

**Comparison of two ultrasound-guided techniques  
(dynamic needle tip positioning and acoustic  
shadowing) with conventional palpation technique  
for radial arterial cannulation in adult patients: a  
randomised controlled trial**



**THESIS**

**Submitted to**

**All India Institute of Medical Sciences, Jodhpur**

**In partial fulfilment of the requirement for the degree of**

**DOCTOR OF MEDICINE (MD)**

**ANAESTHESIOLOGY AND CRITICAL CARE**

**JULY, 2020**

**AIIMS, JODHPUR**

**DR MRUTHYUNJAYA N S**

## DECLARATION



I hereby declare that the thesis titled **"Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomised controlled trial"** embodies the original work carried out by me at All India Institute of Medical Sciences, Jodhpur.

A handwritten signature in blue ink, appearing to read 'Dr. Mruthyunjaya N S', is written over a faint, stylized outline of the AIIMS logo.

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## **DECLARATION**



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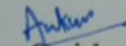
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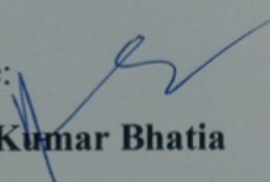
**CERTIFICATE**

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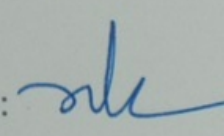
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
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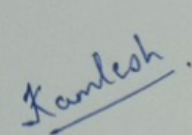
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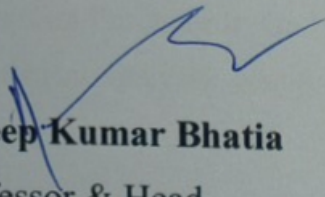
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I also cannot thank my parents and siblings enough, who have stood by me in difficult times. The thesis would not have reached its goal without their daily moral support and faith in me.

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I would also like to extend my sincere thanks to all the study participants, without whom this thesis would not have been complete.

Any omission in this brief acknowledgement does not mean a lack of gratitude. I express my gratitude to everyone who has supported me throughout and been with me as a part of this journey.

**Dr Mruthyunjaya N S**

*Dedicated to my  
Patients,  
Teachers, Family  
&  
my Friends...*

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## **LIST OF ABBREVIATIONS**

<b>Abbreviation</b>	<b>Full Form</b>
ASA	American Society of Anaesthesiologists
AST	Acoustic Shadowing Technique
BMI	Body Mass Index
BP	Blood Pressure
DNTP	Dynamic Needle Tip Positioning
DP	Direct Palpation
2D	2-Dimensional
CI	Confidence Interval
ICU	Intensive Care Unit
IQR	Interquartile Range
JR	Junior Resident
OR	Odds ratio
RA	Radial Artery
RCT	Randomised Control Trail
RR	Risk Ratio
SD	Standard deviation
SR	Senior Resident
TP	Traditional Palpation
TUSG	Traditional Ultra-sonography
US	Ultrasound
USG	Ultra-sonography



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### PRIMARY SOURCES

- |   |   |               |
|---|---|---------------|
| 1 | <a href="http://www.ncbi.nlm.nih.gov">www.ncbi.nlm.nih.gov</a><br>Internet  | 78 words — 2% |
| 2 | Roy K. Kiberenge, Kenichi Ueda, Brett Rosauer.<br>"Ultrasound-Guided Dynamic Needle Tip Positioning<br>Technique Versus Palpation Technique for Radial Arterial<br>Cannulation in Adult Surgical Patients", Anesthesia & Analgesia,<br>2018<br>Crossref | 74 words — 2% |
| 3 | Hua-ping Huang, Wen-jun Zhao, Fang Wen, Xiao-yu<br>Li. "Application of ultrasound-guided radial artery<br>cannulation in paediatric patients: A systematic review and<br>meta-analysis", Australian Critical Care, 2020<br>Crossref                     | 65 words — 1% |
| 4 | <a href="http://journals.lww.com">journals.lww.com</a><br>Internet  | 49 words — 1% |
| 5 | <a href="http://link.springer.com">link.springer.com</a><br>Internet  | 49 words — 1% |
| 6 | <a href="http://bmcmmededuc.biomedcentral.com">bmcmmededuc.biomedcentral.com</a><br>Internet  | 39 words — 1% |
| 7 | Sulagna Bhattacharjee, Souvik Maitra, Dalim K.<br>Baidya. "Comparison between ultrasound guided<br>technique and digital palpation technique for radial artery  | 31 words — 1% |
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## **SUMMARY**

**Background:** Arterial cannulation is commonly done for invasive blood pressure measurement and frequent blood sampling. The most frequent challenge in arterial cannulation is threading the cannula inside the artery without puncturing the posterior wall. This can be accomplished using dynamic needle tip positioning technique by visualising the needle's tip through the course and guiding it. Another challenge in USG-guided cannulation is puncturing the artery while it is visible on the screen. This can be made simple by the acoustic shadowing technique, in which the needle is inserted between the shadows where the artery is made to lie between them. These methods are considered more effective than conventional palpation methods, with a higher rate of successful cannulation and fewer complications. In this study, the dynamic needle and the acoustic shadowing techniques are compared with the traditional palpation method for radial artery cannulation in adult patients.

**Material and Methods:** In this trial, 180 patients older than 18 years requiring arterial cannulation were randomised by a computer-generated method into 3 groups [Traditional palpation (TP), Dynamic needle tip positioning (DNTP) and acoustic shadow technique (AST)]. All the cannulations were performed by experienced anaesthetist who had performed more than 30 arterial cannulations both by palpation and ultrasound guided techniques. The primary outcome of the present study was the success rate of arterial cannulation in the first attempt. The secondary outcomes were total number of attempts in 5 minutes, time taken to cannulate artery, number of cannulas used, and complications related to the procedure (hematoma, bleeding, thrombosis etc.).

**Results:** The first attempt success rate among TP, DNTP and AST were 66.7%, 66.7% and 71.7%, respectively, ( $p=0.794$ ). The median time [IQR] taken for cannulation was 60.5 [37.0, 129.5] sec, 71.0 [50.0, 170.0] sec and 108.0 [58.0, 181.0] sec, respectively, ( $p=0.066$ ) and the median number of cannulation attempts was 1, in all the three groups ( $p=0.773$ ). There was also no difference in the total number of cannulas used, overall success rate of cannulation and complications related to procedure in the three groups.

**Conclusion:** For, radial artery cannulation by TP, DNTP, and AST technique, there is no significant difference in first attempt success rate, the time taken for cannulation, the number of cannulas used and overall complications during cannulation. Hence USG guided



techniques, DNTP and AST, do not show any additional benefits over TP method for radial artery cannulation by experienced anaesthetist in adult patients.

## **INTRODUCTION**

The American Society of anaesthesiologists(ASA) recommends that blood pressure monitoring should be one of the standard monitoring during anaesthesia (1,2). By measuring blood pressure, one can assess the hemodynamic stability of the patient(3); hence blood pressure monitoring is vital.

Blood pressure (BP) monitoring can be done by various methods, broadly classified into non-invasive and invasive BP monitoring. For, non-invasive BP monitoring, there are the palpation method, auscultatory method, and oscillatory method(4), and in the invasive BP monitoring , it is mainly done by cannulation of an artery.

The invasive method, i.e. arterial BP monitoring, gives the beat-to-beat reading. Therefore, invasive BP monitoring is superior to non-invasive for accuracy(5). Arterial cannulation is frequently carried out for the purpose of invasive arterial pressure monitoring and arterial blood gas analysis. It is utilised to direct the treatment of patients who are experiencing respiratory distress, shock, acid-base discrepancy, or electrolyte disturbance.

The most common artery used for cannulation is the radial artery because its easily palpable and with decreased risk of infection (6). Usually, the radial artery is cannulated utilising anatomical landmarks and palpation of the radial pulse.

Cannulation of the radial artery is challenging, mainly in a patient with shock with a feeble pulse, children with smaller diameter arteries and in old age with atherosclerosis. Multiple cannulation attempts may result in arterial hematoma, thrombosis, embolus formation, gangrene, and ischemia of the distal part of the hand (1,7,8). Moreover, for successful use of this technique, one needs experience. There have been several studies showing that ultrasound-guided cannulation of the radial artery has a higher success rate than palpation method (9).

Even though the ultrasound-guided method has improved puncture success, it still largely depends on the ultrasound operator's skill. The main reason for this is because ultrasonic imaging is two-dimensional. In order to overcome this limitation of ultrasound, the operator must acquire excellent hand-eye coordination and technical expertise. Therefore, a novel approach using two lines on the ultrasound probe (acoustic shadowing technique) was devised to address this limitation of ultrasound (10–12).

During cannulation, the short-axis ultrasound approach allows for the visualisation of key structures, including vessels and nerves. The long-axis approach gives good visualisation of the needle's position as it approaches and enters the artery, hence enhancing the success rate of cannula insertion. Dynamic needle tip positioning is a modified ultrasonic approach that resulted in a higher catheterization success than the long-axis in-plane view (13,14). It combines the benefits of short-axis out-of-plane and long-axis in-plane ultrasonic approaches.

To our knowledge, no study has been done to compare radial artery cannulation using the acoustic shadowing technique and dynamic needle tip positioning technique with palpation method with respect to success rate, and time for arterial cannulation. Therefore, in this research, we intend to compare these two ultrasound-guided techniques of radial arterial cannulation with palpation method in adult patients.

## **AIMS AND OBJECTIVES**

### **Aim**

To compare ultrasound guided dynamic needle tip positioning technique, Acoustic Shadowing Technique and Palpation technique for Radial Arterial Cannulation.

### **Outcomes**

#### **Primary**

The success rate of arterial cannulation in the first attempt

#### **Secondary**

Total number of attempts in 5 minutes

Time taken to cannulation of radial artery

Number of cannulas used

Complications related to the procedure (hematoma, spasm, bleeding, thrombosis)



## **REVIEW OF LITERATURE**

1. **Cheryl Peters *et al.***, in their study of ultrasound guidance versus direct palpation for radial artery catheterisation by expert operators among Canadian cardiac anaesthesiologists, showed that there were no differences between the TP (n = 62) vs US-guided (n = 63) groups in median time to cannula placement USG 104 [76–212] sec vs DP 104 [68– 270] sec with a p-value of 0.66, the number of re-directs USG 2 [0–6] vs DP 3 [1–5] with a P value of 0.82, or the number of attempts USG 1 [1–2] vs DP 1 [1–2] with a P value of 0.08. The first-attempt success rate was 56.4% in the DP group and 71.4 % in the US group, with a P value of 0.10. Failure and hematoma rates in the DP group were 21.0% and 22.6%, respectively, compared with 12.7% and 11.1% in the US group (P = 0.24 and 0.10, respectively). It showed that among experienced cardiac anaesthesiologists, the use of USG to facilitate radial arterial cannulation did not affect insertion times, the number of redirects or the number of attempts compared with palpation method (15).
2. **Kiberenge *et al.***, in their study on 260 patients, found the first-pass success rate was 83% in the DNTP group (n = 132) and 48% in the palpation group (n = 128) with a P value of < .001. The overall 5-minute success rate was 89% in the dynamic needle tip positioning technique group compared to 65% in the palpation group, with a P value of 0.001. The number of skin puncture attempts was significantly more in the palpation group, with P < 0.001. The median cannulation times were 81.5 (61–122) sec in the DNTP and 76 (48–175) sec in the palpation group (P=0.7)(13).
3. **Liu *et al.***, their study of modified dynamic needle tip positioning with short-axis, out-of-plane, ultrasound-guided radial artery cannulation in neonates, enrolled 60 term neonates. They found that the success rates of the first attempt in the ultrasound and palpation groups were 40% (n = 30) and 10% (n = 30), respectively, with a P value of 0.007. The success rate was 96.7% in the ultrasound group and 60.0% in the palpation group, with a P value of 0.001. The average time to accomplish radial artery cannulation in the ultrasound and palpation groups was  $91.4 \pm 55.4$  and  $284.7 \pm 153.6$  seconds, respectively, with P < 0.001. In addition, 3.3% of the patients in the ultrasound group and 26.7% in the palpation group suffered puncture hematoma with a p-value of 0.026. They concluded that modified dynamic needle tip positioning short-axis, out-of-plane, ultrasound-guided radial artery cannulation in neonates improved the first-attempt and total success rates and

decreases the total procedural time and incidence of cannulation-related complications(16).

4. **S Bhattacharjee *et al.***, in a meta-analysis including 1895 patients, found that overall radial artery cannulation success rate was similar between ultrasound-guided technique and digital palpation with p value 0.05. Ultrasound-guided radial artery cannulation was associated with a higher first-attempt success rate than digital palpation, with a p-value < 0.001. In their study, no difference was seen in time to radial artery cannulation with a p-value of 0.30 and mean the number of attempts with a p-value of 0.06 between USG guided technique and with palpation technique(9).
5. **Homam Moussa Pacha *et al.***, in a systemic review of 12 randomised controlled trials in the adult population found that ultrasound-guided radial artery cannulation was associated with increased first-attempt success rate and decreased failure rate. There were no significant differences in the risk of hematoma, the mean time to the first successful attempt or any successful attempt between both groups. In their study, the ultrasound-guided technique for radial artery cannulation had higher first-attempt success and lower failure rate than palpation alone, with no significant differences in access site hematoma or time to a successful attempt(17).
6. **ZheFeng Quan *et al.***, in their study on acoustic shadowing facilitation of radial artery cannulation under ultrasound guidance in young children, found that the success rate of cannulation on the first attempt was higher AST group (35 out of 39 [90%]) than the traditional ultrasound group (24 out of 40 [60%]) with a P value of 0.002. The ultrasound localisation time and puncture time were significantly less in the AST group than in the traditional ultrasound group, with localisation time AST 6 [5, 8] vs TUSG 18 [15, 21] seconds; puncture time AST 24 [15, 41] vs TUSG 40 [23, 56] seconds. It was concluded that acoustic shadowing through dual lines significantly improved the success rate of radial artery cannulation in young children (11).
7. **Levin *et al.*** conducted a study for radial artery cannulation in 69 patients and randomised between ultrasound group (34 patients) or palpation technique group (35 patients). The time from skin puncture to successful arterial catheterisation, time taken for cannulation, the number of attempts required, and the number of cannulas used was recorded for each group. Arterial cannulas were introduced on the first attempt in 21 cases (62%) by ultrasound method compared with 12 cases (34%) by palpation method (p = 0.03). The ultrasound group reduced the overall cannulation time ( $55.5 \pm 63.8$  vs  $111.5 \pm 121.5$  s, p

= 0.17). They concluded that ultrasound is a valuable adjunct to arterial cannulation and increased the success rate of the first attempt(18).

8. **Lynn Zaremski *et al.*** conducted a study of palpation versus an ultrasound-guided approach for radial artery cannulation. They found that the success rate of initial radial catheterisation USG 87% vs TP 86.8 % ( $P = 0.999$ ) and cannulation time USG 47 s [IQR, 20-90 s] vs TP 31 s [IQR, 20-75 s] ( $P = 0.179$ ) were not significantly different between the ultrasound and palpation groups respectively. Pulse quality (none, weak, strong) was independently associated with access error in both groups ( $P < 0.001$ ). Obesity was associated with access failure in the palpation group ( $P = 0.005$ ) but not in the ultrasound group ( $P = 0.544$ ). They concluded that the ultrasound-guided radial approach does not appear to provide any significant additional benefit over the palpation-guided approach alone (19).
9. **O'Horo *et al.*** conducted a meta-analysis of 49 studies, including 30,841 arterial catheters as a source of infection in the blood and found that prevalence was significantly higher in the subset of studies. Studies reported cultures of all catheters (1.26/1000 days of catheterisation) compared with studies that only cultured when arterial catheters were suspected as the source of catheter-related bloodstream infections (0.70/1000 days of catheterisation). Pooled data also showed a significantly increased risk of infection at the various arterial catheterisation site compared with the radial artery catheterisation site ( $p=0.001$ ). It is concluded that arterial catheters are an underappreciated cause of catheter-associated bacteraemia. Choosing the radial artery instead of the femoral artery reduces the risk of catheter-associated blood infections(20).
10. **Soo Yeon Kime *et al.***, their study of ultrasound-guided DNTP technique for radial artery cannulation in elderly patients found that the success rates on the first attempt were 85.9% and 72.3% in DNTP and TP, respectively ( $P<0.001$ ) and the overall success rates were 99.2% and 93.0% in DNTP and TP, respectively ( $p=0.01$ ). In their study, the number of attempts were 1(1,1) and 1(1,3), in DNTP and TP respectively with a  $P$  value of  $<0.001$ . Cannulation time for successful attempts was 42 (32.55) sec in the DNTP group and 53 (36.78) sec in the palpation group ( $P < 0.001$ ). The incidence of hematoma was significantly lower in the DNTP group (7%) compared with TP group (24.2%) ( $P < 0.001$ ). Furthermore, it was concluded that ultrasound-guided radial artery cannulation with DNTP improves radial artery cannulation in elderly patients by increasing the success rate while minimising complications(14).

11. **QiZou** *et al.* conducted a study on single and double developing lines for ultrasound-guided radial artery cannulation in obese patients and found that in the single or dual line development group, the success rate of radial artery catheterisation at the first attempt was higher than in the control group (control vs single vs dual, 71% vs 90% vs with 91%,  $P=0.001$ ). In addition, the single and dual lines had a shorter time to the successful procedure on the first attempt and a lower overall rate of complications i. e. vascular spasm and hematoma, compared with the control group (procedure time: control vs single vs double, 63 sec vs 54 s vs 40 s,  $P< 0.001$ ). They concluded that single- and dual lines improved the first trial success rates and reduced complication rates of ultrasound-guided radial artery cannulation in obese patients(12).
12. **Rui Dong** *et al.* conducted a study on the application of the acoustic shadowing for radial artery puncture and cannulation teaching in standardised training for residents. They noted the success rate for radial artery puncture at the first attempt in the AST group was 78.43%. It was significantly higher than the traditional ultrasound-guided group, 58.00% ( $p = 0.027$ ). The ultrasonic positioning time and cannulation time in the AST teaching group were significantly shorter than that of the traditional ultrasound-guided group ( $p = 0.012$ ) respectively. However, no significant differences were observed in the incidence of local hematomas and teaching satisfaction scores between the two groups(10).

## **METHODOLOGY**

### **Study Setting**

Patients in the study group were intervened for radial arterial cannulation in the operation theatre at AIIMS JODHPUR, Rajasthan. This study was submitted to the Clinical Trials Registry of India (with the clinical trial number of CTRI/2021/08/036059) after receiving clearance from the Institutional Ethics Committee of AIIMS JODHPUR with letter no. AIIMS/IEC/2021/3292 on March 12, 2021.

**Study Design:** Randomised control trial

**Study participants:**

#### **Inclusion criteria**

Adult patients, more than 18 years, undergoing major surgeries where an arterial line was required for continuous BP monitoring or arterial blood sampling.

#### **Exclusion criteria:**

- Signs of an infection on the skin or the presence of a wound close to the puncture site
- Circulation abnormalities of the hand (Allen's test positive)
- Patients who were not willing to give consent for the study
- Patients with shock/ hemodynamically unstable patients

### **Methodology**

Patients were randomised into three groups using a web-based randomization tool ([www.randomizer.org](http://www.randomizer.org)).

Group **TP**: Palpation technique

Group **DNTP**: Dynamic needle tip positioning technique

Group **AST**: Acoustic shadowing technique

### **Interventions**

Patients submitted their informed consent in writing before participating in the study. Following enrolment, patients were given a random assignment to one of 3 groups (Group TP, DNTP and AST). The group identification slip was put in a prenumbered, packed, and

dark-colored envelope so the group's identity could remain concealed. Immediately before the radial artery cannulation, the sealed envelopes were opened to determine the group allocation. This was carried out utilizing a predetermined protocol after the onset of general anesthesia.

The patient's arm was abducted, and the wrist was extended by placing a towel roll under the wrist. Under aseptic precaution, the radial artery was cannulated according to group allocation using a 20 G arterial cannula (Becton Dickinson, Sandy, Utah, USA) by either of the 3 techniques.

### **Techniques of arterial cannulation**

**Group TP=Traditional palpation technique [TP]:** The radial arterial pulse was palpated by the operator using their non-dominant hand. The needle and cannula were progressed at a 15° to 30° angle toward the radial artery until a flashback of blood was noticed in the needle hub. When blood began to appear in the hub, the needle angle was gently reduced, and the arterial cannula was advanced.



Fig:1 Traditional palpation technique



**Group AST=Acoustic shadowing technique [AST]:** The x-ray-detectable surgical gauze was used to extract the metal-containing strand, which was then positioned parallel to one another on the ultrasound probe. The ultrasound image of these radio-opaque strands provided acoustic shadow as a cannulation guide. After this, the USG probe was used to visualise the radial artery. The probe was placed in such a way that the radial artery was located between these shadows. The needle was then entered at a 30° angle to the skin along the edge of the probe, in between two strands on the probe. Once the needle was inserted into the radial artery, the angle of the needle was lowered from 30° to 15°, and the needle was gently pushed forward for 1 to 2 mm after withdrawing the needle a few millimetres into the cannula. Following this, the cannula was entirely inserted into the radial artery (11).

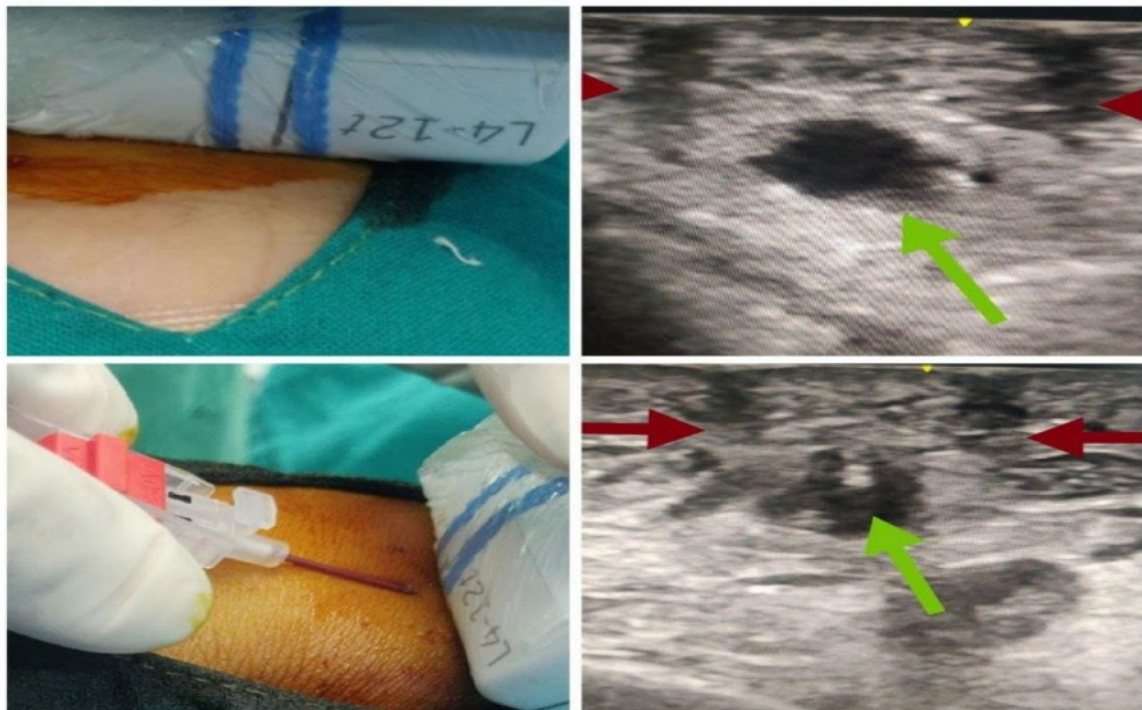


Fig 2: Acoustic shadowing technique, left upper quadrant showing usg probe with blue colour radio opaque thread over it, and corresponding usg image in right upper quadrant with brown arrow showing Acoustic shadow created using radio opaque threads, green arrow showing artery.

**Group DNTP= Dynamic needle tip positioning technique [DNTP]:** After acquiring a short-axis, out-of-plane image of the radial artery, the needle and cannula were inserted at an angle of 30° to 40° into the skin until the hyperechoic needle tip was seen on the ultrasound imaging. The ultrasound probe was then positioned proximally across the arm, away from the needle insertion site, until the needle tip disappeared from the ultrasound imaging. The

needle and cannula were advanced a few millimetres until the ultrasound scan once again revealed the needle tip. At this time, the approach angle was reduced such that the needle tip remained in the centre of the arterial lumen. Within the arterial lumen, the needle and cannula were incrementally advanced for at least 1 cm. The cannula was then threaded on to the needle(13).

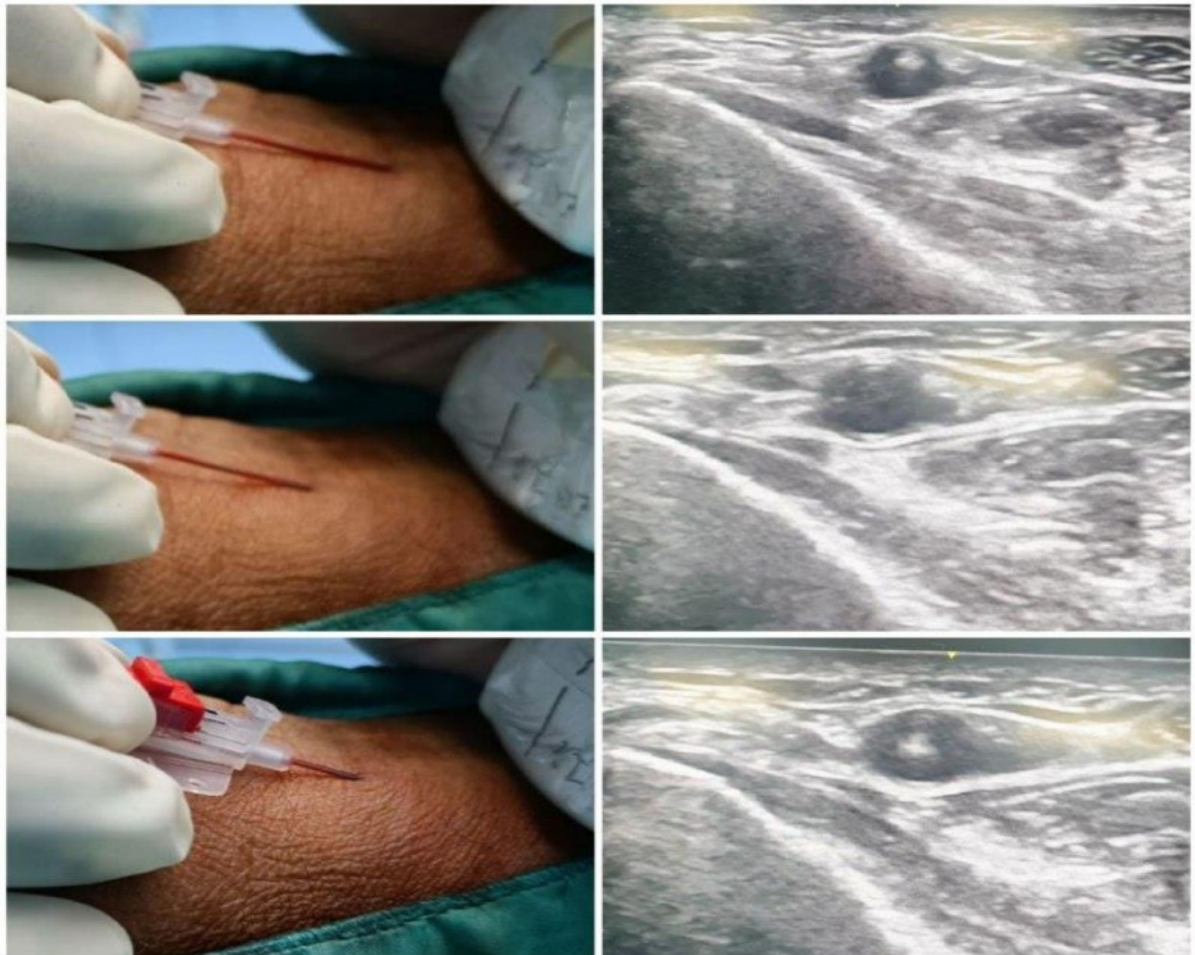


Fig 3: Dynamic needle tip technique

In group DNTP and AST, radial artery was cannulated using a linear probe of an ultrasound machine (GE Venue GO R3, GE Healthcare, WI, USA). All arterial cannulations were performed by experienced anaesthetists who had performed more than 30 arterial cannulations by both by palpation method and ultrasound techniques. An anaesthetist who was unaware of group allocation gathered primary and secondary outcome data for this study.

**Start time:** Beginning of ultrasound scanning in group DNTP/AST group and palpation of the patient's wrist in group TP.

**End Time:** When a free arterial flow in the cannula was seen.



**Technique Failure:** If, after 5 minutes, the targeted radial artery had not been cannulated, it was considered as failure and the operator was free to use any technique.

## STATISTICAL ANALYSIS

### Statistical analysis

- **Sample size:** QUAN ZF(11) found that acoustic shadowing technique of arterial cannulation had a first attempt cannulation success at 90% compared to 60% in the control group. Using this for calculation, we estimated a **sample size of 60 per group**, with 80% power, 95% confidence level (adjusted for three groups) and 20% contingency.
- The total number of patients recruited were **180**.
- Data was entered and analysed using SPSS IBM software version 22 (IBM SPSS Advanced Statistics, Chicago, IL, USA).
- In our study, we used the chi-square test to evaluate nominal data such as gender distribution, first attempt success rate, and number of cannulas changed that are presented as frequency and percentages. The Freeman-Halton extension of the Fisher exact probability test was used to compare the nominal data, which were provided in terms of frequency and percentages for the overall success rate and overall complications.
- The Shapiro Wilk test revealed that age distribution, total cannulation time, and total cannulation attempts, did not follow normal distribution as a result, these are presented as median and IQR [interquartile range] derived and compared using the Mann Whitney U test.
- A p-value of less than 0.05 was regarded as statistically significant.

## RESULTS

This study was conducted in the department of Anaesthesiology and Critical Care at the All India Institute of Medical Sciences, Jodhpur between January 2021 and July 2022. Based on the requirement for arterial cannulation, 180 patients (60 in each group) participated in this study.

Fig 4: CONSORT Diagram

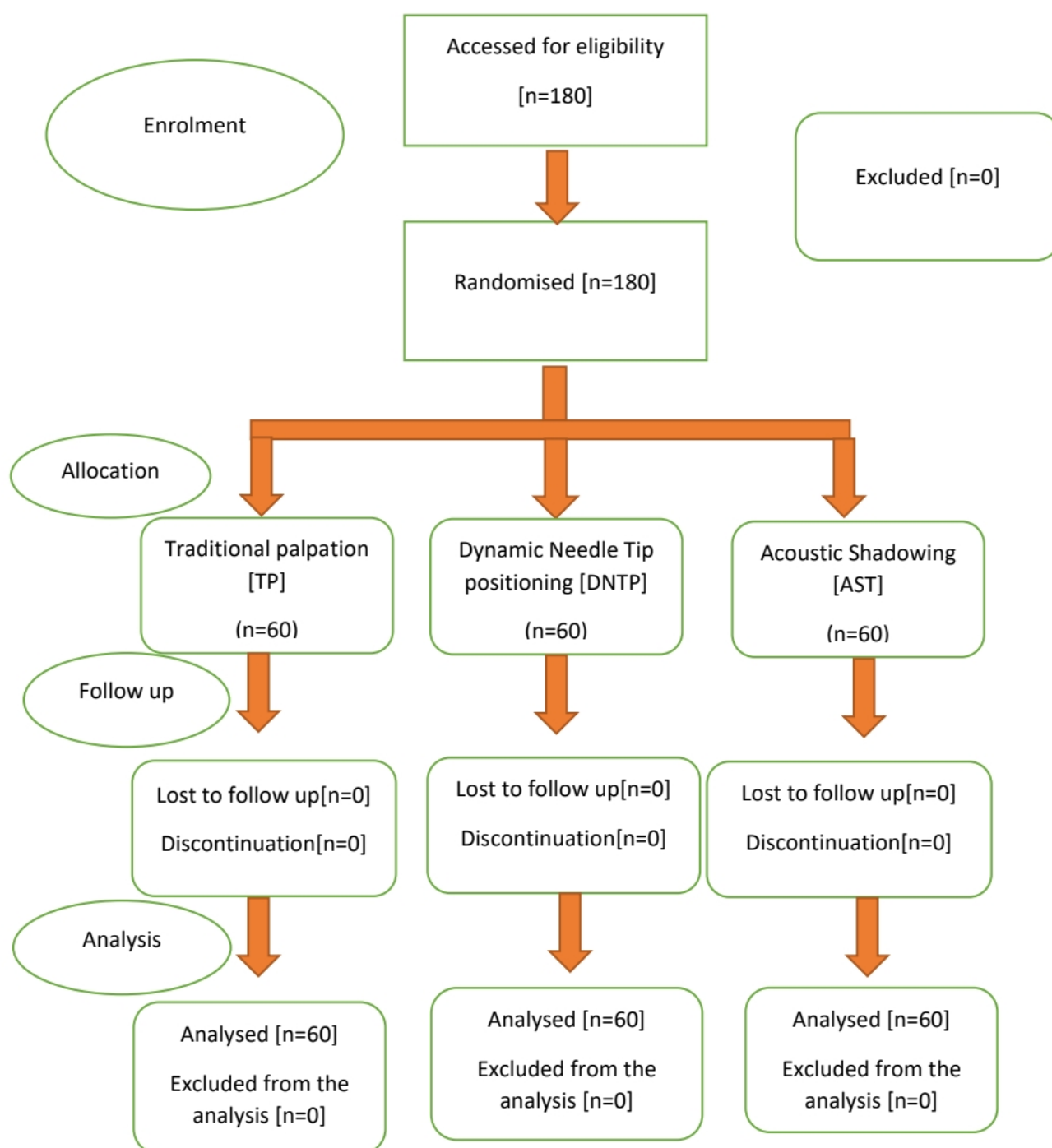


Table 1: Comparison of Age distribution among the three groups.

	Groups								
	Traditional palpation			Dynamic needle positioning technique			Acoustic shadowing technique		
	Median	Q1	Q3	Median	Q1	Q3	Median	Q1	Q3
Age (years)	51.5	41.5	64.0	47.5	36	60.0	50.5	40.5	60.5

The above table shows the comparison of the distribution of age among the three groups. The p-values is 0.466, calculated using Mann Whitney U test, which is statistically insignificant, i.e. age is comparable among the three groups.

Figure 5: Comparison of Age distribution among the three groups.

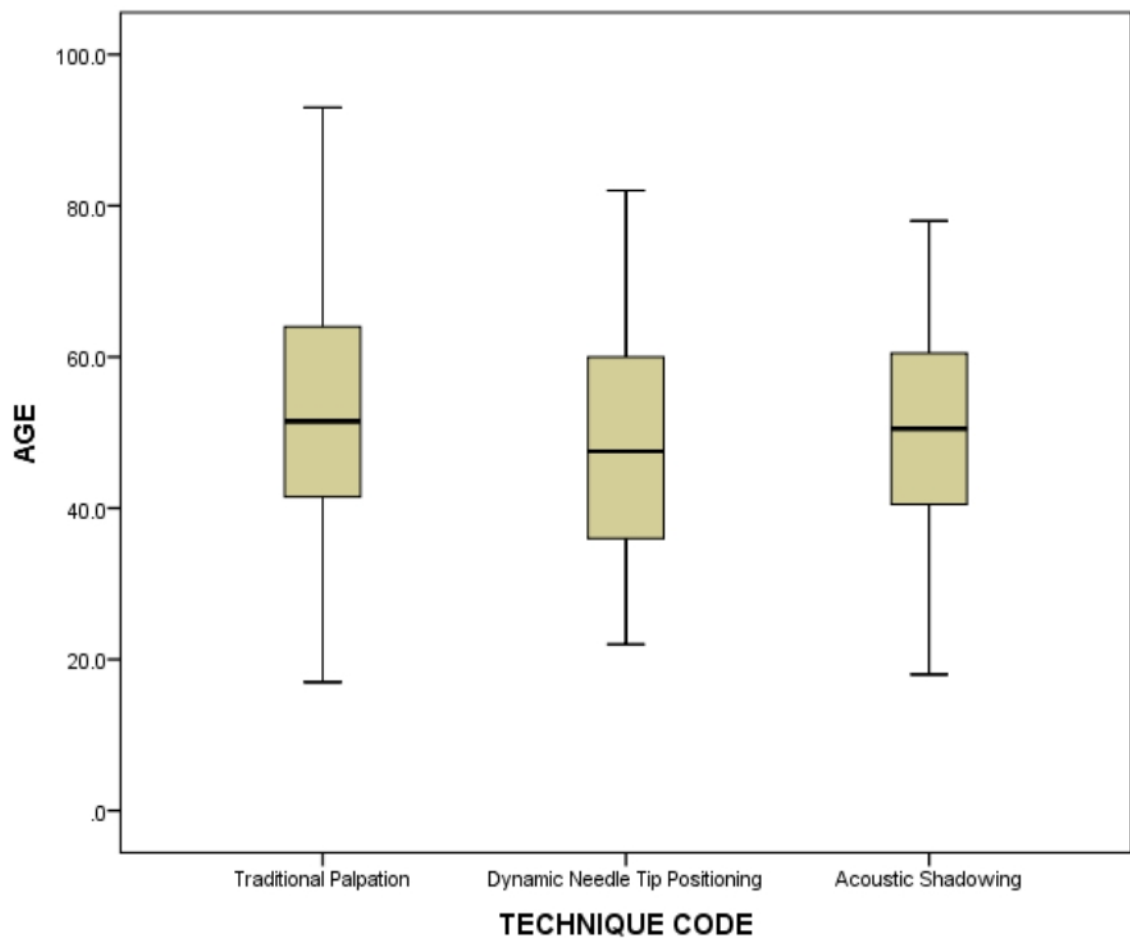


Table 2: Comparison of gender distribution among the three groups

Gender Distribution						
			Groups			Total
			Traditional palpation	Dynamic needle tip positioning	Acoustic shadowing	
SEX	Female	Count	36	37	36	109
		%	60.0%	61.7%	60.0%	60.55%
	Male	Count	24	23	24	71
		%	40.0%	38.3%	40.0%	39.55%
Total		Count	60	60	60	180
		%	100.0%	100.0%	100.0%	100.0%

The above table shows the sex distribution among the groups. The p-value was calculated using the Chi-square test ( $p = 0.977$ ) and is statistically insignificant.

Figure 6: Comparison of gender distribution among the three groups.

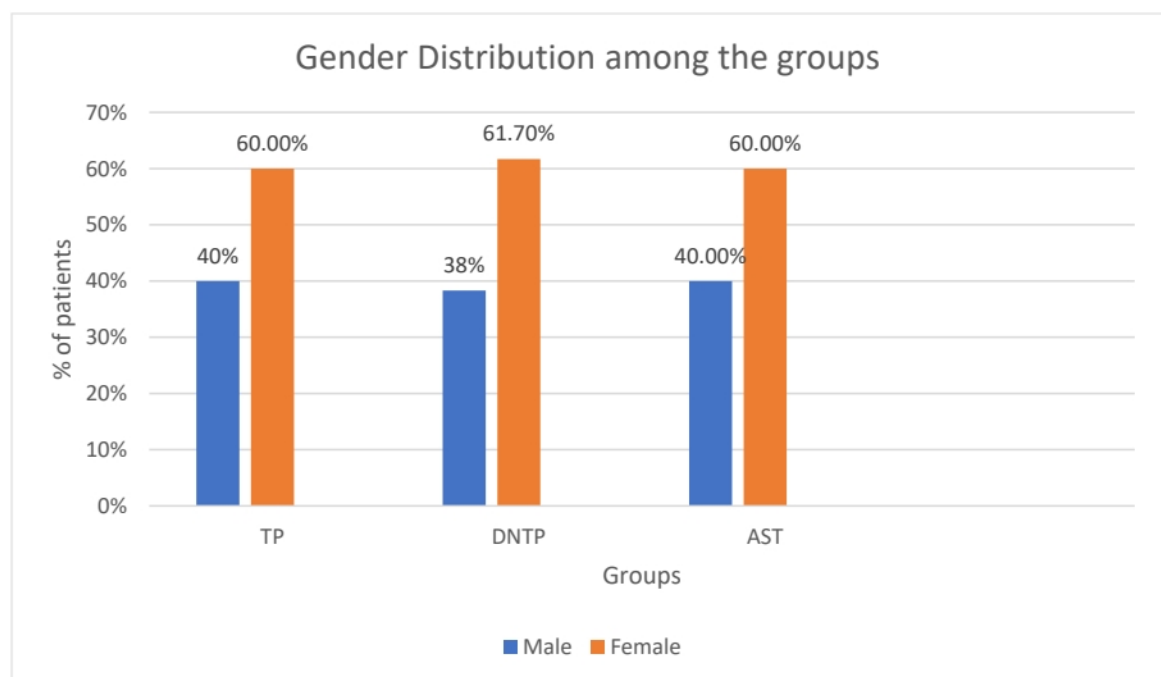


Table 3: Comparison of the first attempt success rate of radial artery cannulation between three groups.

		Groups						P  Value
		Traditional palpation		Dynamic needle tip		Acoustic shadowing		
		Count	Column N%	Count	Column N%	Count	Column N%	
Total number of attempts	First attempt	40	66.7%	40	66.7%	43	71.7%	0.794
	More than one attempt	20	33.3%	20	33.3%	17	28.3%	

The above table shows the comparison of the number of attempts for radial artery cannulation using three techniques. The p-value was calculated using the Chi-square test ( $p = 0.794$ ). It was statistically insignificant, i.e., all three techniques were comparable for the first attempt success rate of radial artery cannulation.

Figure 7: Comparison of the first attempt success rate of RA cannulation between three groups.

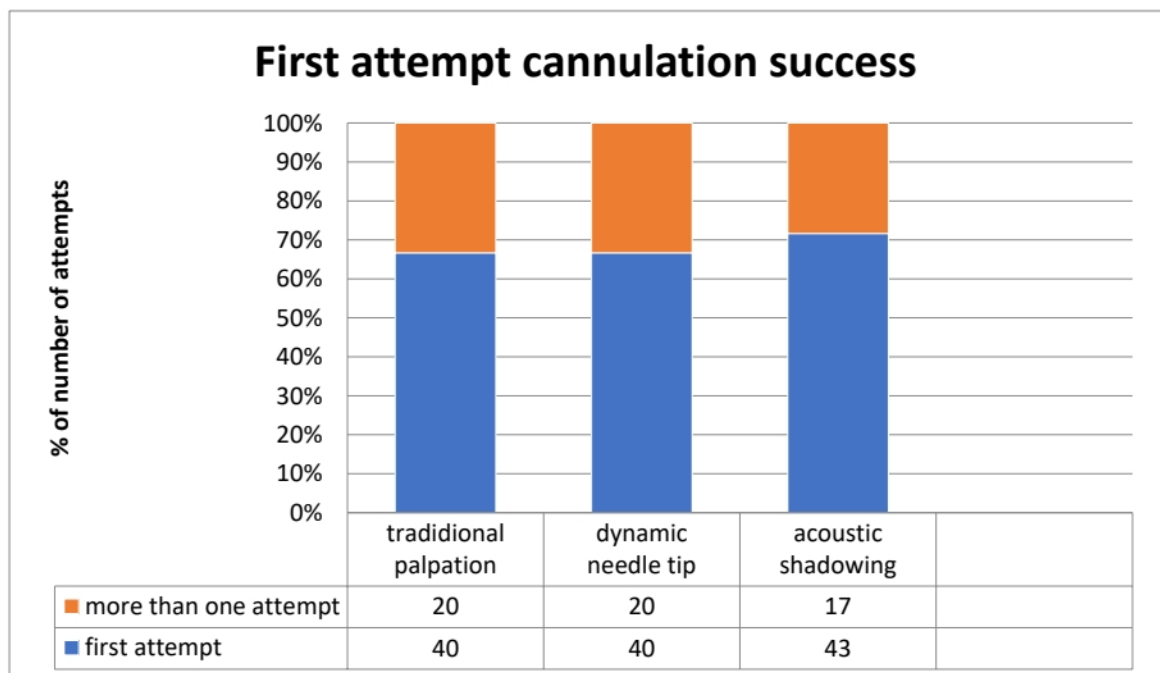


Table 4: Comparison of the total number of attempts for radial artery cannulation between three groups.

		Groups		
		Traditional palpation	Dynamic needle tip positioning	Acoustic shadowing technique
TOTAL NUMBER OF ATTEMPTS	One attempt	40	40	43
	Two attempts	16	15	14
	Three attempts	1	3	0
	Four attempts	1	1	2
	Five attempts	2	1	1

The above table shows the total number of attempts taken for cannulation among the three groups.

Figure 8: Comparison of the total number of attempts for radial artery cannulation between three groups

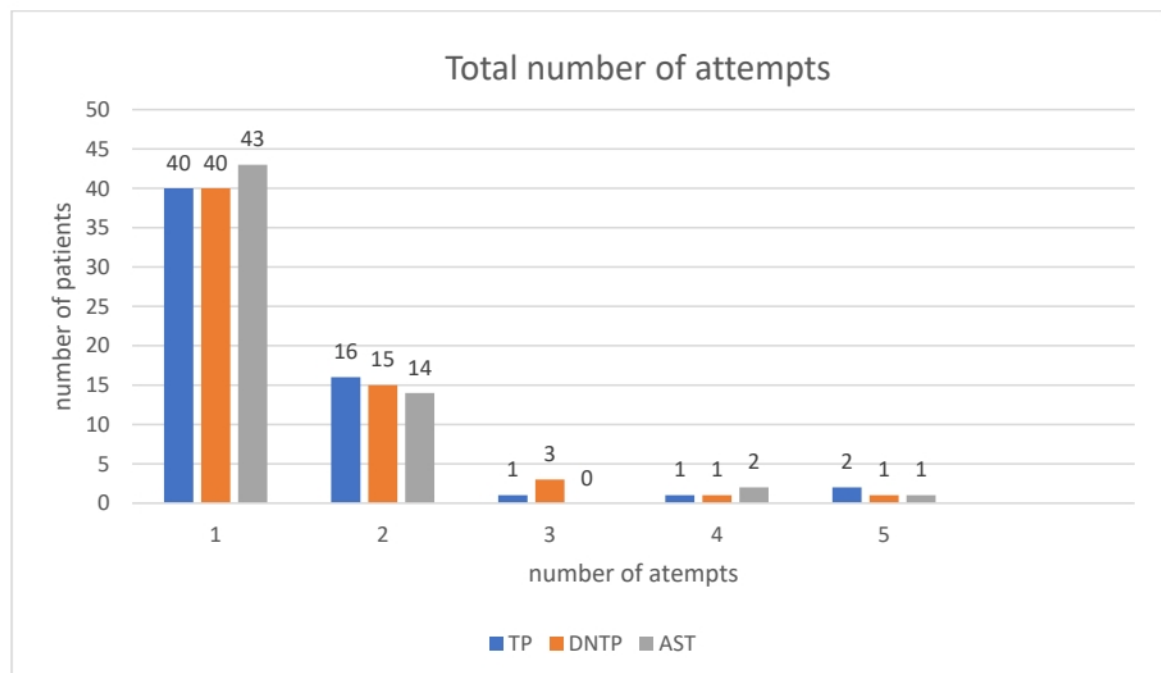


Table 5: Comparison of the median number of attempts taken for radial artery cannulation between three groups

	Groups								
	Traditional palpation			Dynamic needle tip positioning			Acoustic shadowing technique		
	Median	Q1	Q3	Median	Q1	Q3	Median	Q1	Q3
MEDIAN NUMBER OF ATTEMPTS	1.0	1.0	2.0	1.0	1.0	2.0	1.0	1.0	2.0

The above table shows the median number of attempts taken for successful cannulation among the three groups; by Mann Whitney U Test, the p-value is 0.773, which is statistically insignificant.

Figure 9: Comparison of the median number of attempts for radial artery cannulation between three groups.

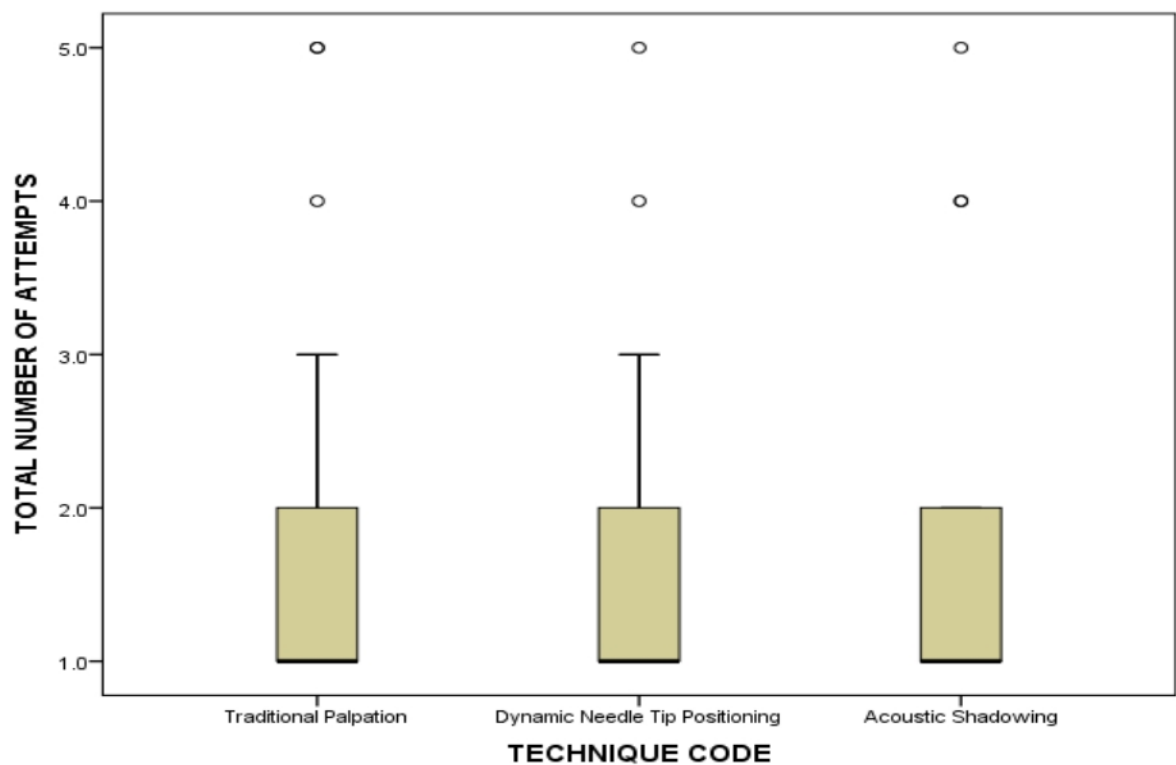




Table 6: Comparison of the time taken for radial artery cannulation between three groups.

Groups									
Traditional Palpation				Dynamic needle tip technique			Acoustic shadowing technique		
	Median	Q1	Q3	Median	Q1	Q3	Median	Q1	Q3
Time for cannulation (Seconds)	60.5	37.0	129.5	71.0	50.0	170.0	108.0	58.0	181.0

The above table shows the comparison of the time taken for cannulation. The median time for radial artery cannulation was statistically insignificant, with a p-value of 0.066 using the Mann-Whitney U Test.

Figure 10: Comparison of the time for radial artery cannulation between three groups.

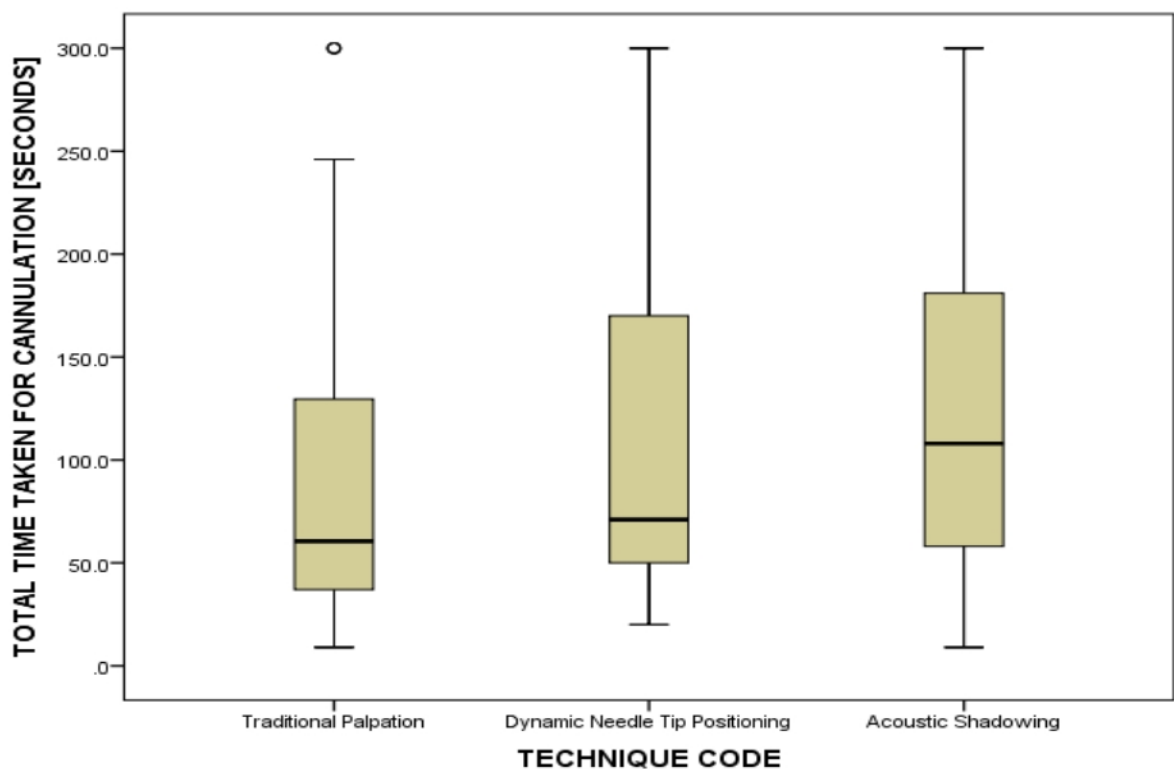


Table 7: Comparison of the Success rate of for radial artery cannulation, at 5 min between three groups

SUCCESS/FAILURE AT 5 MINUTES						
			Groups			Total
			TP	DNTP	AST	
SUCCESS/FAILURE	FAILURE	N	3	1	2	6
		%	5.0%	1.7%	3.3%	3.3%
	SUCCESS	N	57	59	58	174
		%	95.0%	98.3%	96.7%	96.7%
Total		N	60	60	60	180
		%	100.0%	100.0%	100.0%	100.0%

The above table shows the data comparing the overall success/failure rate among the three groups at 5 min. With p value 0.789 using Fisher exact probability test and the Freeman-Halton extension, it shows that it is statistically insignificant.

Figure 11: Comparison of the Success rate of radial artery cannulation, at 5 min between three groups

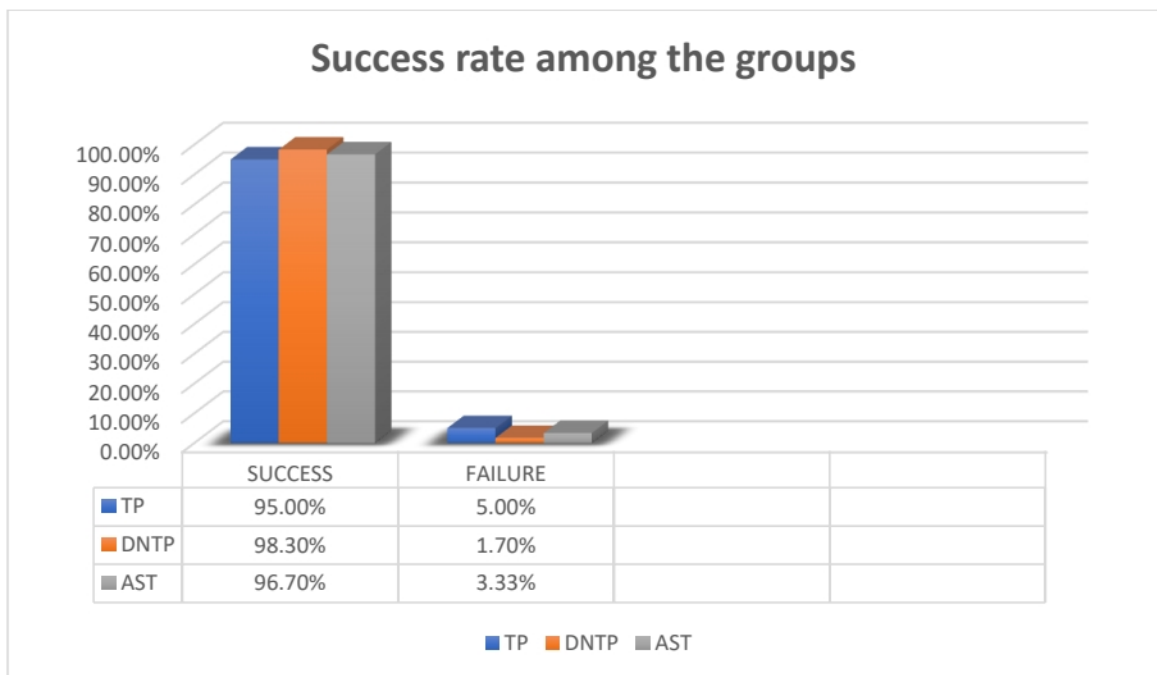


Table 8: Comparison of the total number of cannulas used for radial artery cannulation between three groups.

		Groups						P  Value
		Traditional palpation		Dynamic needle tip technique		Acoustic shadowing technique		
		n	%	n	%	n	%	
The total number of cannulas changed	0	51	85%	53	88.33%	50	83.33%	0.915
	1	8	13.33%	6	10%	8	13.33%	
	2	1	1.66%	1	1.6%	2	3.33%	

The above data shows the number of arterial cannulas used while cannulation using the three techniques. The number of cannulas used was comparable between the three techniques. The p-value was calculated using the Chi-square test ( $p=0.915$ ) and is statistically insignificant, i.e., all three techniques were comparable for the number of cannulas used.

Figure 12: Comparison of the total number of cannulas used for radial artery cannulation between three groups.

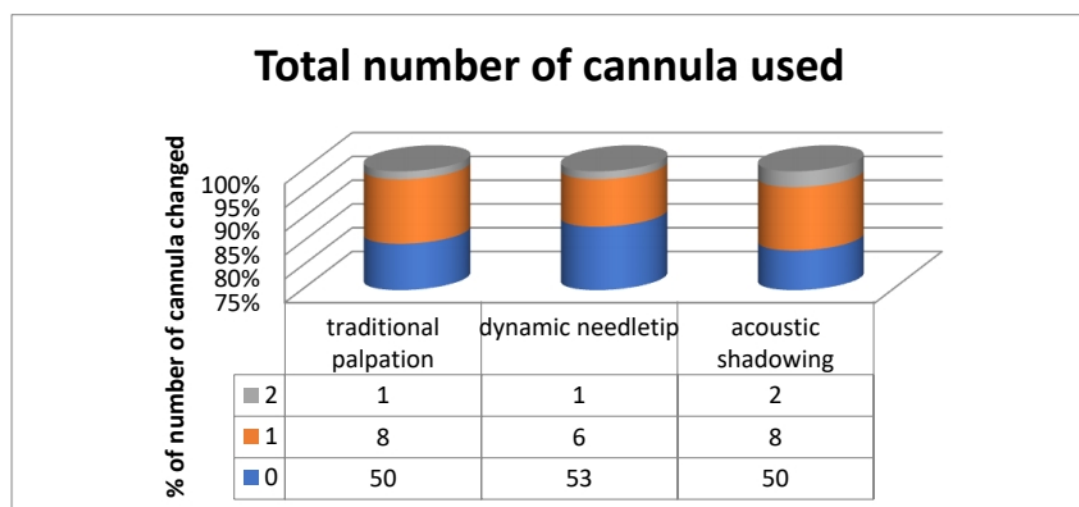


Table 9: Comparison of complications during radial artery cannulation between 3 groups

		Groups					
		Traditional palpation		Dynamic needle tip technique		Acoustic shadowing technique	
		n	%	n	%	n	%
Complications	Hematoma	2	3.33%	0	0.0%	0	0.0%
	Spasm	1	1.7 %	1	1.7%	1	1.7%
	Hematoma and spasm	0	0.0%	0	0.0%	1	1.7%
	None	57	95%	59	98.3%	58	96.7%

The above data shows the complications that occurred while radial artery cannulation using the three techniques.

Figure 13: Comparison of complications during radial artery cannulation between three groups

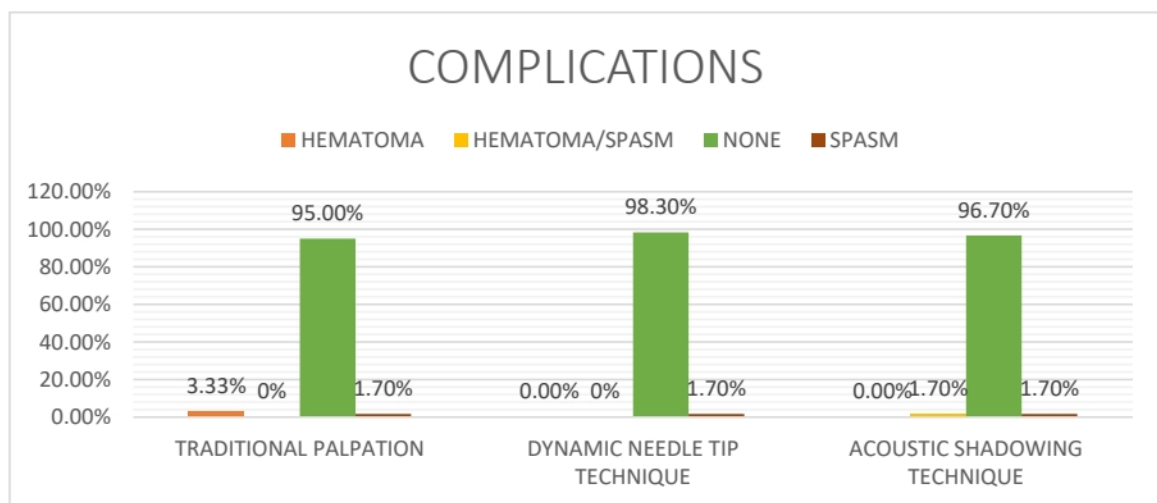
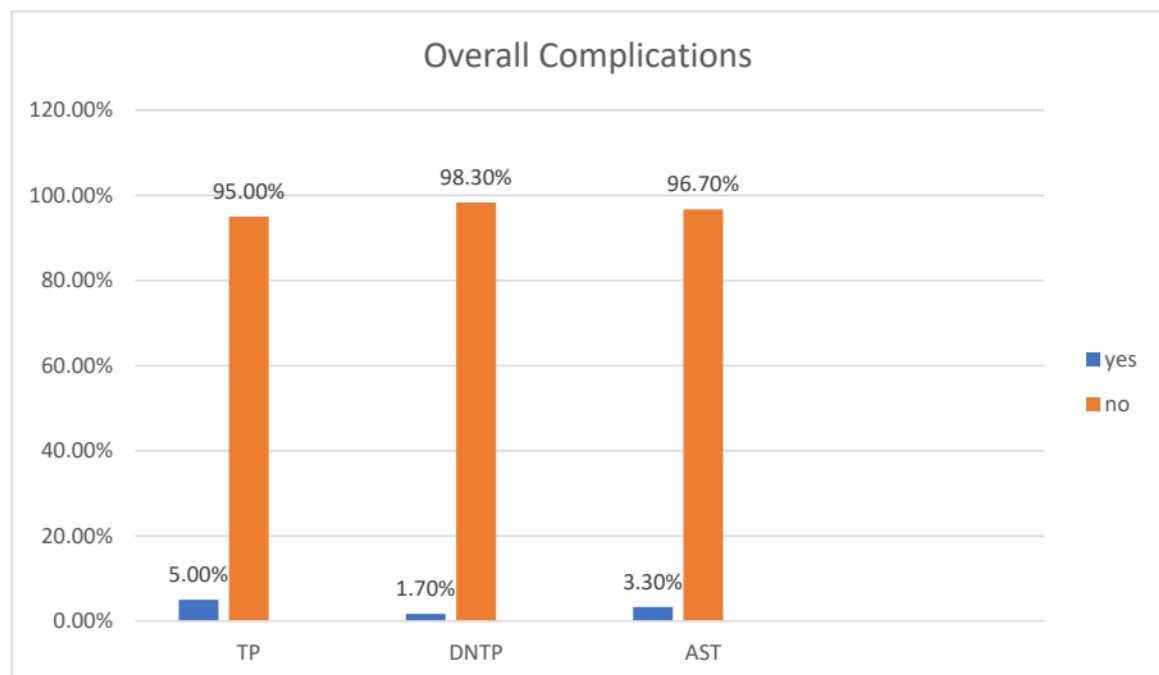


Table 10: Comparison of overall complications during radial artery cannulation between three groups

			Groups			Total
			Traditional palpation	Dynamic needle tip position	Acoustic shadow technique	
COMPLICATIONS	Yes	n	3	1	2	6
		%	5.0%	1.7%	3.3%	3.3%
	No	n	57	59	58	174
		%	95%	98.3%	96.7%	96.7%
Total		n	60	60	60	180
		%	100.0%	100.0%	100.0%	100.0%

The above table shows the comparison of overall complications during radial arterial cannulation among the three groups. With p value 0.789 using Fisher exact probability test and Freeman-Halton extension, it indicates statistically insignificance between the 3 groups.

Figure 14: Comparison of overall complications during radial artery cannulation between 3 groups.



## **DISCUSSION**

There are different methods of arterial cannulation, all of which have their advantages and disadvantages in terms of first attempt success rate, time for cannulation and complications. The common problem in arterial cannulation is the insertion of the cannula through the artery after puncturing because, most of the time, there can be posterior wall puncture, and the cannula tip can pass through the posterior wall. So, the posterior wall puncture can be avoided by USG guided dynamic needle tip positioning technique, where one can visualise the needle tip through the USG and making sure that the tip is inside the artery and not puncturing the posterior wall and the cannula is advanced with the USG making sure the tip is inside the arterial lumen throughout the cannulation time(13,14,16).

The dynamic needle tip technique helps prevent posterior wall puncturing and helps thread the cannula easily(13,14), but a less experienced or trained person with USG may have difficulty in puncturing the artery using USG due to less orientation. This can be achieved by making guide, i.e. acoustic shadows (10,11), which can be created by radio-opaque threads, so that the observer can puncture between the threads after making sure that artery lies between the acoustic shadows.

In the present study, we compared the traditional palpation technique and two new USG techniques, i.e. dynamic needle tip technique and acoustic shading technique for cannulation of the radial artery, most commonly used for invasive blood pressure monitoring. In our study, three groups were comparable for demographic variables i.e. age and sex. The primary outcome of the study was to compare the first attempt success rate between the three techniques of arterial cannulation and secondary outcomes were total number of attempts in 5 minutes, time taken to cannulate, number of cannulas used, and complication related to the procedure (hematoma, bleeding, thrombosis).

The present study comparing for first attempt success rate showed no statistical significance among the three groups with a p-value of 0.794. This is similar to the study by **Cheryl Peters et al.** (15), which showed that the first-attempt success rate was 56.4% in the palpation group and 71.4 % in the USG group with a P value of 0.10. However, **S Bhattacharjee(9) et al.** meta-analysis and **Homam Moussa Pacha et al.** (17), the systemic review showed a significant increase in first attempt success rate in the USG guided technique than in the palpation technique. Furthermore, unlike our study, **ZheFeng Quan et**

*al.* (11) and **Zou et al.** (12) in their study comparing AST and TP techniques showed significant increase in first attempt success rate in AST than in TP group, with a p-value of 0.002 and 0.001, respectively. Contrary to our results, **Kiberenge et al.** (13), **Soo Yeon Kime et al.** (14) and **Liu et al.** (16), comparing DNTP with TP for radial arterial cannulation showed that there was significant increase in first-attempt success rate with a p-value of 0.001, <0.001 and 0.007 respectively. This difference in the first attempt cannulation success can be attributed to the operators experience for arterial cannulation. In the present study, all arterial cannulations were performed by experienced anaesthetists who had performed more than 30 arterial cannulations both by palpation method and ultrasound techniques.

In this study, the total number of attempts required to cannulate the artery was statistically insignificant with a p-value of 0.773 and a median number of attempts was 1 in all the three groups. In this aspect, our study was similar to the study conducted by **Cheryl Peters et al.** (15), who showed that number of attempts for arterial cannulation was 1 [1–2] vs 1 [1–2], respectively, in USG and TP groups (p=0.08). **S Bhattacharjee et al.** (9) in their meta-analysis, showed no difference in the mean number of attempts between palpation and USG guided arterial cannulation. However, there are studies which showed that there is a significant decrease in the number of attempts for arterial cannulation by USG guided cannulation in comparison to palpation method eg. **Kiberenge et al.** (13), **Levin et al.** (18), and **Soo Yeon Kime et al.** (14) with a p-value of < 0.001, 0.003 and <0.001 respectively. This variability in the number of arterial cannulation attempts can be related to the operator's experience with arterial cannulation. All arterial cannulations in this research were conducted by experienced anaesthetists.

In our study, there was no significant difference in time taken for arterial cannulation among the 3 groups, with median time for cannulation among the three groups TP, DNTP, and AST was 60.5 [37.0, 129.5] sec, 71.0 [50.0, 170.0] sec and 108.0 [58.0, 181.0] sec, respectively, (p= 0.066). Our results were similar to the study conducted by **Cheryl Peters et al.** (15), where they showed that there is no difference between the TP vs USG-guided groups for time to arterial cannulation {104 [76–212] sec vs 104 [68–270] sec}, respectively (P = 0.66). Similarly, in a study conducted by **Lynn Zaremski et al.** (19), comparing direct palpation and USG guidance for radial artery cannulation during cardiac catheterisation showed that time to access for artery cannulation was 47 [20-90] sec versus 31 [20-75] sec respectively (p= 0.179). Similar to our results, in a metaanalysis conducted by **S Bhattacharjee et al.** (9) comparing palpation and USG guided radial artery cannulation also

concluded that there was no difference in time to cannulate(  $p = 0.30$ ). Our result was also similar to the study conducted by **Kiberenge et al** (13) where they compared DNTP and palpation method for radial artery cannulation which showed that the median cannulation times were 81.5 (61–122) sec in the DNTP group and 76 (48–175) sec in the palpation group ( $p=0.7$ ). However, our study's result is not similar to the study conducted by **Liu et al.** (16), comparing the DNTP technique and palpation technique for radial artery cannulation which showed that the average time taken for radial artery cannulation in the ultrasound and palpation groups were  $91.4 \pm 55.4$  sec and  $284.7 \pm 153.6$  sec, respectively ( $P < .001$ ). **Soo Yeon Kime et al.** (14) in their study comparing DNTP and palpation method for radial artery cannulation also showed that cannulation time was 42 (32,55) sec in the DNTP group and 53 (36,78) sec in the palpation group ( $P<0.001$ ), which was not similar to our study. Contrary to our result, **Rui Dong et al.** (10) in their study including residents undergoing training, showed that arterial cannulation time in the AST group was significantly shorter than that of the traditional ultrasound-guided group. It can be due to the difference in operator experience between our and other studies. All arterial cannulations in this study were performed by anaesthetists with sufficient expertise.

In the present study, we also compared the overall success rate of cannulation within five minutes, which was also statistically insignificant with a p-value of 0.789. Successful cannulation rates were 95%, 98.3%, and 96.7% among TP, DNTP, and AST, respectively, which was similar to the study done by **Cheryl Peters et al.** (15) which also showed that there was no significant difference for overall success rate between palpation and USG guided techniques. Similar to our study, **S Bhattacharjee et al.** (9) showed that overall cannulation success rate was similar between ultrasound-guided technique and palpation method. However, a study conducted by **Kiberenge et al.** (13) comparing DNTP and TP methods in radial artery cannulation showed that the overall 5 minute success rate was 89% in the DNTP group compared to 65% in the palpation group ( $P < .001$ ), which was not similar to our study. Also, unlike our study, **Liu et al.** (16) in their study showed that the total success rate was 96.7% in the ultrasound group and 60.0% in the palpation group ( $P = .001$ ), but here the study population was neonates unlike adults in our study.

Our study also compared overall complications such as hematoma and arterial spasm, in the 3 groups. The rate of overall complications between the three groups TP, DNTP and AST, were 5.0 %,1.7% and 3.3%, respectively, with a p-value of 0.789, which is insignificant. In our study, there were no complications related to infection/sepsis because the



arterial cannulations were done only for perioperative monitoring of arterial blood pressures, after which the cannula was removed in the postoperative care unit and then the patient was shifted to the ward, so maximum time patient had arterial cannulation was less than 12 hours; hence, the risk of infection was also less. In our study, hematoma and arterial spasms were also less in all three groups. Similar to our study, **Cheryl Peters et al.** (15), **Homam Moussa Pacha et al.** (17) and **Rui Dong et al.** (10) in their study concluded that there was no difference in overall complications between the study groups. Unlike our study, **Soo Yeon Kime et al.** (14) in their study found that hematoma formation was substantially less in the DNTP group 7% vs TP group 24.2%; ( $P < 0.001$ ). Contrary to our result, **Liu et al.** (16), in their study, found that 3.3% of the neonates in the USG group and 26.7% in the palpation group had puncture hematoma ( $P = .026$ ). This difference of complications in various studies can be attributed to the difference in the age group of study population and operator's experience for arterial cannulation.

A 20 G arterial cannula (Becton Dickinson, Sandy, Utah, USA] costs around 564 rupees/unit. During cannulation, if it takes time, cannula may get blocked, and sometime during the threading of the cannula, there are chances that the cannula may get shear off. All these may lead to a change in the cannula, burdening the hospital or the patient. In our study, we also compared the number of cannulas used in all the three groups. We found no significant number of cannulas changed among the three groups during arterial cannulation ( $p = 0.915$ ).

## **Study Strengths and limitation**

To our knowledge, no study has been done to compare radial artery cannulation between three groups, TP, DNTP and AST, for first-attempt success rate, time taken for cannulation, number of cannulas changed and complications. Our study is a randomised trial which included a reasonable number of patients.

It did, however, have certain limitations.

1. The research was conducted in a single centre.
2. With the DNTP approach, needle alignment with the USG beam could be difficult for inexperienced operators.
3. These techniques in emergency settings warrant more research because this study was done in an operating room.
4. In our study, we compared adult patients, where pulse palpation was relatively easy, compared to neonates and infants, where USG may have a role in cannulation. Hence further research for arterial cannulation in these age groups should be carried out (16,21).
5. In our study, we included adult patients who were hemodynamically stable with normal BP; hence further research should be done in patients with hypotension and shock where palpation of the pulse is difficult (22).
6. In our study, the operator, i.e. who did cannulation, were experienced anaesthetist, who had performed more than 30 arterial cannulations both by palpation method and ultrasound techniques. Hence further studies involving operators i.e. residents with less experience in cannulation should be done (10).
7. Here, we used the dynamic needle tip positioning technique and acoustic shadowing technique separately for cannulation, where both have their limitations. So further studies involving both techniques in the same arterial cannulation may increase the first attempt success rate and decrease the time taken for cannulation.
8. Here, we compared all three techniques for cannulation for radial artery cannulation, which is more frequently done. However, other arteries like posterior tibial artery(23), dorsalis pedis artery(23) etc. may be considered in future studies.

9. More studies with larger sample sizes and comparisons with alternative techniques of USG-guided arterial cannulation are needed in the future.

## **CONCLUSION**

The current study compared TP, DNTP and AST techniques for radial artery cannulation by experienced anaesthetists in adult patients for first-attempt success rate, the total number of attempts for cannulation, time taken for cannulation and complications.

Neither of the techniques TP, DNTP or AST, have a higher first-attempt success rate for radial artery cannulation. This means neither of the three techniques has advantages over others with respect to the first attempt success rate in radial artery cannulation.

Also, there is no significant difference in the total number of attempts, time taken for cannulation and complications among the three groups.

Hence, we conclude that USG guided DNTP and AST techniques for radial arterial cannulation in adult patients by experienced anaesthetists do not have any advantages over palpation method.

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## ANNEXURES

### Annexure - 1



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर  
All India Institute of Medical Sciences, Jodhpur  
संस्थागत नैतिकता समिति  
Institutional Ethics Committee

No. AIIMS/IEC/2021/3457

Date: 12/03/2021

#### ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2021/3292

Project title: "Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomized controlled trial"

Nature of Project: Research Project Submitted for Expedited Review  
Submitted as: M.D. Dissertation  
Student Name: Dr. Mruthyunjaya N S  
Guide: Dr. Ankur Sharma  
Co-Guide: Dr. Pradeep Bhatia, Dr. Nikhil Kothari, Dr. Shilpa Goyal & Dr. Kamlesh Kumari

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation. If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

  
Dr. Praveen Sharma  
Member Secretary  
**Member secretary**  
Institutional Ethics Committee  
AIIMS, Jodhpur



**Annexure - 2**

**All India Institute of Medical Sciences Jodhpur, Rajasthan**

**Patient Informed Consent Form (PICF)**

Title of the project: **"Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomised controlled trial"**

Name of the PG Student: **Dr Mruthyunjaya N S.**

Tel. No. : **9449197078**

Patient/Volunteer Identification No. : \_\_\_\_\_

I, \_\_\_\_\_ S/o or D/o \_\_\_\_\_ R/o \_\_\_\_\_

\_\_\_\_\_ give my full, free, voluntary consent to be a part of the study **Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomised controlled trial**" the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand my participation is voluntary, and I am aware of my right to opt-out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by a responsible individual from AIIMS, Jodhpur. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

Date: \_\_\_\_\_

\_\_\_\_\_

Place: \_\_\_\_\_

Signature/Left thumb impression

This is to certify that the above consent has been obtained in my presence.

Date: \_\_\_\_\_

\_\_\_\_\_

Place: \_\_\_\_\_

Signature of Principal Investigator

1. Witness 1

2. Witness 2

\_\_\_\_\_

\_\_\_\_\_

Signature

Signature

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Address: \_\_\_\_\_

### Annexure - 3

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साइंसिस जोधपुर, राजस्थान

#### रोगी सूचित सहमति प्रपत्र

प्रोजेक्ट का शीर्षक: " वयस्क मरीजों में अल्ट्रासाउंड-गाइडेड डायनेमिक नीडल टिप पोजिशनिंग टेक्नीक का अकॉस्टिक शैडोइंग टेक्नीक के साथ रेडियल धमनी का केन्युलेशन: एक यादृच्छिक नियंत्रित परीक्षण"

प्रमुख अन्वेषक: डॉ मृत्युंजय एन एस

टेल. संख्या: 9449197078

रोगी पहचान सं. : \_\_\_\_\_

मैं, \_\_\_\_\_ पुत्र/पुत्री \_\_\_\_\_ निवासी \_\_\_\_\_

\_\_\_\_\_ " वयस्क मरीजों में अल्ट्रासाउंड-गाइडेड डायनेमिक नीडल टिप पोजिशनिंग टेक्नीक का अकॉस्टिक शैडोइंग टेक्नीक के साथ रेडियल धमनी का केन्युलेशन: एक यादृच्छिक नियंत्रित परीक्षण का हिस्सा बनने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति देता हूँ, जिसकी प्रक्रिया और प्रकृति मुझे अपनी भाषा में अपनी पूर्ण संतुष्टि के लिए समझाया गया है। मैं पुष्टि करता हूँ कि मुझे प्रश्न पूछने का अवसर मिला है।

मैं समझता हूँ कि मेरी भागीदारी स्वैच्छिक है और किसी भी कारण के बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार से अवगत हूँ।

मैं समझता हूँ कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्र की गई जानकारी एम्स, जोधपुर से जिम्मेदार व्यक्ति द्वारा देखी जा सकती है। मैं इन व्यक्तियों के लिए अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूँ।

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूँ।

तारीख: \_\_\_\_\_

स्थान: \_\_\_\_\_

हस्ताक्षर / बाएं अंगूठे चिह्न

यह प्रमाणित करने के लिए कि उपर्युक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।

तारीख: \_\_\_\_\_

स्थान: \_\_\_\_\_

प्रधान अन्वेषक के हस्ताक्षर

1. गवाह 1

2. गवाह 2

हस्ताक्षर

हस्ताक्षर

नाम:

नाम:

पता

पता

#### **Annexure - 4**

##### **All India Institute of Medical Sciences Jodhpur, Rajasthan PARTICIPANT INFORMATION SHEET (PIS)**

Title of the project: **"Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomised controlled trial"**

Name of the PG Student: **Dr Mruthyunjaya N S.**

Tel. No.: **9449197078**

I have been explained in my own understanding language by the attending anaesthesiologist that they are comparing the success rate of three different techniques of radial artery cannulation. I may be placed in group P [palpation technique] or group D [Ultrasound guided-Dynamic Needle Tip technique], or [Ultrasound guided-Acoustic Shadow technique] as per the randomisation number, but I will be unaware of the group I belong to. I will participate in this study from the beginning of anaesthesia till artery cannulation by either technique. I will be monitored in the intraoperative and postoperative periods per the hospital's anaesthesia protocol.

If this technique is superior, it will help reduce the number of attempts of artery cannulation, lesser duration of cannula insertion time, and its complications like digital ischemia, haemorrhage, thrombosis, and hematoma formation.

I have been explained that the occurrence of any significant side effects due to the use of the study techniques is extremely rare as both techniques are found to be very safe. I had a chance to go through the literature supporting the safe use of both these techniques in human beings. If any complication does occur, I will be provided free treatment by the hospital. No disability or death is expected from the study. I may withdraw myself from this study at any time, and it will not affect my routine care. The data obtained from me will be used for the purpose of the study only. All my records will be kept confidential. No extra cost and blood samples are required. I confirm that I have had the opportunity to ask questions.

Date: \_\_\_\_\_

Place: \_\_\_\_\_

Signature/Left thumb impression

This is to certify that the above consent has been obtained in my presence.

Date: \_\_\_\_\_

Signature of Principal Investigator

Place : \_\_\_\_\_

Witness 1

2. Witness 2

Signature

Signature

Name: \_\_\_\_\_

Name: \_\_\_\_\_

## Annexure - 5

### ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साइंसिस जोधपुर, राजस्थान रोगी सूचना पत्रक

प्रोजेक्ट का शीर्षक: "वयस्क मरीजों में अल्ट्रासाउंड-गाइडेड डायनेमिक नीडल टिप पोजिशनिंग टेक्नीक का अकॉस्टिक शैडोइंग टेक्नीक के साथ रेडियल धमनी का केन्युलेशन: एक यादृच्छिक नियंत्रित परीक्षण"

मुख्य अन्वेषक: डॉ मृत्युंजय एन एस

टेल. संख्या: 9449197078

मुझे अपनी भाषा में एनेस्थेसियोलॉजिस्ट द्वारा समझाया गया है कि वे रेडियल धमनी केन्युलेशन की तीन अलग-अलग तकनीकों की सफलता दर की तुलना कर रहे हैं। मुझे यादृच्छिकता संख्या के अनुसार, समूह पी [पैलपेटरी तकनीक] या समूह डी [अल्ट्रासाउंड गाइडेड-डायनेमिक नीडल टिप तकनीक] या समूह ए [अल्ट्रासाउंड गाइडेड-अकॉस्टिक शैडो तकनीक] में रखा जा सकता है। लेकिन मैं उस ग्रुप से अनजान रहूंगा। मैं इस अध्ययन में एनेस्थीसिया की शुरुआत से लेकर दोनों तकनीक में से किसी एक के द्वारा धमनी के केन्युलेशन होने तक मैं हिस्सा लूंगा मुझे अस्पताल के एनेस्थीसिया प्रोटोकॉल के अनुसार दोनों अंतःक्रियात्मक और इसके पश्चात की अवधि में निगरानी में रखा जायेगा।

यदि इस तकनीक को बेहतर पाया जाता है, तो यह धमनी केन्युलेशन के प्रयासों की संख्या, केन्युलेशन समय की अवधि और साथ ही यह डिजिटल इस्केमिया, रक्तस्राव, घनास्त्रता और हेमटोमा गठन जैसी जटिलताओं को कम करेगा।

मुझे समझाया गया है कि इन अध्ययन तकनीकों के उपयोग के कारण किसी भी महत्वपूर्ण दुष्प्रभाव की घटना अत्यंत दुर्लभ है क्योंकि दोनों तकनीकों को बहुत सुरक्षित पाया गया है। मुझे इन दोनों तकनीकों के मानव में सुरक्षित उपयोग का समर्थन करने वाले साहित्य को जानने का मौका मिला। यदि कोई जटिलता होती है, तो मुझे अस्पताल द्वारा मुफ्त उपचार प्रदान किया जाएगा। अध्ययन से कोई विकलांगता या मृत्यु होने की सम्भावना नहीं है। मैं किसी भी समय इस अध्ययन से खुद को हटा सकता हूं और यह मेरी नियमित देखभाल को प्रभावित नहीं करेगा। मुझसे प्राप्त डेटा का उपयोग केवल अध्ययन के उद्देश्य के लिए किया जाएगा। मेरे सभी रिकॉर्ड गोपनीय रखे जाएंगे। कोई अतिरिक्त लागत और रक्त के नमूने की आवश्यकता नहीं है। मैं पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है।

तारीख: \_\_\_\_\_

स्थान: \_\_\_\_\_

हस्ताक्षर / बाएं अंगूठे चिह्न

यह प्रमाणित करने के लिए कि उपर्युक्त सहमति मेरी उपस्थिति में प्राप्त की गई है।

तारीख: \_\_\_\_\_

स्थान: \_\_\_\_\_

प्रधान अन्वेषक के हस्ताक्षर

1. गवाह 1

2. गवाह 2

हस्ताक्षर

नाम:

पता

हस्ताक्षर

नाम:

पता

**Annexure - 6**

**Proforma**

S.No.

Date:

**Thesis Title: Comparison of two ultrasound-guided techniques (dynamic needle tip positioning and acoustic shadowing) with conventional palpation technique for radial arterial cannulation in adult patients: a randomised controlled trial**

IPD Serial no/Sticker:

Observer: Name:

OT number:

Surgery/procedure:

Technique: Traditional Palpation/Dynamic needle tip /Acoustic shadowing.

Start time:

Number of times the cannula off from the skin:

Number of cannulas changed:

End Time (when the free flow is established in the cannula):

Total time taken for cannulation:

Total number of attempts:

Complications, if any, observed:

Result of canalising the selected artery (after 5 min): successful/failure

Remarks, if any, from the observer:

