2D ultrasound guidance for femoral artery catheterization decreases life-threatening vascular complications and improves first-pass success rate (4).

CONCLUSION

Ultrasound-guided femoral artery access achieved a higher rate of cannulation at the first attempt as well as shorter time to access with lower rate of vascular complications, including hematomas and venipuncture compared to conventional approach.

Disclosure

No disclosures

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