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Ultrasound- Versus Landmark Guided Subclavian Vein Catheterization In Neonate

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ORIGINAL ARTICLE

Ultrasound- Versus Landmark Guided Subclavian Vein Catheterization In Neonate

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Abstract

Background: Vascular access is frequently required in neonates. Although SCV cannulation has the benefit of established landmarks, it is possible to have potentially serious consequences, such as pneumothorax and hemothorax.

Aim: This study aims to compare the success rate and complications of the landmark technique to an ultrasound-guided technique for subclavian vein catheterization in neonates.

Methods: This is a prospective randomized controlled study conducted on 100 neonates equally allocated to receive either landmark- or ultrasound-guided subclavian vein catheterization. All patients were assessed using the procedure parameters, which included procedure duration, cannulation site, number of attempts, and success rate. Procedural complications such as pneumothorax, hematoma and malposition were also measured, and comparisons between the groups were conducted.

Results: The ultrasound technique was more time-consuming, with a mean of 9.3 minutes, ranging from 7 to 12 minutes, with a significant comparison with the landmark guide, with a mean of 2.5 minutes ranging from 2 to 4 minutes. The first-placement success rate was significantly more prevalent in the ultrasound group compared to the landmark group (86% vs. 42 %, p<0.001). This study reported a statistically significant difference between the two groups regarding the need for mechanical ventilation cessation during the procedure (p <0.001). The overall complication rate was significantly higher in B compared to group A (14%vs 10%, p <0.001).

Conclusion: This study concluded that with a low incidence of complications and similar success rate, subclavian vein cannulation with landmark-guided method showed comparable safety and efficacy to the US-guided method in neonates. The landmark-guided technique is less time-consuming than the ultrasound-guided technique. It is recommended in emergency circumstances to utilize the landmark technique of subclavian vein cannulation.

Keywords: Subclavian vein; Neonates; Ultrasound, Landmark

1. Introduction

Vascular access is frequently required in pediatric patients. However, placing a peripheral line might not be possible or acceptable, particularly in newborns and infants. Over time, more options are available to physicians.1

Ultrasonography is a more helpful adjunct when inserting percutaneous central lines in neonates and infants.2

In intensive care, the subclavian vein is frequently used as a location for percutaneous access for central vein cannulation. This location has a few benefits, like reduced risk of thrombosis and infection brought on by central venous catheters, improved studied case comfort, and simpler nurse care.3 When the internal jugular vein is difficult to detect, like in hypovolemic or obese studied cases, SCV can be used instead.4

Although SCV cannulation has the benefit of established landmarks, it is possible to have potentially serious consequences, such as pneumothorax or hemothorax, which are probably attributable to the operator’s inexperience.

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Following National Institute for Health and Clinical Excellence’s recommendations in 2002, the use of ultrasound for IJV catheterization has become an accepted standard of care. Still, the same guidelines stated that there had been insufficient evidence to support its use for SCV catheterization. In comparison to anatomical landmark technique for subclavian or femoral vein cannulation, 2D ultrasound offers marginal safety and quality advantages, according to a Cochrane systematic review published in 2015. On the contrary, current studies have demonstrated that using the US reduced complications and increased 1st-pass success.5,6

The goal of this research is primarily to compare the success rate and problems of the landmark method to an ultrasound-guided technique for SCV catheterization in neonates

2. Patients and methods

This is prospective research conducted on neonates who needed a central venous line. Upon approval by the hospital’s research ethics committee and written parental consent, 100 neonates were admitted to the Neonatal Intensive Care Unit of AL-Azhar University Hospitals.

Using computer-generated random numbers, studied cases were split into arms (50 each):

- Group (A): Percutaneous central Venous Catheterization using the landmark-guided technique.
- Group (B): percutaneous Central Venous Catheterization using Ultrasound-guided method.

Sample size calculation

MedCalc version 11.3.0.0 was used to compute the sample size in order to produce a representative sample and ensure the validity of the results. A sample size of 90 cases was found to be credible after adjusting for a 95% confidence interval, 80% power, and a 1:1 case-to-control ratio. Assuming a 10% dropout rate, we ultimately included 100 cases.

2.1. Inclusion criteria

- Full-term and Preterm neonates requiring CVC positioning were included.

2.2. Exclusion criteria

- Exclusion criteria included neonates with hemolytic disorder and any other contraindication for central venous catheterization, such as local site infection.

2.3. Procedure

- All the procedures were conducted under sedation and in the supine position. Standard monitoring included ECG, NIBP, SaO2, and temperature. Sevoflurane 3 MAC inhalational anesthesia was used for the maintenance of anesthesia.

In group A, the clavicle ("break" or transition point, which is the junction among medial one-third and lateral two-thirds of the clavicle) and sternal notch were employed as landmarks in the infra-clavicular approach. The proper position for cutaneous puncture had been one to two cm below and laterally to the clavicular transition point, which had been below the clavicle and above 1st rib. The subclavian muscle had been passed through with the needle advancing parallel to 4 until it reached the subclavian vein.

In group B, we adopted an "in-plane" longitudinal strategy. By inserting the linear transducer into the infra-clavicular fossa and rotating it until a longitudinal view had been obtained, the transducer was then tilted until it vanished below the clavicle to visualize the vessel. This allowed visualization of subclavian and axillary veins. This view allowed for imaging of the pleural line and change from medial axillary to lateral subclavian vein, which allowed for visualization of lung sliding and potential identification of pre- and post-procedural pneumothorax. The needle had been put at the midway of the transducer in longitudinal orientation, producing in-plane orientation. The vessel had finally entered its lateral boundary, far from the confluence of cephalic and clavicle veins and right before the acoustic shadow of the clavicle, as the needle had progressively advanced and its tip visualized during the process. Following the vessel’s needle puncture, a guide wire was placed and was immediately visible.

By post-procedural chest X-ray or US, depending on clinical judgment, correct catheter placements had been verified. After CVC installation, Both contrast-enhanced ultrasonography and B-mode ultrasound were used. 1st, SV and IJV were both examined using standard B-mode ultrasonography. 10th, the heart was seen through epigastric and subcostal acoustic windows along the short heart axis to confirm catheter placement by simultaneously observing the right atrium and cava veins. CVC tip being in the right atrium or in vain other than superior vena cava or SVC-to-right atrium junction had been used to defend catheter misplacement.

2.4. Measurements

Patient demographics, delivery and surgery characteristics were reported and compared. All patients were assessed using procedure parameters, including procedure duration, cannulation site, number of attempts, and success rate. Procedural complications such as pneumothorax, hemothorax, hematoma and malposition were also measured, and comparisons between the groups were conducted.

2.5. Statistical Analysis

SPSS version 23.0 is considered for statistical analysis. The normality of the variables was taken into consideration before presenting them. In the case of normally distributed variables, mean and
standard deviation are used to explain data, whereas the median and interquartile range are used to characterize non-normally distributed data. For comparative analysis across groups, the Mann-Whitney U test and the student t-test were mentioned to analyze non-normally and normally distributed data. In addition, the Chi-square (x)2 test was used to examine the significance of relationships among categorical variables. The significance level had been determined as 0.05.

3. Results

Patients and Demographic Characteristics

After obtaining ethical approval from the Al-Azhar ethical review committee and individual parental informed consent, this prospective study finally enrolled 100 full-term and preterm neonates requiring CVC insertion. Figure 1 shows a flow diagram of the study process and reasons for exclusion throughout the study period. Regarding demographic and patient characteristics, no significant change was reported between the 2 study groups (P > 0.05). Also, no significant comparison was reported regarding birth characteristics and type of surgery Table 1.

![Figure 1. CONSORT flaw diagram](image)

**Table 1. Age and gender distribution among the study population**

<table>
<thead>
<tr>
<th>Group</th>
<th>Group A(n = 50)</th>
<th>Group B(n = 50)</th>
<th>Test of</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>X2</td>
<td>0.861</td>
</tr>
<tr>
<td>Male</td>
<td>28 (56%)</td>
<td>26 (52%)</td>
<td>0.031</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22 (44%)</td>
<td>24 (48%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age on admission (days)</th>
<th>X2</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8-28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight on admission (gram)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3200 ± 1485</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (min - max)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2941 - 4812</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

x2: Chi-Square test

P: P-value > 0.05: Non significant

Moreover, there was no statistical variation among the 2 studied groups regarding the indications of subclavian vein catheterization. The most prevalent indications for CVC were the need for long-term venous access and parenteral nutrition in groups A and B, with a non-significant comparison between the two groups (54% and 38%) vs. (58% and 30%), respectively Table 2.

**Table 2. Indications of CVC insertion among the study population**

<table>
<thead>
<tr>
<th>Group</th>
<th>Group A(n = 50)</th>
<th>Group B(n = 50)</th>
<th>Test of</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term I.V. access</td>
<td></td>
<td></td>
<td>X2</td>
<td>0.118</td>
</tr>
<tr>
<td>Parenteral nutrition</td>
<td></td>
<td></td>
<td>X2</td>
<td>0.657</td>
</tr>
<tr>
<td>Catecholamine’s Infusion therapy</td>
<td></td>
<td></td>
<td>X2</td>
<td>0.281</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
<td>X2</td>
<td>0.392</td>
</tr>
</tbody>
</table>

x2: Chi-Square test

P: P-value > 0.05: Non significant
The cannulation site was more prevalent in the right rather than the left subclavian vein, with no significant comparison among the two study groups regarding complications.

Table 3 showed a high statistically significant variation between the two 2 groups regarding the need for mechanical ventilation cessation during the procedure (p < 0.001). Out of 50 patients, 41 required cessation of mechanical ventilation in group B compared to 2 patients in group A. In addition, the ultrasound technique was more time-consuming, with a mean of 9.3 minutes, ranging from 7 to 12 minutes, with significant comparison with the landmark guide, with a mean of 2.5 minutes ranging from 2 to 4 minutes. The cannulation site was more prevalent in the right rather than the left subclavian vein, with no significant comparison among the two study groups Table 3.

Table 4. Comparison between the groups regarding cannulation outcomes

<table>
<thead>
<tr>
<th>Procedure parameters among the study population</th>
<th>Group A (n = 50)</th>
<th>Group B (n = 50)</th>
<th>Test of p</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical ventilation cessation</td>
<td>2 (4%)</td>
<td>41 (82%)</td>
<td>X2 = 0.319</td>
<td></td>
</tr>
<tr>
<td>Cannulation site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>32 (64%)</td>
<td>38 (76%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>18 (36%)</td>
<td>12 (24%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of the procedure (min)</td>
<td>2.5±1.2</td>
<td>9.3±1.5</td>
<td>t = 4.261</td>
<td>0.082</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>2 (2-4)</td>
<td>8 (7-12)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Post-procedure parameters among the study population

<table>
<thead>
<tr>
<th>Length of ICU stay (days)</th>
<th>Group A (50)</th>
<th>Group B (50)</th>
<th>Test of p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>3.24 ± 1.44</td>
<td>4.36 ± 2.06</td>
<td>t = 0.082</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>2 (1-5)</td>
<td>3 (2-7)</td>
<td></td>
</tr>
<tr>
<td>Length of hospital stay (days)</td>
<td>7.87 ± 2.58</td>
<td>8.91 ± 3.08</td>
<td>t = 0.175</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>5 (3-10)</td>
<td>7 (4-14)</td>
<td></td>
</tr>
</tbody>
</table>

Table 6. Comparison between the groups regarding complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group A (n = 50)</th>
<th>Group B (n = 50)</th>
<th>Test of p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumothorax</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
<td>X2 = 0.512</td>
</tr>
<tr>
<td>Arterial puncture</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
<td>X2 = 1.182</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2 (4%)</td>
<td>3 (6%)</td>
<td>X2 = 0.829</td>
</tr>
<tr>
<td>Malposition</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
<td>X2 = 0.182</td>
</tr>
<tr>
<td>Overall</td>
<td>5 (10%)</td>
<td>7 (14%)</td>
<td>X2 = 0.512</td>
</tr>
</tbody>
</table>

x2: Chi- Square test
P: P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.001: Highly significant
4. Discussion

Despite the fact that neonates have few crucial indications for central venous catheterization, catheterization is difficult due to their small size and the ease with which veins may collapse. The internal jugular vein is shallower and more collapsible than a subclavian vein, which runs behind the clavicle and is linked to a lower rate of infection. Real-time ultrasonography guiding enables safe and effective subclavian vein catheterization.

Indeed, the subclavian vein is frequently used as a location for percutaneous access to central vein cannulation. This location has advantages, having reduced risk of thrombosis and infection, improved case comfort, and simpler nurse care.

When the internal jugular vein cannot be located, like in hypovolemic cases, SCV can be used instead. Although SCV cannulation has the benefit of established landmarks, it is possible to have potentially serious consequences, such as pneumothorax and hemothorax.

Even with ultrasound guidance, central venous cannulation in neonates can be challenging. Younger age lowers central venous cannulation success rates and raises complication rates. Particularly for neonates, ultrasonography is demonstrated to be superior to the traditional landmark approach. According to the Agency for Healthcare Research and Quality, using US recommendations for the insertion of central venous catheters is one of the best practices with the most solid supporting data.

Moreover, another benefit of employing the US is the ability to confirm vein patency, anatomic variations, and artery and pleura locations before cannulation in a systematic manner. This enables precise site selection and reduces the likelihood of adverse events.

In comparison to anatomical landmark strategy for subclavian or femoral vein cannulation, 2D ultrasound offers only minor safety and quality advantages, according to a Cochrane systematic review published in 2015. On the contrary, current studies have demonstrated that using the US reduced complications and increased 1st-pass success occurrence.

In this study, we demonstrated that regarding gender, there had been no statistically significant variation among the 2 studied groups. Age had been comparable among the two study groups, with non-significant. Age between 8 and 28 days was more prevalent in the two groups compared to the age groups (<1 and 2-7 days). In addition, cleft lip and palate were the most prevalent surgery done in group A (38%) and group B (42%), with non-significant comparison between the two groups.

Consistent with this finding, Bruzoni et al. included eighty-four cases in the landmark group and sixty-six cases in the ultrasound group. All surgeons decided to access the subclavian vein. When comparing demographic information, there had been no distinction.

In this study, we illustrated that there had been no statistically significant variation among the 2 studied groups regarding the indications of subclavian vein catheterization. The most prevalent indications for CVC were the need for long-term venous access and parenteral nutrition in groups A and B, with a non-significant comparison between the two groups. Moreover, we cleared that there had been a high statistically significant variation between the two 2 groups regarding the need for mechanical ventilation cessation during the procedure (p <0.001). Out of 50 patients, 41 required cessation of mechanical ventilation in group B compared to 2 patients in group A.

Sidoti et al. found similar results. When compared to the landmark-guided group, only 1.3 % of studied cases in the US-guided group had their mechanical breathing interrupted (p< 0.001). Mechanical complications were significantly less in the US- than landmark-guided group (3/74 vs. 13/74, p < 0.001).

Supportingly, Ahmed et al. reported the effectiveness of the US in lowering mechanical complications and cannulation efforts.

Moreover, Oulego et al. showed that installation of central venous catheters on 1st try was increased using ultrasound, and number of punctures attempted and frequency of mechanical difficulties were also decreased.

In this study, we found that the ultrasound technique was more time-consuming, with a mean of 19.3 minutes ranging from 2 to 35 minutes, but no significant comparison was reported.

In accordance with our results, Subramony et al. found that the ultrasound group demonstrated a statistically significantly longer time to success as compared with the landmark group when successful cannulation was measured in both groups.

Trabelsi et al. found that the mean US scanning time had been longer for the SCV group (16.54 ±
Contrary to our findings, Singam et al. showed that access time in the US group had been 27.26 ± 0.46.2 seconds, while access time in the LM group had been significantly longer at 36.56 ± 17.35 seconds (p=0.0062). This may be due to differences in operators’ experience.

In this study, we demonstrated that the cannulation site was more prevalent in the right rather than the subclavian vein, with no significant comparison among the 2 study groups.

Sidoti et al. found that right-side cannulation had been preferred, and it had been used in sixty-nine % of US-guided procedures and seventy-seven % of landmark-guided procedures.14

Yang et al. found that thirty-four studied cases (82.9%) had catheters put on the right side of their bodies out of forty-one successful CVC insertion attempts.18

Rhondali et al. found that Due to right-handed anaesthetists, right SCV had been cannulated more frequently (seventy-three %) than left.19

In this study, we showed that the overall success rate had been higher in group A (98%), with a non-significant comparison to group B (92%) (p = 0.082). Nevertheless, the first-placement success rate was significantly more prevalent in group A compared to group B (86vs 42 %, p<0.001). Indeed, 9 of 46 cases in group B required more than 3 attempts to achieve successful subclavian catheter insertion, while 100% of successfully inserted catheters in group A required less than three attempts (p<0.001).

Sidoti et al. found that, although the fact that both groups had success rates of ninety-six % in the US-guided group and ninety-two % in the landmark-guided group, the former had higher % age of first-time successes (86.5vs 40%, p <0.001). In addition, we discovered that the mean number of tries in the ultrasound-guided group had been considerably (p <0.001) fewer than in the landmark group, i.e., 1.14 (0.40) versus 2.08 (1.29).14

Fragou et al. found that, in the US group, subclavian vein cannulation was successful in one hundred % of studied cases compared to 87.5 % of studied cases in the landmark group (P= 0.05). Comparing the US group to the landmark group, the average access time and number of attempts were significantly lower in the US group.20

Bruzzi et al. found that sixty-five % of studied cases in the ultrasound group and forty-five % of studied cases in the landmark group both had success on 1st try (p=0.021). In addition, ninety-five % of the ultrasound group and seventy-four % of the landmark group both had success after three trials (p <0.0001).13

Singam et al. found that among US teams With US guidance, thirty studied cases (one hundred %) had been successfully cannulated. In contrast, twenty-six studied cases (86.66%) had been effectively treated with the landmark method. The Success rate on 1st try in the US group was 83.33 %, which was considerably higher than 56.67%success rate in the LM group (p=0.025).9

In this study, we illustrated that Group B had a considerably greater total complication rate than Group A (36 vs. 18 %, p <0.001)

Sidoti et al. 2019 found that subclavian arterial punctures took place in 5 studied cases of the landmark-guided group but not in any studied cases of the US-guided group (p = 0.018). However, pneumothorax happened equally often in both groups (p = 0.591).14

Fragou et al. found that In landmark group, rates of arterial puncture and hematoma (5.4% and 5.4 %, respectively) as well as hemothorax (4.4 %and 4.9%), pneumothorax (1.5 %, brachial plexus (2.9%), phrenic nerve (1.5%), and cardiac tamponade (0.5%), all higher than in US group (P < 0.05).20

Wang et al. found that the ultrasound group experienced fewer problems (7.3%vs. 20.4%; p = 0.008) and a lower rate of arterial puncture (2.1%vs. 14.3%; p = 0.002) as compared to anatomic landmarks group.21

An early meta-analysis by Randolph et al. reported that there were considerable reductions in catheter placement failure, complications, and attempts with ultrasound-guided technique, according to eight randomized trials, contrasting it with conventional landmark strategy.22

In this study, we found that the positive bubble test was significantly more prevalent in group A compared to group B (68 vs 32%, p <0.001).

Sidoti et al. found that more studied cases in the US-guided group than in the landmark-guided group had accurate cannulation demonstrated by the bubble test (44 vs. 17 %, p <0.001).14

5. Conclusion

We concluded that with a low incidence of complications and a similar success rate, subclavian vein cannulation with the landmark-guided method showed comparable safety and efficacy to the US-guided method in neonates. The landmark-guided technique is less time-consuming than the ultrasound-guided technique. It is recommended in emergency circumstances to utilize the landmark technique of subclavian vein cannulation.

5.1 Limitations

There are some extra restrictions on this research. No measurements or characterizations of the veins were made. Several doctors were engaged, which could have introduced prejudice
based on background. No success or failure factors were investigated. The sample size was also rather tiny. To verify findings, larger multicenter trials involving various studied case populations in various hospital settings are required.

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Conflicts of interest
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References