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Comparative study of ultrasound-guided in-plane and anatomical landmark cannulation of infraclavicular subclavian vein in intensive care unit – a prospective randomized control trial.

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Abstract

Background: Subclavian vein cannulation is a critical procedure in the intensive care unit (ICU) for administering medications, fluids, and hemodynamic monitoring. Traditional anatomical landmark techniques, while widely practiced, are associated with higher complication rates. The use of ultrasound-guided techniques has emerged as a safer alternative with improved success ra**tes.**

Objectives: To compare ultrasound-guided in-plane cannulation and anatomical landmark cannulation of the infraclavicular subclavian vein in terms of success rates, complication rates, procedural time, and hemodynamic changes in ICU patients.

Materials and methods: This prospective randomized controlled trial included 60 ICU patients requiring subclavian vein cannulation, who were randomly assigned to two groups: Group U (ultrasound-guided, n=30) and Group L (landmark-guided, n=30). Primary outcomes included time to locate the subclavian vein and the number of attempts. Secondary outcomes were success rate, failure rate, complications, and hemodynamic changes. Data were analyzed using appropriate statistical tests.

Results: The groups were comparable in baseline demographics. The mean time to locate the vein was 4.0 ± 1.0 minutes in Group U and 4.2 ± 1.0 minutes in Group L ($p = 0.44$). The success rate was higher in Group U (87%) compared to Group L (85%), while the corresponding failure rates were 13% and 15% respectively, though differences were not statistically significant ($p = 0.59$). Complications were slightly lower in the ultrasound group (18%) versus the landmark group (20%) ($p = 0.72$). Heart rate changes post-cannulation remained stable in both groups, with a significant difference noted only at 5 minutes ($p = 0.05$).

Conclusion: Ultrasound-guided in-plane subclavian vein cannulation demonstrates slightly higher success rates, fewer complications, and comparable procedural time, confirming its clinical advantage over the anatomical landmark technique in ICU settings.

Recommendations: Ultrasound-guided subclavian vein cannulation should be routinely implemented in ICUs to enhance safety, procedural success, and patient outcomes.

Keywords: *Subclavian vein cannulation; Ultrasound guidance; Anatomical landmark technique; Central venous catheterization; Intensive care unit; Vascular access*
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Introduction

Insertion of a central venous catheter is a crucial intervention in the care of critically ill patients admitted to the intensive care unit (ICU). Subclavian vein cannulation is frequently preferred due to its lower infection rates, greater patient comfort, and suitability for long-term vascular access [1,2]. Traditionally, the anatomical landmark technique has been widely used for subclavian vein cannulation. However, this technique is associated with significant risks, including pneumothorax, arterial puncture, malposition, and failed cannulation, particularly in patients with difficult anatomy or abnormal body habitus [3].

The introduction of ultrasound guidance for vascular access has significantly transformed the practice of central venous catheterization by allowing real-time visualization of vascular structures, thus improving both the accuracy and safety of the procedure [4]. Ultrasound-guided in-plane techniques, in particular, enable continuous visualization of the needle during insertion, reducing the risk of inadvertent complications and increasing first-attempt success rates [5]. This approach is increasingly being recommended as the standard of care in various guidelines and expert reviews due to its demonstrated efficacy and safety benefits [1,6].

Despite the proven advantages of ultrasound guidance, its routine implementation remains limited in many clinical settings, often due to a lack of equipment, training, or familiarity with the technique. Therefore, a direct comparison of ultrasound-guided versus anatomical landmark-guided cannulation is essential to reinforce evidence for broader clinical adoption and to guide training and practice improvement initiatives [2,5].

This study aims to compare the efficacy and safety of ultrasound-guided in-plane cannulation versus traditional anatomical landmark-guided cannulation of the infraclavicular subclavian vein in ICU patients. The primary outcomes include time to locate the vein and number of attempts, while secondary outcomes assess success rates, failure rates, complications, and hemodynamic stability. By providing evidence on procedural efficiency and patient safety, this study seeks to inform clinical practice and support the broader adoption of ultrasound-guided techniques in critical care settings.

Materials and methods

Study design and trial method

This was a prospective, parallel-group, randomized controlled trial with a 1:1 allocation ratio comparing ultrasound-guided in-plane versus anatomical landmark-guided cannulation of the infraclavicular subclavian vein.

Study setting

The study was carried out in the Intensive Care Unit (ICU) of Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu, a tertiary care teaching hospital serving a large population of critically ill patients. The trial was conducted between August 2022 and June 2024 after obtaining approval from the Institutional Ethics Committee. Written informed consent was secured from all participants before enrollment.

Study population and size

A total of 60 adult ICU patients requiring subclavian vein cannulation were included. The study size was determined based on feasibility within the study period and reference to similar published trials, ensuring adequate power to detect clinically relevant differences. Participants were randomly assigned to two groups:

Group U (n = 30): Ultrasound-guided in-plane cannulation.

Group L (n = 30): Anatomical landmark-guided cannulation.

Eligibility criteria

Inclusion

Patients aged 18–65 years, of either sex, admitted to the ICU, weighing 45–80 kg, and providing informed consent.

Exclusion

Refusal to participate, coagulopathy, local infection or sepsis at the insertion site, previous subclavian cannulation, intravenous drug abuse, subclavian vein thrombosis, or anatomical deformities of the clavicular region.

Bias control measures

To reduce selection bias, allocation concealment was maintained through sealed opaque envelopes. Procedural outcomes were documented by an independent observer blinded to the intervention group to minimize assessment bias. Baseline demographic comparability was verified between groups.

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Randomisation and allocation

Sequence generation

A computer-based random number generator was used to create the allocation sequence with simple randomization.

Implementation

The sequence was generated by an investigator not involved in patient recruitment. ICU residents enrolled participants, while sealed opaque envelopes determined the assigned intervention.

Blinding

Operators could not be blinded due to the nature of the techniques. However, patients were unaware of group assignment, and data collection on outcomes was carried out by an independent observer blinded to intervention.

Procedure

All cannulations were performed under strict aseptic precautions with standard monitoring (ECG, NIBP, SpO_2). Local anesthesia with 2% lignocaine was infiltrated at the puncture site.

Group U: Cannulation performed under real-time ultrasound guidance using a high-frequency linear probe and the modified Seldinger technique.

Group L: Cannulation performed using classical anatomical landmarks and the modified Seldinger technique.

In both groups, a triple-lumen central venous catheter was inserted following successful cannulation.

Data collection

Parameters recorded included:

Primary outcomes

Time to locate the subclavian vein (minutes) and the number of attempts required for successful cannulation.

Secondary outcomes

Success and failure rates, procedure-related complications (pneumothorax, arterial puncture, hematoma, malposition), and hemodynamic changes (heart rate, blood pressure, SpO_2) before and after cannulation.

Statistical analysis

Data were compiled and analyzed using SPSS software version 25.0. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the Independent Student's t-test. Categorical variables were compared using the Chi-square test. A p-value < 0.05 was considered statistically significant.

Ethical considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee of Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu, and written informed consent was obtained from all participants, ensuring patient confidentiality, safety, and adherence to ethical guidelines for human research.

Results

Participant flow

A total of 60 patients were screened and enrolled in the trial. Thirty participants were randomly allocated to Group U (ultrasound-guided) and 30 to Group L (landmark-guided). All participants received the assigned intervention. Data from all 60 participants were available for analysis of the primary and secondary outcomes.

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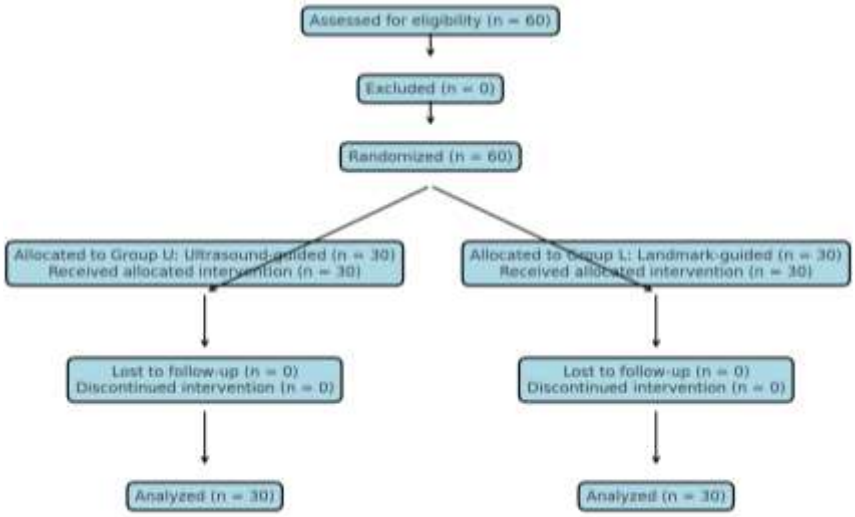

Figure 1. Participant flow diagram

Recruitment

The recruitment of participants took place between **August 2022 and June 2024** in the Intensive Care Unit of Government Mohan Kumaramangalam Medical College and Hospital, Salem. All patients meeting the inclusion criteria during this period were consecutively enrolled. The trial was completed as planned without premature termination.

A total of 60 patients admitted to the intensive care unit who met the inclusion criteria were enrolled and randomly assigned into two groups: Group U (Ultrasound-guided in-plane technique, n = 30) and Group L (Anatomical landmark technique, n = 30). The demographic and baseline characteristics of the participants are summarized in Table 1.

Table 1: Demographics and baseline characteristics of study participants (n=60)

Parameter	Group U (Mean ± SD)	Group L (Mean ± SD)	P-value
Age (years)	46.3 ± 9.4	42.8 ± 11.1	0.10 (NS)
Weight (kg)	76.1 ± 6.1	71.5 ± 6.0	0.001 (HS)
Heart Rate (Pre) (bpm)	80.6 ± 5.2	80.3 ± 5.0	0.81 (NS)
Blood Pressure (Pre) (mmHg)	126.2/83.0 ± 8.0/5.5	124.2/79.6 ± 6.6/4.9	0.05 (S)
SpO_2 (%)	95.1 ± 1.4	95.1 ± 1.4	1 (NS)

NS: Not Significant; HS: Highly Significant; S: Significant

The mean age in Group U was 46.3 ± 9.4 years, slightly higher than 42.8 ± 11.1 years in Group L, which was not statistically significant (p = 0.10). The mean body weight was significantly higher in Group U (76.1 ± 6.1 kg) compared to Group L (71.5 ± 6.0 kg) (p = 0.001, highly significant). Both groups were comparable in terms of baseline heart rate, blood pressure, and oxygen saturation, indicating similar pre-procedural clinical status.

The primary outcomes of the study, including success rates and complication rates of subclavian vein cannulation, are presented in Table 2.

Table 2: Comparison of success rate and complications between groups

Outcome	Group U (%)	Group L (%)	P-value
Success Rate	87.0%	85.0%	0.59 (NS)
Complications	18.0%	20.0%	0.72 (NS)

NS: Not Significant

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The success rate was marginally higher in Group U (87%) compared with Group L (85%), with corresponding failure rates of 13% and 15%, respectively. These differences were not statistically significant (p = 0.59). Complication rates were also slightly lower in Group U (18%) than in Group L (20%), though the difference was not significant (p = 0.72). The mean time required to locate the subclavian vein was 4.0 ± 1.0 minutes in Group U and 4.2 ± 1.0 minutes in Group L (p = 0.44), indicating that both techniques were comparable in terms of procedural efficiency (Table 3).

Table 3: Time taken to locate the subclavian vein

Parameter	Group U (Mean ± SD)	Group L (Mean ± SD)	P-value
Time to Locate Vein (minutes)	4.0 ± 1.0	4.2 ± 1.0	0.44 (NS)

NS: Not Significant

The secondary outcomes assessed the hemodynamic stability of patients by monitoring heart rate changes at 5-, 10-, and 15-minute post-cannulation. As illustrated in Table 4,

Table 4: Heart rate changes post-cannulation

Time Point	Group U (Mean ± SD)	Group L (Mean ± SD)	P-value
5 minutes	80.0 ± 4.5	79.2 ± 5.1	0.05 (S)
10 minutes	79.5 ± 4.0	78.8 ± 4.6	0.53 (NS)
15 minutes	78.8 ± 4.3	78.2 ± 5.0	0.62 (NS)

S: Significant; NS: Not Significant

There was a statistically significant difference in heart rate at the 5-minute mark, with Group U showing a slightly lower mean heart rate (80.0 ± 4.5 bpm) compared to Group L (79.2 ± 5.1 bpm) (p = 0.05). However, at 10 minutes and 15 minutes post-procedure, the heart rate differences were not statistically significant between the two groups (p = 0.53 and p = 0.62, respectively), indicating overall hemodynamic stability in both groups following cannulation.

Ancillary analyses

Exploratory analyses were conducted to examine outcomes in relation to baseline body weight. Patients with higher baseline weight (>75 kg) showed a non-significant trend toward longer procedural time in both groups. No subgroup differences in success or complication rates were observed. These were exploratory analyses and not pre-specified in the study protocol.

Harms

No major harms or life-threatening complications were reported in either group. Minor adverse events included

Discussion

Central venous catheterization remains a cornerstone in the management of critically ill patients, particularly in intensive care settings. Among the various access routes, the subclavian vein is often preferred due to its lower risk of infection and greater patient comfort. However, the traditional anatomical landmark technique carries well-documented risks such as pneumothorax, arterial puncture, and failed cannulation [12].

In this study, both groups were comparable at baseline, allowing for a fair assessment of the outcome. The success rate was marginally higher in the ultrasound-guided group (87%) compared with the landmark group (85%), with corresponding failure rates of 13% and 15%, respectively. Although this difference was not statistically significant, the trend favors ultrasound guidance. This observation is consistent with earlier studies that have shown improved first-attempt and overall success rates when real-time ultrasound is employed [7,8].

The incidence of complications was slightly lower in the ultrasound-guided group (18%) compared with the landmark group (20%). Although the absolute difference was modest, the reduction highlights the advantage of direct vascular visualization. Prior systematic reviews and observational studies confirm

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that ultrasound reduces risks such as arterial puncture and pneumothorax, thereby improving safety margins in critically ill patients [9,10]. Importantly, no major life-threatening complications were observed in either group, underscoring the overall safety of the procedure when performed under strict aseptic conditions by trained operators.

With respect to procedural efficiency, the mean time required to locate the subclavian vein was similar between the two groups (4.0 ± 1.0 vs 4.2 ± 1.0 minutes). This finding indicates that ultrasound guidance does not prolong cannulation once the operator is adequately trained. Earlier studies reported longer times during the learning phase or due to equipment preparation [11]; however, more recent work, in agreement with our findings, suggests that the efficiency gap disappears with experience. Both groups also maintained stable hemodynamic parameters following cannulation, indicating that neither technique compromised physiological stability.

Taken together, these findings reinforce the evidence that ultrasound-guided infraclavicular subclavian vein cannulation offers clinical benefits in terms of safety and procedural success without sacrificing efficiency. With the increasing emphasis on minimizing complications and improving patient outcomes, routine incorporation of ultrasound guidance into ICU practice appears justified and aligns with evolving recommendations for safer vascular access [9,12].

Generalizability

The results of this study are most applicable to tertiary care ICU settings in resource-limited regions, where patient anatomy and operator training can influence outcomes. While our single-center design and modest sample size may limit external validity, the findings demonstrate that ultrasound-guided cannulation can be safely integrated into routine practice without compromising efficiency. These results may not be directly generalizable to pediatric or high-volume emergency populations, but they provide supportive evidence for wider adoption of ultrasound in adult ICU patients requiring central venous access.

Conclusion

This prospective randomized controlled study demonstrated that ultrasound-guided in-plane cannulation of the infraclavicular subclavian vein offers a marginally higher success rate, fewer complications, and comparable procedural time compared to the traditional anatomical landmark technique. Although some differences did not reach statistical significance, the overall trend favors the use of ultrasound guidance for improving safety and efficiency in critically ill patients requiring central venous access. Both techniques maintained hemodynamic stability post-cannulation. Incorporating ultrasound guidance into routine practice may enhance patient outcomes, reduce procedural risks, and align with evolving clinical guidelines promoting safer vascular access. Adequate operator training remains essential for maximizing the benefits of this technique.

Limitations

This study was limited by a relatively small sample size and was conducted in a single-center setting, which may limit the generalizability of the findings. Operator experience and learning curves with ultrasound could also have influenced the results.

Recommendations

Based on the findings of this study, it is recommended that **ultrasound-guided in-plane cannulation** of the infraclavicular subclavian vein be adopted as the preferred technique in intensive care units, wherever feasible. This approach offers improved success rates, reduced complication risks, and comparable procedural efficiency compared to the anatomical landmark technique. Regular **training programs and hands-on workshops** should be implemented to enhance clinician proficiency in ultrasound-guided vascular access. Additionally, efforts should be made to ensure the **availability of ultrasound equipment** in critical care settings. Further multicenter studies with larger sample sizes are recommended to strengthen the evidence base.

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List of abbreviations

ICU – Intensive Care Unit

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CVC – Central Venous Catheter/Catheterization
CVP – Central Venous Pressure
SCV – Subclavian Vein
USG – Ultrasonography / Ultrasound Guidance
bpm – Beats Per Minute
SpO_2 – Peripheral Capillary Oxygen Saturation
BP – Blood Pressure
NS – Not Significant
S – Significant
HS – Highly Significant
SD – Standard Deviation
ECG – Electrocardiogram
NIBP – Non-Invasive Blood Pressure

Source of funding
The study had no funding.

Conflict of interest
The authors declare no conflict of interest.

Author contributions
LG-Concept and design of the study, results interpretation, review of literature, and preparation of the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **EG**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, revision of the manuscript. **RM**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation. **PP**-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.

Data availability
Data is available on request.

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