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An Interventional Study to Compare the Efficacy and Safety of Radial Artery Cannulation with Focused Acoustic Shadowing Facilitated Ultrasound Guided Technique and Unaided Ultrasound Guided Technique in Hypotensive Patients in ICU

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ABSTRACT

Arterial lines may be required in critically ill patients in a variety of settings including the Emergency department, Peri-operative setting and ICU. These patients may require close monitoring of blood pressure with vasoactive medication, intravenous fluid administration, intravenous antihypertensive regimens among other reasons. Our study aim was to compare the efficacy of radial arterial cannulation using focused USG guided acoustic shadowing technique with that of traditional ultrasound guided technique in hypotensive patients in ICU. The study was conducted as a randomized interventional study in the department of anesthesiology and critical care Dr. S.N. Medical college, Jodhpur after obtaining institutional ethics committee approval (Ref. No. SNMC/IEC/2020/plan/309) and written informed consent from study subject's relatives. Sample size was calculated to be a minimum of 40 subjects in each group. First attempt success rates was significantly higher in Focused ultrasound group (88.9%) compared to traditional ultrasound group (66.7%) and the difference was statistically significant (p value 0.01). USG localization time was significantly shorter in focused ultrasound group (25.91±2.90s) compared to traditional ultrasound group (43.51±3.09s) and the difference between the two groups was statistically significant. ($p<0.05$). Puncture time was significantly shorter in focused ultrasound group(43.81±2.45s) compared to traditional ultrasound group (57.42±2.11s) and the difference between the two groups was statistically significant. ($p<s0.05$). Total cannulation time compared to traditional ultrasound group (100.14±4.16s)and the difference between the two groups was statistically significant. ($p< 0.05$). Incidence of bleeding in TU group was 10 out 45 patients and in FU group 4 out 45 patients which is lower in FU group when compared with TU group and P-value being 0.14 which is statistically insignificant. Incidence of hematoma in TU group was 4 out 45 patients and in FU group 2 out of 45 patients which is lower in FU group when compared with TU group with P-value being 0.67 which is non-significant. The focused acoustic USG guided technique of radial artery cannulation not only helps shorten the ultrasound location and puncture time, but also improves the success rate of radial artery puncture at the first attempt in hypotensive patients and thereby facilitates radial artery cannulation in hypotensive patients admitted in ICU.

INTRODUCTION

Arterial blood pressure is a basic vital sign routinely measured in all patients. Blood pressure can be measured either by non-invasive or invasive methods. Non-invasive and invasive methods employ different techniques to measure blood pressure, resulting in varied values even during simultaneous measurements. Non-invasive measurement done manually by sphygmomanometer, automatically by non-invasive blood pressure devices and invasive blood pressure measurement by arterial line pressure transducer.

Arterial line cannulations are generally performed in patients mainly forinvasive blood pressure monitoring and arterial blood sampling for arterial blood gas analysis. Invasive blood pressure monitoring is essential in major surgical patients in operation theatres and critically ill patients in intensive care units. Arterial blood gas analysis is done for managing acid base disturbances in critically ill patients.

The first recorded arterial cannulation was performed in 1714 by the reverend, Stephen Hales[1]. Continuous recording of arterial blood pressure during the perioperative period with small plastic catheters was first described in 1949 by Peterson[2]. He inserted them into the brachial artery through a metal needle. In 1953, the Swedish radiologist Sven Seldinger described the now used catheter over guide wire technique[3]. There are multiple sites for arterial cannulation such as the radial, posterior tibial, femoral, brachial, axillary, ulnar, dorsalis pedis and temporal arteries. As per the Centre for disease control and prevention, radial artery is the first choice for arterial cannulation because of its superficial location and presence of collateral blood supply to the hand via ulnar artery in most patients[4]. Adequate collateral circulation is assessed from the ulnar artery before cannulation by using Allen test or modified Allen's test. Traditionally, radial artery cannulation is done by locating the vessel via the palpatory method or by anatomical landmarks. Unfortunately, anatomic landmarks may not locate the radial artery in up-30% of patients[5]. The radial pulse may be weak or absent in patients with severe hypotension, morbidly obese and in patients with atherosclerosis. This makes locating the artery via palpation difficult this leads to prolonged puncture duration and increased puncture frequency in which the prolonged repeated needle stimulation to the vascular wall tends to aggravate and prolong the hyper reactivity of radial artery[6], deteriorating the arterial spasm. Radial arterial cannulations are often associated with significant morbidity because the procedure involves significant amount of pain and anxiety therefore fast and secure method of radial artery cannulation is needed in ICU for which introduction of ultrasound technique may be beneficial

MATERIALS AND METHODS

The study was conducted as a randomized interventional study in the department of anesthesiology and critical care Dr. S.N. Medical college, Jodhpur after obtaining institutional ethics committee approval (Ref. No. SNMC/IEC/2020/plan/309) and written informed consent from study subject's relatives. Sample size was calculated to be a minimum of 40 subjects in each group.

Inclusion Criteria:

- Hypotensive patients (MAP=<65 mmHg) of aged 18-80 years in the ICU were included in the study.

Exclusion Criteria:

- Patients having h/o forearm surgery.
- Local infection.
- Local artery embolism.
- Negative Allen's test.
- Abnormal ulnar artery.
- Patients who had undergone arterial puncture within one-month period immediately preceding the commencement of the trial.
- Abnormal coagulopathy.
- Patients relatives who do not give informed consent.

The subject who satisfied the above eligibility criteria were approached for participation in the study. An information sheet having the details of the study was provided and nature of the study was verbally explained to patient's relatives. Written informed consent was obtained. Enrolment, recording of the baseline information and randomization was done immediately after written informed consent. Screening assessment of eligibility criteria and obtaining consent was done by the principal investigator.

Pre-Procedural Evaluation:

- Basic demographic data like age sex were recorded.
- Baseline data of each patient such as name, age, sex, registration no, diagnosis, any co morbid illness, date of admission in ICU were recorded.
- Patient routine investigations were checked out as mentioned below.
- Patient's relatives were explained in detail about the procedure.

Investigations Required: In all patients, base line investigation has done to rule out any hematological abnormality and active viral infections, bleeding time, Clotting time, Prothrombin time/ INR, Viral markers for HIV, hepatitis B surface antigen, hepatitis c virus antigen.

Randomization and Blinding: Ninety patients of age 18-80 years, who required arterial cannulation were taken up for the study. The patients were randomly assigned to two groups, each having equal number of patients using computer generated numbers and the principle examiner is not blind for the groups in which patients are allocated.

- **Traditional Ultrasound Group(TU):** Cannula inserted in the radial artery through conventional ultrasound technique
- **Focused Ultrasound Group (FU):** Cannula inserted in the radial artery through ultrasound guided acoustic shadowing by metal containing strands

Monitoring and Follow up: In both Groups TU and FU the following parameters were monitored and followed up by primary investigator.

Success/Failure: More than three attempts were taken as a failure and cannulation was attempted at other site.

No of Attempts: Attempt-Defined as new penetration of the skin with the needle followed by <3 needle redirections under the skin. Multiple attempt-Two or more attempts defined as multiple attempts.

USG Localization Time: Defined as time from the placement of USG probe over the skin to the penetration of the puncture needle into the skin.

Puncture Time: Defined as time that elapsed between the penetration of the puncture needle into the skin to successfully inserting the cannula into the radial artery.

Total Cannulation Time: Defined as the time from the beginning of assessing the radial artery using the ultrasound to the appearance of arterial waveform on the monitor

Complications Observed:

Bleeding: Defined as small amount of staxis occurred around the stoma continuously within 3 hours after cannulation.

Haematoma: Defined as a visible or palpable swelling around the cannulation site after the procedure.

RESULTS AND DISCUSSIONS

Mean age comparison of patients between both groups. Unpaired student t-test was run on the above data. Mean age in years in TU group was 56.56+13.19 where as in FU group was 59.91+10.79 and there was no statistical difference between the two groups (P-value= 0.33). Fisher exact test was done on data of gender wise distribution of patients. The P-value was 0.82 i.e. statistically insignificant.

Table 1: Type of Shock wise Distribution of Patients

Type of shock	Traditional Ultrasound Group (n=45)		Focused ultrasound Group (n=45)		p-value
	No.	%	No.	%	
Septic shock	32	71.1	34	75.6	0.88
Cardiogenic shock	8	17.8	7	15.6	
Hypovolemic shock	5	11.1	4	8.9	

Chi square test

The above table shows Type of shock patients in the two groups. All patients belonged to Septic shock, Cardiogenic shock and Hypovolemic shock comparable between both groups. There were more patients who had septic shock than cardiogenic and hypovolemic shock in both groups. The P-value between the two group was 0.88 i.e. statistically insignificant

Table 2: Mean arterial Pressure (MM HG) At the Time of Cannulation

	Traditional Ultrasound Group (n=45)	Focused ultrasound Group (n=45)	p-value
	Mean±SD	Mean±SD	
Mean Arterial pressure (mm Hg)	59.78±1.72	60.49±2.34	0.10

Unpaired t-test

The above table indicates the MAP (mmHg) of the two groups. Unpaired t-test was performed on the above data. There was no statistical difference in MAP of both groups. (P-value >0.05) the Amount of Nor-epinephrine support at the time of cannulation of the two groups. Unpaired t-test was performed on the above data. There was no statistical difference between two groups. (P-value >0.05).

Table 3: Apache-II Score

	Traditional Ultrasound Group (n=45)	Focused ultrasound Group (n=45)	p-value
	Mean±SD	Mean±SD	
Apache-II score	26.18±3.18	25.98±4.37	0.80

Unpaired t-test

The above table indicates the APACHE II Score of the two groups. Unpaired t-test was performed on the above data. There was no statistical difference between APACHE II Scores in two groups. (P-value 0.80)

Table 4: Coagulation Parameters

	Traditional Ultrasound Group (n=45)	Focused ultrasound Group (n=45)	p-value
	Mean±SD	Mean±SD	
PT (sec)	13.93±0.74	13.86±0.61	0.62
INR	1.28±0.13	1.27±0.12 0.68	
APTT (sec)	41.28±7.88	40.63±6.80	0.67
Platelet count (109/L)	180.82±22.49	184.51±26.58	0.47

Unpaired t-test

The above table depicts the coagulation parameters of the two groups. Unpaired t-test was performed on the above data. Coagulation parameters were compared between the two groups and there was no statistical

difference between the two groups with respect to Prothrombin time, INR, APTT, Platelet count. (P>0.05).

Table 5: Depth of Radial Artery from Skin and Inner Diameter of Radial Artery

	Traditional Ultrasound Group (n=45)	Focused ultrasound Group (n=45)	p-value
	Mean±SD	Mean±SD	
Depth of radial artery from skin (mm)	4.26±0.17	4.31±0.22	0.18
Inner diameter of radial artery (mm)	1.54±0.17	1.54±0.17	0.94

Unpaired t-test

The above table demonstrates the depth of radial artery from skin and inner diameter of radial artery in two groups. Unpaired student t-test was performed on the above data. There was no statistical difference in depth of radial artery from skin and inner diameter of radial artery in two groups. (P-value >0.05)

Table 6: Number of Attempts to Cannulate Radial Artery

Traditional Ultrasound		Focused ultrasound		p-value
No.	%	No.	%	
30	66.7	40	88.9	0.01
8	17.8	3	6.7	0.19
1	2.2	0	0.0	1.0
6	13.3	2	4.4	0.26

Fisher exact test

The above table depicts no of attempts for successful arterial cannulation. Fisher exact test performed on the above data. In TU group 30 patients (66.7%) were cannulated in first attempt while 40 patients (88.9%) were cannulated in FU group in first attempt. On statistical analysis the difference in the first attempt success rates between the two groups were statistically significant (P-value=0.01)

Mean USG localization time (Defined as the time from the placement of USG probe over the skin to the penetration of the puncture needle into the skin) was found to be 43.51+3.09s in the TU group and 25.91+2.90s in the FU group. The USG Localization time were compared among the two groups and statistically significant difference was found between the two groups (P<0.001)

Table 7: Puncture Time

	Traditional Ultrasound Group (n=45)	Focused ultrasound Group (n=45)	p-value
	Mean±SD	Mean±SD	
Puncture time (s)	57.42±2.11	43.81±2.45	<0.001

Unpaired t-test

The above table depicts puncture time. Unpaired student t-test was performed on the above table. Mean puncture time (Defined as time that elapsed between the penetration of the puncture needle into the skin to successfully inserting the cannula into the radial artery). Was found to be 57.42+2.11s in TU group and 43.81+2.45s in FU group. The puncture times were compared among two groups and statistically significant difference was found between the groups (P-value<0.001).

Mean total cannulation time(Defined as the time from the beginning of assessing the radial artery using the ultrasound to the appearance of arterial waveform on the monitor) was found to be 100.14+4.16s in TU group and 69.35+3.83s in FU group. The total cannulation times were compared among the two groups and statistically significant difference was found between the groups.(P<0.001).

Complications:

Table 8: Vascular Complication During radial Artery Puncture

Complications	Traditional Ultrasound Group (n=45)		Focused ultrasound Group (n=45)		p-value
	No.	%	No.	%	
Bleeding	10	22.2	4	8.9	0.14
Hematoma	4	8.9	2	4.2	0.67

Fisher exact test

Incidence of bleeding in TU group was 10 out 45 patients and in FU group 4 out 45 patients with P-value 0.14. Incidence of hematoma in TU group was 4 out 45 patients and in FU group 2 out of 45 patients with P-value 0.16. Bleeding and hematoma were comparable between both groups and there is no statistical significant difference between the groups. There were no statistically significant differences in the two groups included in this study in terms of various demographic parameters (age, gender), type of shock, norepinephrine infusion, APACHE II score, coagulation parameters, depth of radial artery and inner diameter of radial artery. The mean age group of patients in group TU was 56.56+13.19years and in group FU was 59.91+10.79 years with P-value being 0.33 which is non-significant. The difference between two groups on the basis of gender was also non-significant with P-value being 0.82.

The number of septic shock, cardiogenic shock and hypovolemic shock patients in TU group were 32, 8 and 5 patients respectively and in TU group the number of septic shock, cardiogenic shock and hypovolemic shock patients were 34, 7 and 4 patients respectively with the P-value being 0.88 (non-significant).

The mean norepinephrine infusion in group TU was 0.209+0.09 microgram/kg/min and in group FU was 0.204+0.06 microgram/kg/min with P-value being 0.91 (non-significant). Mean APACHE II score in group TU was 26.18+3.18 and in group FU was 25.98+4.37 with P-value being 0.80 (non-significant).

Coagulation parameters like mean PT in TU group was 13.93+0.74s and in group FU was 13.86+0.61swith P-value 0.62 (non-significant), mean INR in TU group was 1.28+0.13 and in FU group was 1.27+0.12 with P-value being 0.68 (non-significant), mean APTT in TU group was 41.28+7.88s and in FU group was 40.63+6.80s with P-value 0.67 (non-significant) and mean platelet count in TU group was $180.82+22.49*10^9$/L and in FU group was

184.51+26.58*10^9/L and P-value being 0.47 which is non-significant.

Mean depth of radial artery from skin in TU group was 4.26+0.17 mm and in FU group was 4.31+0.22 mm with P-value being 0.18 (non-significant). Mean inner diameter of radial artery in TU group was 1.54+0.17 mm and in FU group was 1.54+0.17 mm with P-value being 0.94 which is non-significant. P-value of less than 0.05 was accepted as statistically significant in this study.

First Attempt Success Rates: In our study 30 patients in TU group and 40 patients in FU group underwent cannulation in first attempt as per the criteria set by us as Successful puncture of the artery and visualization of blood in the hub of cannula in the first attempt with <3 needle directions under the skin and without withdrawing the needle from skin at any stage during its advancement. Only then the attempt would be considered successful thus first attempt success rates were higher in FU group (88.9%) when compared with TU group (66.7%) and the difference was statistically significant(p value 0.01).This is attributed to the fact that fast positioning and accurate guidance provided by ultrasound with double developing lines in FU group Our result is consistent with the study of Ming Tian[7] and Aishvarya[8] who concluded that the cannula insertion success rate on the first attempt was significantly higher (88.9%) inthe modified Short axis-out of plane group in which suture was tied on the midpoint of ultrasound probe as a guide compared with the long axis-in plane group (73.2%) and they attributed to the developing line on the probe which helps to position the artery in the center for accurate puncture

Usg Localization Time: Mean USG localization time (defined as time from the placement of USG probe over the skin to the penetration of the puncture needle into the skin.) In our study was found to be 43.51+3.09 sec in the TU group and 25.91+2.90 sec in the FU group. The results were statistically significant with p-value being <0.001. Our study results correlates with other relevant studies undertaken till now in which less time was needed to identify the radial artery using USG with developing line[7,8].

In the study conducted by Ishii22 *et al* average access time (skin to artery) was significantly shorter with ultrasound approach (18.5s) when compared with palpatory approach (30s). Ming Tien[7] in their study concluded that access time to radial artery was significantly lower with modified short axis-out of plane approach in which suture was tied on USG probe, when compared to long axis in plane approach. They did both approach with USG. Quan[9] found that time required to find radial artery was significantly less with novel USG technique with mean value of 6s compared to 18s with traditional USG technique.

Puncture Time: Mean puncture time (defined as time that elapsed between the penetration of the puncture needle into the skin to successfully inserting the cannula into the radial artery) in our study was found to be 57.42+2.11s in TU group and 43.81+2.45s in FU group.Puncture time was significantly shorter in FU group when compared with TU group and p-value is significant <0.001. The shorter time for radial artery puncture in FU group is attributed to the double developing lines of USG probe, which helps in locating the projection point of the midpoint of the radial artery on the skin surface to enable quick and accurate determination of the puncture point. This focused acoustic USG guided technique isolates the contact between the USG probe and skin through the double developing lines on the ultrasound probe there by displaying a vertical low-density shadow in the USG image which helps in positioning of needle accurately prior to skin penetration which indirectly compensates for the short comings of traditional USG guided techniques of radial arterial cannulation.

Similar results were found by Quan[9] who compared the puncture time between traditional USG guided radial artery puncture and radial artery puncture guided by acoustic shadowing USG with double developing lines in 79 young children undergoing surgery under general anesthesia.They observed that Puncture time (24s (15-41s) vs 40s(23-56s)) in the novel USG group was significantly shorter than that in the traditional USG group. However they observed better results compared to our study this is because in our study we included hypotensive patients on vasopressor support and the peripheral arteries have undergonevasoconstriction due to the stimulation of alpha1 receptors by norepinephrine making it difficult and time consuming.

Total Cannulation Time: Total cannulation timedefined as the time from the beginning of assessing the radial artery using the ultrasound to the appearance of arterial waveform on the monitor. This was summation of USG localization time and puncture time. In our study it was 100.14+4.16 s in TU group and 69.35+3.83 s in FU group which is significantly shorter in FU group when compared with TU group and it was statistically significant with p-value<0.001.

The shorter total cannulation time in FU group is attributed to two reasons One, fast positioning and accurate guidance provided by ultrasound with double developing lines. Second, helps locating the projection point of the midpoint of the radial artery on the skin

surface to enable quick and accurate determination of the puncture point. However, this finding differs from a randomized controlled trial conducted by Kyung song[10] in which they compared short axis and long axis approaches of USG guided technique of radial artery cannulation in children. They concluded that there was no statistically significant difference in the total time to cannulate between the two groups. They reported that even though short axis approach required less time for localization and puncturing the artery but total cannulation time was similar with long axis approach it is because in short axis approach following posterior wall puncture withdrawal of the needle tip back into the lumen and sliding it successfully inside the artery could have been difficult and time consuming.

Complications: In our study the incidence of bleeding in TU group was 10 out 45 patients and in FU group 4 out 45 patients which is lower in FU group when compared with TU group and P-value being 0.14 which is statistically insignificant. Incidence of hematoma in TU group was 4 out 45 patients and in FU group 2 out of 45 patients which is lower in FU group when compared with TU group with P-value being 0.67 which is non-significant. The lower incidence of bleeding and hematoma FU group is likely attributable to the higher initial success rate of the puncture in FU group.

Previous studies which are consistent with our results, Ming Tian[7] compared the complications between modified SA-OOP and LA-IP USG guidance approaches in 164 patients who underwent liver surgery or splenic resection under general anaesthesia. They found that complications like hematoma, vasospasm and thrombosis were not statistically significant between the short axis and the long axis group. But there was a slightly lower incidence of hematoma in the modified short axis approach.

CONCLUSION

The focused acoustic USG guided technique of radial artery cannulation not only helps shorten the ultrasound location and puncture time, but also improves the success rate of radial artery puncture at the first attempt in hypotensive patients and thereby facilitates radial artery cannulation in hypotensive patients admitted in ICU. Hence, it is a quick and secure cannulation method and is appropriate for use in clinics.

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