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Original Research Article

Comparative evaluation of safety and efficacy of radial arterial cannulation using conventional blind palpation technique with ultrasound guided Technique perioperatively - Raccuet study

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Abstract

Introduction: Radial cannulation is needed in perioperative management of many patients requiring invasive hemodynamic monitoring during surgery and may be not only time consuming and at times difficult to attain in untrained centers.

Objectives: Comparative evaluation of safety and efficacy of Radial Arterial Cannulation using Conventional blind palpation technique with Ultrasound guided Technique perioperatively – *Raccuet Study*.

Materials and Methods: This randomized controlled, prospective, single blind comparative study was conducted on 142 adult ASA I to IV patients of either sex, scheduled for elective major surgery requiring general anesthesia of which 71 patients underwent radial cannulation by classical palpatory method (group P) and the other 71 underwent radial cannulation under ultrasound guidance (Group U). All procedures were evaluated using Siemens *Acuson X500 ultrasound* machine with 5-13Hz linear array transducer. All patients were evaluated for efficacy by measuring time to cannulation (TTC), mean time to first attempt cannulation (mTFA), and number of attempts for cannulation (NA). Safety was assessed by evaluating incidence of hematoma and spasm in both the groups. Statistical analysis was done using (SPSS) Version 22.0. Independent t test and Mann Whitney test have been used for carrying out significant P value.

Results: Patients were demographically similar in both the groups. TTC in group U (37.97±18.14sec) was significantly less than that in Group P (58.38±21.45sec) (P =0.007).mTFA was 34.81±15.77 seconds in group U compared with 55.58±19.29 seconds with group P (P=0.01). There was trend towards lower NA in group U as compared to group P (P=0.06).Incidence of hematoma formation and vasospasm were similar amongst both groups but study was underpowered to evaluate the same.

Conclusion: Ultrasound guided radial artery cannulation improves the success rate of cannulation in lesser time with similar complication rates as compared to classical palpatory method of cannulation.

Introduction

Continuous blood pressure monitoring via radial artery cannulation along with easy access for blood sampling can provide the clinician with vital information in the perioperative period.[1] The consistent anatomic accessibility, ease of cannulation and a low rate of complications make the radial artery the preferred site for arterial cannulation.[1,2] Indications for arterial cannulation include continuous blood-pressure monitoring, frequent arterial blood-gas analysis, repeated blood sampling for laboratory evaluation.[3]

Traditionally, radial artery cannulation has been performed using anatomic knowledge and pulse palpation as a guide to placement.[3] However, patients requiring arterial lines may be hypotensive or obese, resulting in difficult palpation of the pulse and also the catheter may not be passed successfully into the artery, despite apparent good blood return on initial puncture, or the artery may develop spasm after a failed attempt, thus making any further attempts more difficult.[3]

Ultrasound (US) is being used with increasing frequency as an adjunct in vascular access. Numerous studies have shown that US guidance for central venous access provides significant benefits over the traditional external landmark technique but little has been published on the use of US guidance for radial artery catheter placement.[3,6] Despite increased access to ultrasound machines, fewer clinicians are familiar with ultrasound-guided techniques of arterial catheterization. Ultrasound-guided arterial catheterization can be easily learned if the operator has familiarity with other ultrasound-guided procedures.[2] We sought to evaluate the application of US guidance to radial-arterial cannulation to determine whether it offers advantages over the traditional palpation technique or not.

The efficacy primary end point of the study was defined as measuring time to cannulation (TTC), mean time to first

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attempt cannulation (mTFA) and the number of attempts for cannulation (NA). Secondary endpoints were safety end points defined as amputation, spasm or hematoma formation.

Materials and Methods

This study was conducted on 142 adult ASA I to IV patients of either sex, scheduled for elective major surgery requiring general anesthesia between period of January 2016 to December 2016 at IKDRC, B. J. Medical college, Ahmedabad. After approval by the institutional ethics committee, written informed consent was obtained from all the patients. The study adhered to Helsinki declaration and GCP (good clinic practice) and WHO guidelines. Patients with local site skin inflammation, negative Allen's test, cardiac anomalies (congenital heart diseases, Coarctation of aorta, transposition of great vessels) were excluded from the study. Patients with negative Allen's test were not included in the study. Since the exclusion was prior to randomization hence it did not influence the statistical outcome. Cardiac patients were excluded to preserve the radial artery for subsequent radial cannulation for cardiac catheterization if needed and so also due to their altered hemodynamics. Patients were divided randomly by the sealed envelope technique into two equal groups of 71 patients each.

Group U comprised of patients whose radial artery was cannulated under USG guidance.

Group P comprised of patients whose radial artery was cannulated blindly by conventional palpatory method.

All patients were kept fasting for solid food for 6 hours. In the operating room, an intravenous infusion was started and electrocardiography, pulse Oximetry, non-invasive blood pressure monitors was applied and baseline vital parameters were noted in the form of heart rate, oxygen saturation and blood pressure. Balanced general anesthesia was given to all patients. Positioning of hand in which radial artery cannulation to be done was given by keeping the hand outstretched and supine and slight extension of wrist which was obtained by keeping a 100ml pint below the wrist of the patient and the hand was fixed. (Fig. 1) All USG guided cannulations were performed on Siemens Acuson X500 ultrasound machine with 5-13Hz linear array probe for group U patients. Acquisition imaging and display settings were preset at a lowest depth penetration of 2 cm. After proper antisepsis radial artery was localized in the axial plane by holding the probe perpendicular to the course of the artery for longitudinal course localization. The artery is visualized as echo lucent structure that pulsates on mild compression. The artery was aligned with the centerline guide on the display by appropriately moving the probe. The addition, color Doppler sector should demonstrate phasic blood flow in either the short axis or the long axis orientation. The real-time guided insertion of the catheter (with or without a guide wire) was preferred over a skin-marking static imaging technique. The non-dominant hand of the operator holds the ultrasound transducer, while the dominant hand holds the arterial catheter. The catheter-needle system was inserted at an angle of 30^0-45º to the skin and was advanced under ultrasound guidance, with angulation being readjusted if needed to make the needle is advanced towards the artery till the needle pierced the artery wall till subsequent pulsatile back flow of the blood was seen in the needle which was followed by catheter insertion and securing it in the position. An independent observer was assigned to record time with a stopwatch measuring how long the anesthetist took to achieve the successful placement.

In the Ultrasound (US) group, starting time or time zero was defined the point of time at which the sonography probe was placed on the wrist to visualize the artery. For the blinded approach control arm, the time zero was defined as the time at which the anesthetist's fingers were placed on the wrist to palpate the radial pulse to attempt the radial puncture for the needle placement. The point of time of the placement was considered the moment at which the cannula was successfully placed, with appropriate pulsatile back blood flow was seen. The study used radial sheaths from Medtronic and Terumo Inc.

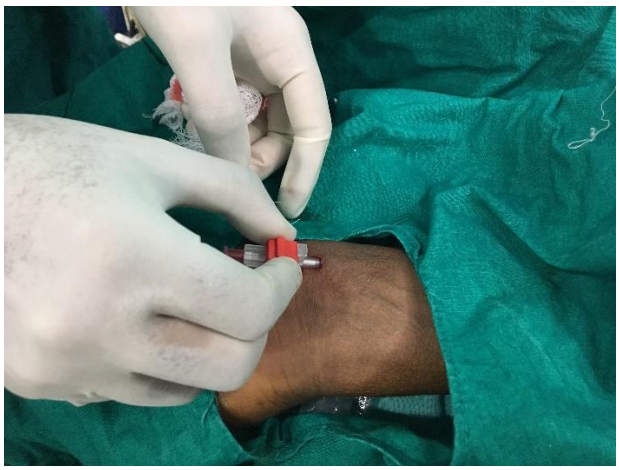

Fig. 1

Statistical Analysis

Sample size calculations were based on observations of the time required for arterial cannulation. All patients were evaluated for efficacy by measuring time to cannulation (TTC), mean time to first attempt cannulation (mTFA) and the number of attempts for cannulation (NA). A sample size of greater than or equal to 71 would give the study of a power 80% with 5% level of significance was calculated based on previous other studies and our own pilot study. The sample size was calculated using primary endpoints of TTC and mTFA as dependent variable from our pilot sample using formula -

$$\text{Sample Size} = \frac{Z^2 * (P) * (1-P)}{C^2}$$

Where, Z = Z value, p=percentage picking a choice in decimals and c=confidence interval in decimals. The selection bias of the unblinded observer was nullified since the measurement of parameters was predefined in terms of zero time for both the groups.

All collected data were entered into SPSS V22. Continuous data were expressed as mean ± SD. Continuous data follow parametric and non parametric data. Independent

t test and Mann Whitney test have been used for carrying out significant P value. Non-continuous data are countable and are expressed in frequency or in percentages. Chi square test and Fischer exact test have been used for carrying out significant P value. P value < 0.05 is considered to be statistically significant.

Results

The study was done to compare safety and efficacy of radial arterial cannulation using conventional blind palpation technique with ultrasound guided technique. It included 142 patients of ASA physical status I to IV, aged 18 years to 60 years, undergoing major surgeries like robotic renal transplant, open renal transplant, liver transplant, radical cystectomy, adrenelectomy etc. and divided into two groups, 71 patients in each group. Patients were demographically similar in both the groups and baseline vital parameters in the form of heart rate and blood pressure were comparable in both the groups without any significant difference as elucidated in Table 1(p> 0.05).

Efficacy parameters as measured are shown in Table 2 and show that TTC in group U (37.97±18.14sec) was significantly less than that in Group P (58.38±21.45sec) (P = 0.007).mTFA was 34.81±15.77 seconds in group U compared with 55.58±19.29 seconds with group P (P= 0.01).There was trend towards lower NA in group U as compared to group P (P=0.06).Incidence of hematoma formation and vasospasm were similar amongst both groups but study was underpowered to evaluate the same.

Discussion

Our study compared ultrasound guided radial artery cannulation against the traditional blind technique. Patients in our study were demographically similar in both the groups (Table 1). There were no statistically significant variations regarding age, gender, and body weight and body mass index. All patients had surgical procedures like renal transplant, liver transplant, radical cystectomy, robotic renal transplant requiring arterial cannulation for various reasons. We found that time required for radial artery cannulation using ultrasound guidance (37.97±18.14sec) was significantly less than the conventional palpatory (58.38±21.45sec) method which is similar to data from Stephen shiver[3] et al study in 2006 which compared ultrasound with traditional palpatory technique for radial artery cannulation for 30 patients in each group respectively. K Ueda[4] et al and Amina nasreen[5] et al also had similar results who had significantly less time for ultrasound guided cannulation as compared with palpatory method. This supports the role of ultrasound guided cannulation to reduce the time to radial cannulation and also number of attempts needed to cannulate radial artery in emergency scenario perioperatively. Also we compared the duration of first successful attempt in both the groups in which ultrasound guidance had significantly less duration than palpatory method. Another study by Amina Nasreen[5] et al had duration of 72.4±23.0 seconds in ultrasound group against 94.6±13.7 seconds in palpatory group for 1st successful attempt. This clearly elucidates that the time taken in our study was much lesser than this study Ariel L Shiloh[2] et al did systematic review and meta-analysis of ultrasound guided catheterization of radial artery in 2011 with 152 subjects in palpation group and 159 in ultrasound guided group. They concluded that ultrasound guidance for arterial catheterization was associated with a 71% improvement in the likelihood of first attempt success. The numbers of attempts needed for successful cannulation were less in ultrasound group as compared to palpation technique however the difference was not statistically significant. Amina nasreen[5] et al had similar results but other studies like shiver et al[3] and ueda[4] et al had significantly lesser numbers of attempts in ultrasound group. The reason our difference was not significant may be our sample size was smaller relatively or the inserters in their study may be more skilled with ultrasound method of cannulation. Our study is the first to our knowledge study conducted in India in similar fashion with similar results. This study is similar to other studies in terms of the outcome but also shows that TTC and mTFA were much shorter than other studies.

As ultrasound is newer modality, it takes time to acquire skills for its usage. It becomes necessary to practice as much with the machine and get used to it to obtain good results over the traditional methods. In this study ultrasound guidance was successful more frequently and took less time to establish the arterial line as compared with palpation group.

Table 1: Age, sex, weight, ASA, BMI data of both the groups

	Group U (N=71)	**Group P (N=71)**	**P-value**
Age(years)	39.82±13.24	40.45±14.78	0.79 (NS)
Male	53 (74.65%)	52 (73.24%)	
Female	18 (25.35%)	19 (26.76%)	0.84 (NS)
Weight(Kg.)	54.32±11.21	54.27±10.94	0.98 (NS)
ASA grade	3.38±0.57	3.27±0.68	0.38 (NS)
BMI($kg/m^{2)}$	22.19±2.47	22.37±2.19	0.77 (NS)

As per the table, both the groups were comparable with respect to age, gender, and weight and body mass index without any significant difference (p > 0.05)

Table 2: Comparison of Number of attempts, time to cannulation (TTC), mean time to first attempt cannulation (mTFA)

	Group U	**Group P**	**P value**
No. of attempts	1.13±0.38	1.37±0.78	0.06 (NS)
Time to cannulation (sec.)	37.97±18.14	58.38±21.45	<0.007
Mean time for 1st attempt (sec.)	34.81±15.77	55.58±19.29	<0.01

The rate of complications seen in this study, with ultrasound machine is less in the form of hematoma seen in 4 of 71 patients and 8 of 71 patients and also spasm encountered in 2 patients in palpation group and none in usg group. As the cannula was passed under vision in ultrasound group leading to lesser incidence of hematoma which can further compromise blood supply to the hand and thereby it becomes safer technique. K Ueda[2] et al had 29 of 256 cases of complications in the form of hematoma and ischemia against 27 in 259 cases of ultrasound group supporting our study. Although the difference was insignificant but this can further become significant when the operators become more skilled with the use of ultrasound probe for arterial cannulation.

Conclusion

The RACCUET study found that ultrasound significantly decreases the time taken for successful cannulation and also reduced time for successful cannulation in first attempt. The numbers of attempts with ultrasound were less than blind method, however the difference was insignificant. Incidence of hematoma formation and vasospasm were similar amongst both groups but study was underpowered to evaluate the same.

The ultrasound offers better efficacy for radial artery cannulation compared with blind technique which improves the success rate of cannulation in lesser time with fewer complications.

Limitations

This was single center study assessing only immediate and short term outcomes and did not attain significance in certain parameters.

Conflict of Interest: None.

Source of Funding: None.

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