Original Article

Supraclavicular or infraclavicular subclavian vein: Which way to go- A prospective randomized controlled trial comparing catheterization dynamics using ultrasound guidance

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ABSTRACT

Background and Aims: Subclavian vein (SCV) catheterization via the supraclavicular (SSV) or infraclavicular (ISV) approaches under real time ultrasonographic (USG) guidance is being performed routinely in critically ill patients in ICU. The aim of this study is comparative evaluation of SSV and ISV approaches in terms of success rate, time taken and incidence of complications.

Settings and Design: In this prospective study, 110 critically ill patients were randomly divided into two groups of 55 each. Right SCV catheterization was performed using real time USG by single experienced operator.

Methods: Success rate, first attempt success rate, time taken for venous visualization, puncture, catheterization, total procedure, incidence of mechanical, and infectious complications were variables used for comparison among groups.

Statistical Analysis Used: Normality tests were performed using the Kolmogorov-Smirnov test. All data are expressed as the mean (SD), number (%), or median [interquartile range (IQR)] as indicated. Data were compared using the $\chi^2$ test, the Mann–Whitney U-test, Fisher’s exact test and Student’s $t$-test as appropriate.

Results: Total procedural time was significantly lesser in SSV group than ISV group ($P < 0.0001$). Time for visualization, puncture and catheterization were significantly higher in ISV group ($P < 0.001$). Success rate was 100% in both groups. First attempt success rate was more in SSV ($P = 0.171$). Two incidence of malposition was found in ISV group. Infectious complications were comparable in both groups. Conclusions: Real time USG-guided supraclavicular subclavian approach is a viable and preferable alternative with significantly lesser total procedural time, similar success rate, fewer attempts, faster and lesser complication rates as compared with infraclavicular approach.

Key words: Catheterization, infection, subclavian vein, ultrasound

INTRODUCTION

Central venous catheterization (CVC) is an integral and routine part of modern era in critically ill patients in Intensive Care Unit (ICU) and it serves both invasive monitoring as well as therapeutic purposes. Infraclavicular approach of subclavian vein is the ‘traditional’ and routinely practiced technique but the literature describes that supraclavicular approach too has some distinct advantages. Supraclavicular approach to subclavian vein is a feasible route of central venous access and is reported to have with high success rate and safety record.[1] As with other procedure, ultrasound (US) use in venous access has resulted in with fewer needle passes and lesser...
complication rates when compared to classical landmark technique.\textsuperscript{[2,3]} Use of ultrasound was studied in supraclavicular route and has high catheterization success rates.\textsuperscript{[4,5]}

However, to date, information regarding their comparative efficacy in adult Indian population is limited. There has been very little data reported from critically ill adult Indian patients in ICU in terms of success rate, procedural time, mechanical and infectious complications of the two modes of subclavian venous catheterization using USG guidance. Therefore, an attempt was made to compare the advantage and difficulties of subclavian venous catheterization using supraclavicular versus infraclavicular approach under real time ultrasound guidance. Total procedural time was taken as primary outcome. Secondary outcomes were success rate, first attempt success rate, venous visualization time, venous puncture time, catheterization time, mechanical and infectious complications.

**METHODS**

This prospective, hospital based, randomized, comparative study was conducted on 110 critically ill patients requiring CVC insertion after obtaining institutional ethical committee approval and registration at Clinical Trial Register India (CTRI), at ICU (Trauma and Surgical) in Department of Anesthesia and Critical Care, Dr. S.N. Medical College and Associated group of Hospitals, Jodhpur (Rajasthan). Written informed consent from patient’s relative was obtained. Enrollment, recording of the baseline information and randomization was done immediately after written informed consent. The 110 patients who had been admitted to trauma or surgical ICU for intensive management whether mechanically ventilated or not of age group 20 to 80 years were randomly assigned to two groups of 55 each: Group SSV, in which CVC was inserted in subclavian vein through supraclavicular approach, and Group ISV, where CVC was passed through infracavicular approach. Randomization was done by computer generated number. The allocations were concealed in sequentially numbered, sealed, opaque envelopes.

Those patients who were having coagulopathies, patient on anticoagulants, distorted chest anatomy, superior vena cava syndrome, infection at the cannulation site, pregnant patients, patients with obvious source of infection (fever, pneumonia, urinary tract infection, cellulitis, septicemia by history, clinical examination, blood culture, chest X-ray, urine examination etc., and relevant investigations pertaining to the suspected infection), patients having infective endocarditis, retroviral disease and on immunosuppressive drugs were excluded. A triple lumen (16 G, 18 G, 18 G) 16 cm long CVC (TRACE CVC Kit TCVCTK 3-7-16 NI, alspl) was used in all the patients. The US machine used was ACUSON X300 portable ultrasound system, premium edition. A linear vascular probe was used to localize the vein.

**Position, preparation and technique**

We preferred right subclavian vein because of straight pathway of superior vena cava and absence of thoracic duct. All patients were placed in supine position with 20-30° Trendelenburg tilt to distend the veins and to minimize accidental air embolism. The head was turned to contralateral side. The right arm was pulled down gently towards the knee.\textsuperscript{[6]} For better visualization and to maintain good ergonomics, the ultrasound machine was placed on the left side of the patient while operator stood at the right side of the patient. Flushing of central catheters, needle and dilator with heparinized saline was done prior to placement to avoid air embolism and blood cloting. After proper positioning, cleaning and draping using all aseptic precautions as described above, a linear vascular transducer (frequency 5-13 Hz) of the USG machine was used to obtain a 2D image display. Transducer wrapped in sterile sheath with ultrasonic gel, was placed at the appropriate level to visualize the vein. Compressibility of the vein and visible pulsations of the artery were observed in all patients. The Doppler profile across the vessel showing a continuous flow pattern was checked in all patients. Local infiltration was done at the puncture site with 3-5 ml of 2% lignocaine. After proper sterile preparations, USG probe was kept in neck area and IJV was traced down the neck and after reaching the IJV-SV junction in supraclavicular area, the probe was turned laterally to visualize the SCV and the brachiocephalic vein in long axis and Doppler profile checked [Figure 1]. For infracavicular approach, US probe was kept on the chest wall below the clavicle to get clavicle cranially and subclavian vessels in long axis view caudally [Figure 2]. In both approach, for obtaining the best longitudinal view of subclavian vein, the US probe was slightly rotated and tilted with the subclavian artery in view.
The needle was introduced in plane under real time USG guidance and the needle tip was visualized till it entered the vein and a free aspirate of blood was obtained in the syringe. Although no separate pleura view was made; the needle was always advanced slowly, taking note of the lung pleura underneath the vessels. If needle visualization was lost, needle advancement was stopped, withdrawn slightly and re-visualized before proceeding. Using supraclavicular view, guide wire was demonstrated in the subclavian vein entering the brachiocephalic vein in both approaches [Figures 1 and 2].

Catheterization was completed using Seldinger method. Catheter was sutured with 2.0 sterile silk. Sterile transparent dressing was applied. The use of topical antibiotic ointments or creams at the insertion site was avoided.

More than two attempts were taken as a failure. Successful aspiration of blood in the first attempt without withdrawing the needle at any stage during its advancement was defined as single attempt and two attempts were defined as multiple attempts. Venous visualization time was defined as the time taken from the point of placing the US probe over the skin to the point where a clear image of the subclavian vein was obtained. Venous puncture time was the duration of time between the initial skin puncture to the aspiration of blood from the subclavian vein through the needle. Catheterization time was the time taken from the point of aspiration of blood through the needle to the point of successful aspiration of blood from the catheter. Total procedural time was the time taken from the point of placing the ultrasound probe over the skin to the point of successful aspiration of blood from the catheter not including time taken for suturing and fixation. Mechanical complications such as catheter malposition, arterial puncture, hematoma formation, pneumothorax and hydrothorax were noted. Catheter malposition defined as position of the tip of the catheter anywhere within 2 cm from the superior vena cava – right atrium junction or in the upper right atrium. Post-procedure chest x-ray was done for catheter tip position, kinking or any malposition and repositioning, if necessary.

All patients were followed up daily and the CVC insertion site was examined for purulence or soiling. Hand hygiene procedures were strictly followed (even when gloves were worn) before and after injection, blood sampling, dressing or any contact with the CVC or insertion site. If catheter tip colonization/infec- tion or catheter-related bloodstream infection (CRBSI) was suspected, the CVC was removed and the tip of the catheter along with two sets of blood was sent for culture analysis. CVC was inspected for the presence of infection until removal of catheter. Catheter tip colonization was defined as growth of more than 15 colony forming units on culture of the distal segment of the CVC with or without clinical signs of infection. CRBSI was defined as isolation of the same organism from the catheter tip culture and at least one of two blood cultures, along with signs and symptoms of infection. Catheter tip culture and blood culture were sent for microbiological evaluation whenever catheter tip infection was suspected, after recovery or death. Patients were followed up for any new onset fever, total parenteral nutrition infusion, blood transfusion after catheterization. If the patient recovered, discharged or expired, CVC was removed and sent for culture.
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Statistical analysis
Sample size estimations were performed in accordance with data from a pilot study performed in 20 patients, in which the mean puncture times [standard deviation (SD)] were 54 (60) s and 102 (88.2) s in the SC and IC groups, respectively. We estimated that a random assignment of 98 subjects was required to provide a 0.6 effect size, with 80% power at the 5% significance level, and taking into consideration possible 10% loss of study participants. Statistical analyses were performed using SPSS 22.0 (SPSS, Inc., Chicago, IL, USA). Normality tests were performed using the Kolmogorov–Smirnov test. All data are expressed as the mean (SD) [range], number (%), or median [interquartile range (IQR)] as indicated. Data between the groups were compared using the $\chi^2$ test, the Mann-Whitney U-test, Fisher’s exact test and Student’s t-test as appropriate. Statistical significance was defined as $P < 0.05$.

RESULTS

Two patients, who had catheter malposition, were excluded from statistical analysis of catheterization and total procedural time. The demographic parameters such as age and sex were comparable between the two groups [Table 1]. Total procedural time (mean ± SD) was lesser in SSV group than ISV group (177.92 ± 12.46 vs 199.66 ± 18.53 seconds with 95% CI) respectively and the difference was statically significant. Success rate of catheterization was 100% for both SSV and ISV group [Figure 3]. No failure was found in either group.

First attempt success rates were found to be higher in the SSV group when compared to ISV groups although the difference was not statistically significant ($P$ value = 0.357). Venous visualization time was significantly higher in ISV group than SSV group [Table 2]. The puncture time in SSV was significantly short compared to the ISV approach. There was significant difference in catheterization time. There were two incidences of catheter malposition in ISV group. Both CRBSI and catheter tip colonization were included as infectious complications and were more in SSV group although the difference was not statistically significant. There was no statistically significant difference in the catheter tip colonization with positive blood culture, catheter tip colonization with negative blood culture, only blood culture positive among both groups [Figure 4]. CRBSI was found in two members of each group and was statistically insignificant. Statistically insignificant incidence of positive catheter tip culture was seen in SSV group. The most common organism isolated in catheter tip colonization was Klebsiella (38.10% in SSV and 37.5% in ISV) in both groups. Other organisms were Pseudomonas, Acinetobacter, CONS, E. Coli, GPB, Staph. Aureus. The difference was statistically nonsignificant. The most common organism isolated in blood culture was Klebsiella followed by Pseudomonas and Staph. Aureus. This was also statistically nonsignificant. Out of 4 CRBSI, two were Klebsiella and two were Pseudomonas and distributed equally between the groups.

DISCUSSION

The intention of this study was to evaluate which approach to subclavian CVC access was better in critically ill patients admitted to the ICU. The success rates observed are similar to those of published studies although they had statistically significant difference in terms of attempt rate. This may be because two or greater number attempts were considered as multiple attempts.

| Table 1: Demographic parameters |
|--------------------------------|
|                        | SSV   | ISV   | P    |
| Age (Mean±SD) (year)    | 41.09±17.73 | 41±17.26 | 0.974 |
| Sex                     |       |       |      |
| Male%                   | 56.36 | 61.82  | 0.698 |
| Female%                 | 43.64 | 38.18  |      |

There were two incidences of catheter malposition in ISV group. Both CRBSI and catheter tip colonization were included as infectious complications and were more in SSV group although the difference was not statistically significant. There was no statistically significant difference in the catheter tip colonization with positive blood culture, catheter tip colonization with negative blood culture, only blood culture positive among both groups [Figure 4]. CRBSI was found in two members of each group and was statistically insignificant. Statistically insignificant incidence of positive catheter tip culture was seen in SSV group. The most common organism isolated in catheter tip colonization was Klebsiella (38.10% in SSV and 37.5% in ISV) in both groups. Other organisms were Pseudomonas, Acinetobacter, CONS, E. Coli, GPB, Staph. Aureus. The difference was statistically nonsignificant. The most common organism isolated in blood culture was Klebsiella followed by Pseudomonas and Staph. Aureus. This was also statistically nonsignificant. Out of 4 CRBSI, two were Klebsiella and two were Pseudomonas and distributed equally between the groups.
attempt, but only two attempts were permitted. The higher incidence of second attempts in ISV group may be due to anatomical factors as SSV is more superficial than ISV. There is also a higher chance of encountering the clavicle in case of infraclavicular approach. The high success rate may be due to that catheterization was performed under real time USG guidance and by an operator experiences in USG guided catheterization by these approaches. Catheterization with landmark technique has been associated with high failure rate compared to USG guided technique.\cite{2,9-11} A study comparing US and landmark technique found that time to obtain vascular access and number of attempts were significantly lower using real time US \cite{11} guidance (\(P < 0.05\)).\cite{11} The statistically significant longer visualization time in the infraclavicular approach may be because of the anatomic proximity of the vein to the clavicle and the difficulty in getting a longitudinal visualization because of the acoustic shadow of clavicle.\cite{3,5,7,8} In review articles, the longitudinal approach for subclavian vein catheterization using a micro-convex ultrasound probe has been shown to improve visualization.\cite{12,13} Also, a new insertion site for the infraclavicular approach at the junction of axillary and subclavian veins was reported to have better visualization and is said to be technically easier.\cite{11} It has been already reported that the real time access in the infraclavicular approach is limited by vessel identification in a single planar view and a more applicable multiplanar approach (which is a combination of transverse, oblique and longitudinal view) has been suggested to improve visualization.\cite{15}

The significant difference in catheterization time might be due to the fact that clavicle is more commonly encountered during positioning the guide wire in ISV approach than SSV.\cite{5} Apart from this, the catheterization time also included the additional time taken by us to demonstrate the guide wire in innominate vein (using supraclavicular view in both groups). The supraclavicular placement of ultrasound probe might have made it easy for locating the guide wire in the subclavian vein and brachiocephalic vein after its insertion making the catheterization time shorter in the supraclavicular approach when compared to infraclavicular approach in which the probe had to be shifted to locate and confirm the guide wire in the subclavian vein.

The longer total procedural time taken in the infraclavicular approach may be due to the anatomic proximity of the vein to the clavicle. It is also difficult to get a longitudinal visualization because of the acoustic shadow of clavicle and to maintain the US view of the vein and the needle simultaneously.\cite{5,7} There is technical difficulty while positioning the guide wire in the infraclavicular approach.\cite{5} In a similar study comparing the access time, success rate, number of attempts, ease of insertion among the infraclavicular and

| Time (second) | SSV Median | Range | Mean±SD | ISV Median | Range | Mean±SD | \(P\) |
|---------------|------------|-------|---------|------------|-------|---------|------|
| Total procedural | 175        | 157-201 | 177.92±12.46 | 194        | 173-240 | 199.66±18.53 | <0.0001 |
| Venous visualization | 17        | 12-20 | 16.36±2.64 | 21        | 16-28 | 22.10±0.81 | <0.0001 |
| Venous puncture | 32        | 31-58 | 35.29±10.42 | 40        | 31-75 | 46.25±15.01 | <0.0001 |
| Catheterization | 125        | 121-139 | 126.27±5.85 | 131        | 121-142 | 131.20±6.33 | <0.0001 |

Figure 3: Success rate and complications

Figure 4: Association of fever and risk factors

Table 2: Different times
supraclavicular approach of SSV catheterization found that access time is less in SSV approach and landmarks accessibility, success rate and rate of complications were all comparable.\textsuperscript{[16]} Although a mean difference of 22 s in the total procedural time seems neglectable clinically but in situations of emergency and life threatening situations SSV is more preferable than ISV.

The guide wire was demonstrated in the innominate vein (using supraclavicular view in both groups) in every case. The advantage of this method is that catheter malposition (catheter going into ipsilateral IJV) can be minimized since the guide wire is already demonstrated in the brachiocephalic vein. This also explained the low incidence of catheter malposition in our study. There was no hematoma formation, arterial puncture, pneumothorax or hemothorax in any of the patients in either group. Our cannulation site was more lateral in ISV which has lesser incidence of catheter tip malposition. As quoted in a study, in which, out of 19 malpositions, 14 were in the midpoint approach and 5 in the lateral approach, the difference was statistically significant.\textsuperscript{[17]}

It is a well-documented and accepted fact that CRBSI incidence is more in critically ill patients. Our aim was to find and document if there was any difference in CRBSI among the two groups SSV and ISV. Higher incidence of positive catheter tip culture in SSV group may be attributable to more proximity to the oral cavity similar to IJV catheterization. Supraclavicular fossa can have collection of secretions, sweating etc., resulting in greater incidence of infection in SSV group. Incidence of specific complications in a series of 420 intracaval catheters placed in 388 patients, using six transcutaneous puncture techniques: supraclavicular and infraclavicular subclavian, external and internal jugular, antecubital and brachiocephalic approaches have been analyzed, and it was reported that the incidence of infectious complications were as follows: brachiocephalic (2.5%), infraclavicular (4.4%) subclavian, supraclavicular (5.3%) subclavian and internal jugular (7%) veins; a 10% incidence was associated with external jugular and antecubital techniques.\textsuperscript{[18]} Prolonged ICU stay and longer catheterization are major risk factors for CVC infection.\textsuperscript{[19]} There are very limited studies comparing the infectious complications among SSV and ISV approach of subclavian venous catheterization.

Association of fever among both groups was comparable. Our study population had patients admitted in Trauma ICU and Surgical ICU which also include head injury patients. They may have developed hyperthermia due to central cause which we would have considered as fever. The risk factors associated with infectious complications of CVC such as number of catheter days \textit{insitu} (\(\leq 7\) days or \(>7\) days), blood transfusions and total parenteral nutrition infusion through CVC were comparable in both groups. There are very limited studies comparing these risk factors among both groups.

This study has some limitations. All central venous catheterizations were performed on the right side subclavian vein; hence, study results may not apply to left subclavian venous catheterization. The low incidence of complications makes this study unsuitable to compare complications among the study groups. A study with much larger sample size may be needed to evaluate and compare such variables. The operator in this study was not blinded to the patient group. We limited the number of attempts in view of the higher mechanical complication rates when more than two attempts were used.

**CONCLUSION**

It may be concluded from the study that the supraclavicular approach is associated with shorter time required for visualization, to puncture, to catheterize and the overall total procedure time. Infraclavicular approach may require more attempts but the success rate and the incidences of mechanical and infectious complications were similar in both approaches. Hence, supraclavicular approach to the subclavian vein for ultrasound-guided central venous catheter insertion in critically ill patients admitted in the ICU is a useful alternative to the infraclavicular approach.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.
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