

Original research article



Assessing ultrasound-guided axillary vein cannulation using a cumulative sum analysis: A single operator experience

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Abstract

Background: Ultrasound-guided axillary vein (AxV) cannulation has been described as an effective alternative to internal jugular vein cannulation in adult cardiac surgical patients. However, the learning curve for this technique has not yet been addressed. This study aimed to determine the number of cases required to achieve proficiency in performing AxV cannulation among novice anesthesiologists.

Methods: This prospective study included the first 60 patients who underwent ultrasound-guided AxV cannulation performed by a single third-year resident who was trained in adult cardiac anesthesia. This study investigated the number of cases required to gain technical proficiency by applying cumulative sum analysis on the learning curve (LC-CUSUM) of ultrasound-guided AxV cannulation.

Results: Based on the assessment of the CUSUM plots, a descending inflection point for decreasing the overall procedural time for AxV cannulation was observed after patient 29. Regarding the procedural outcomes, comparing the early-experience group with the late-experience group (29 vs 31 cases), the former group had longer operating time (1526 s vs 1120 s, p < 0.001) and identification time (110 s vs 92 s, p < 0.001) and lower first-attempt success rate (8, 27.6% vs 30, 96.8%, p < 0.001) than the latter group.

Conclusions: CUSUM demonstrated that at least 29 successful cases are required to achieve an expertized manipulation in ultrasound-guided AxV cannulation for inexperienced novices. The learning curve for ultrasound-guided AxV cannulation was observed in 29 cases. After adequate training, the overall procedural time and the first-attempt success rate, and puncture-related complications for AxV cannulation improved with increased experience.

Keywords

CUSUM analysis, learning curve, ultrasound, axillary vein, ultrasound-guided axillary vein cannulation

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Introduction

Central venous catheter (CVC) insertion is routinely performed in adult cardiac surgical patients. Although land-mark-based approaches for CVC insertion have been used successfully for many years, they are still associated with a 20% insertion failure rate and complications, even in experienced anesthesiologists. Based on evidence of low rates of thrombosis and catheter-related bloodstream infections, a subclavian site, rather than an internal jugular or femoral site, is recommended for CVC insertion. However, for novice anesthesiologists, the preference for subclavian vein catheterization is hindered by the risk of mechanical complications, primarily pneumothorax and arterial puncture.

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The real-time ultrasound-guided AxV cannulation might serve as an alternative to the internal jugular vein (IJV) cannulation in cardiac surgical patients, especially when conditions such as infection, IJV thrombus, etc. existed.³ With the advent of point-of-care ultrasound, use of real-time needle visualization techniques has been shown to improve results with success rates and reduce complications, the number of attempts, and time to access.⁴⁻⁷ However, previous studies on ultrasound-guided CVC insertion were mostly related to IJV cannulation because the subclavian vein is not easily amenable to ultrasound due to its location. The axillary vein (AxV) can be clearly visualized in a more lateral infraclavicular position, which offers several potential advantages over blind, subclavian vein techniques.

Ultrasound-guided infraclavicular AxV cannulation has been confirmed to be an effective alternative to IJV cannulation in adult cardiac surgical patients.³ However, the learning curve of the success rate and time to establish infraclavicular axillary access has not been well examined. The number of cases required to achieve proficiency in performing AxV cannulation among novice anesthesiologists remains unclear. Therefore, the present study aimed to establish a learning curve for ultrasound-guided infraclavicular AxV cannulation performed by a single third-year resident.

Methods

Study design/selection of participants

This prospective observational study was conducted in the First Affiliated Hospital of Nanjing Medical University. Approval was obtained from the Institutional Review Board of the hospital (No.: 2020-SR-104), and the trial was registered in the Chinese Clinical Trial (No.: ChiCTR2100042761). Adult patients scheduled for elective cardiac surgeries were recruited for this study. Patients with body mass index (BMI) > 26 kg/m², infection at the sites of insertion, previous venous cannulation in the past 6 months, potential arteriovenous fistula, anatomical variations of the AxV, and underlying lung disease were excluded. Written informed consent was obtained from all the enrolled patients.

The cumulative summation test for learning curve (LC-CUSUM) is often used to quantitatively assess the learning curve (LC) of a procedure and precisely present the association between the number of cases performed and a practitioner's ability in a specific procedure. 8,9 The initial training period of LC represents the rapid change in the ability to complete the task until "failure" is eliminated or reduced to a minimum constant rate. Cutoff values were selected based on the points of downward inflection revealed by the plots. To further illustrate the necessity of conducting the LC of AxV cannulation, the patient cohort was divided into the early-experience group and the late-experience group. The investigators defined a third-year

resident with no experience in the ultrasound-guided AxV cannulations as a novice. Once this resident demonstrated marginally acceptable performance, he was considered to be an advanced beginner. 10,11 All ultrasound-guided AxV cannulations were performed by this single third-year resident who was trained in adult cardiac anesthesia. This resident's previous experience with US-guided CVC insertion was limited to the internal jugular or femoral lines. The procedure was performed under the supervision of an attending anesthesiologist who was experienced in ultrasound-guided AxV cannulation. This resident studied the ultrasonic anatomy of the AxV in detail through standard anatomy texts and viewed an instruction video regarding ultrasound-guided AxV cannulation. The standard video was downloaded from https://www.sonosite.com/clinicalmedia?keys=vein+catheters&field clinical specialties tid=All&field media library type tid=1781&zip=. In the operating room, the resident learned by watching the attending anesthesiologist performing AxV cannulation in five patients.

Ultrasound-guided axillary vein (AxV) cannulation

Under general anesthesia, the patient was intubated and placed in the supine position. Peripheral oxygen saturation, electrocardiography, and invasive blood pressure were monitored during AxV cannulation. A Wisonic ultrasound system (Shenzhen Wisonic Medical Technology Co., Ltd) with a high-frequency linear transducer (15– 6 MHz) was used. After skin sterilization, the transducer was placed in the infraclavicular fossa with the probe marker pointing toward the lateral end of the clavicle. Once the AxV was identified, the probe was moved clockwise to obtain the longitudinal axis image of the vessel. AxV may collapse with external probe pressure. 12 Besides, the AxV was further confirmed from the artery by placing pulse wave Doppler over the structure; the artery demonstrates a high-frequency pulsatile acoustic signal and visual pattern, while the AxV gives a lower pitched signal with less marked pulsatility (Figure 1(a) and (b)). A 7-Fr, 20-cm-length, 3-lumen CVC (B. Braun Melsungen AG, Germany) was used in all patients. Subsequently, the right AxV was accessed using the Seldinger method with ultrasound guidance under the in-plane technique (Figure 1(c)). After confirming the free aspiration of venous blood, the guidewire was threaded by simultaneous using the US probe to apply pressure to the IJV. Once the guidewire entered the superior vena cava (SVC), the needle was removed. If the guidewire was malpositioned into the IJV, the wire was withdrawn, and the attending anesthesiologist who was on standby in sterile personal protective equipment (PPE) would compress the IJV to help the wire enter the SVC. Subsequently, dilation and the 3-lumen catheter were threaded. The real-time supervision of intracardiac Zhu et al. 3

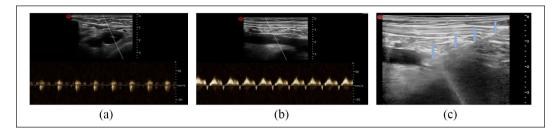


Figure 1. Short-axis/transverse image (a), longitudinal or in-plane view (b) of the right axillary vein, and ultrasound-guided puncture of the right axillary vein under the in-plane technique (c). The needle is seen as a hyperechoic linear structure (blue arrows).

electrocardiography by using a mental clip to locate the catheter. Once the *p*-wave amplitude significantly increased, the catheter tip was considered to reach far enough into the cavoatrial junction.¹³ After confirming the free aspiration of blood from all ports, the catheter was secured and dressing applied. During the performance of AxV cannulation, the attending staff anesthesiologist could provide verbal advice on AxV cannulation. In case of failure to secure right AxV cannulation, the alternative site proposed was the right IJV.

Outcome measures

Patients' baseline demographic variables were recorded, including age, gender, BMI, American Society of Anesthesiologists Physical Status (ASA-PS) classification, type of surgery, and comorbid conditions. The primary endpoint was defined as the number of procedures required to decrease the overall procedural time. Secondary endpoints included identification time, the overall procedural time, number of needle attempts, wire malposition, and puncture-related adverse events. The overall procedural time was defined as the time interval between probe placement and adhesive plaster affixment. The identification time was defined as the period used to obtain a clear image of the AxV along the longitudinal axis. The number of needle attempts was recorded as a deliberate additional skin puncture. Wire malposition was defined as the absence of a guidewire into the superior vena cava after two attempts. Occurrence of puncture-related complications such as an unintended arterial puncture, local perivascular hematoma, wire malposition, and pneumothorax was recorded. After four failed needle attempts, guidewire malposition, or occurrence of puncture-related complications, the procedure was considered a failure, and the attending anesthesiologists continued thereafter. Catheter-related complications, including blood stream infection and intravascular thrombosis, were also recorded.

Statistical analysis

In this research, the LC-CUSUM was performed to explore the association among the duration of AxV identification, the overall procedure time, and sequence number of the AxV cannulation.8 The results are presented in CUSUM charts, which are a graphical presentation of the course of outcomes of a series of consecutive procedures performed over time. The CUSUM series was defined as $\operatorname{Sn} = \Sigma(X_i - X_0)$, where X_i was the individual examination and X_0 was a predetermined reference level and was set as the mean operative time for all cases in the present study. Sn was plotted against the regular procedures. Cutoff values were selected based on the points of downward inflection revealed by the plots. LC-CUSUM was used to analyze the duration of AxV identification and the total practical lasting time. It is understood that the operator has mastered the new skill when the curve eventually flattens (after the cutoff). Since the trainee is competent from the beginning of the procedure, a learning curve is deemed to be completed when an inflection is observed in the CUSUM plot.

The patients were divided into two groups according to the cutoff point of the CUSUM score: group I (≤ cutoff value) representing the early-experience group and group II (> cutoff value) representing the late-experience group. Variables included the proportions, means, or medians with variability estimates in the form of standard deviations and confidence interval (depending on the normality of the variable), as appropriate. The chi-squared test or Fisher's exact test was used to compare the distribution of categorical variables between the groups. The Student t-test or Mann-Whitney U test was used to compare continuous variables among groups and between phases. Statistical significance was defined as a two-sided p-value of <0.05. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 23.0 (International Business Machines [IBM] SPSS Statistics for Windows, IBM Corporation, Somers, NY) unless otherwise specified.

Results

Baseline patient characteristics

A total of 70 adult patients scheduled for cardiac surgery were enrolled in this study. Three patients were excluded because of anatomical variations in the AxV. One patient with a giant bulla in the right upper lobe and one patient

Table 1. Baseline demographics of participant
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Variables	Total $(n=65)$	Group I (n = 29)	Group II $(n=31)$	p Value
Age (year)	57.23 ± 10.09	57.59 ± 10.13	57.84 ± 10.17	0.92
Gender (M/F)	48/17	22/7	23/8	1.00
BMI (kg/m²)	23.64 ± 2.26	23.73 ± 1.89	23.65 ± 2.57	0.89
ASA class (II/III/IV) (n)	19/37/9	8/17/4	10/17/4	0.73
Operation type <i>n</i> (%)				0.66
CABG	32 (49.23)	15 (51.72)	16 (51.61)	
Heart valve replacement	19 (29.23)	6 (20.69)	10 (32.26)	
Cardiac vascular surgery	13 (20.00)	7 (24.14)	5 (16.13)	
AAA	l (l.54)	l (3.44)	0 (0)	
Comorbidities n (%)	,	, ,	,	0.82
Hypertension	47 (72.31)	21 (72.41)	23 (74.19)	
Diabetes	10 (15.38)	4 (13.79)	5 (16.13)	
Others	8 (12.31)	4 (13.79)	3 (9.68)	

Values are mean ± standard deviation, number, or percentage of patients.

ASA: American Society of Anesthesiologists; BMI: body mass index; CABG: coronary artery bypass surgery; AAA: abdominal aortic aneurysm.

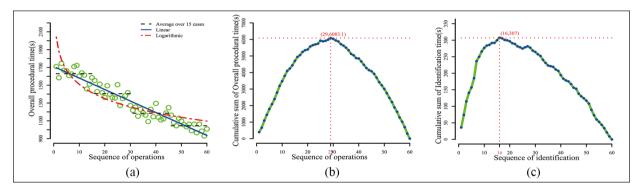


Figure 2. Learning curve of the first 60 consecutive axillary vein cannulation. Correlation between the length of the operating time and the sequence of the operation performed (a); cumulative sum plot for the overall operating time (b) and identification time (c).

with a BMI > 26 kg/m² were also excluded. Overall, 65 patients were included in the final analysis. Baseline demographic variables including age, BMI, gender, ASA-PS classification, type of surgery, and comorbid conditions are listed in Table 1.

AxV cannulation-related parameters

In total, successful AxV cannulation was performed in 60 of the 65 (92.3%) patients. The resident successfully cannulated the AxV with the first needle attempt in 38 of the 60 (63.3%) procedures and with the second, third, and fourth needle attempts in 17 (28.3%), 4 (6.7%), and 1 (1.7%) procedures, respectively. No obvious hematoma or puncture-related pneumothoraces were observed. No catheter-related complications, such as infection or thrombosis, were observed. Among the five patients for whom the resident failed to insert the AxV catheter, two patients with more than four attempts were successfully accessed by the attending anesthesiologist; three patients received the right IJV cannulation by the attending (one failed to thread

through the guidewire into the SVC; two developed hematoma).

Cumulative sum analysis of the operating time for AxV cannulation and its components

Evtually, 60 patients succeeded in receiving AxV cannulation were included to conduct the CUSUM analysis. As shown in Figure 2, the CUSUM analysis showed that the operating time of AxV cannulation ranged from 930 s to 1746 s with an average of 1316 s. The average time for the first 15 cases was 1629 s, which improved to 1044 s in the last 15 cases. The operating time for AxV cannulation presented a statistically significant linear correlation (R^2 =0.92, P<0.001) and a significant logarithmic correlation (R^2 =0.78, P<0.001) (Figure 2(a)).

Based on the assessment of the CUSUM plots, a descending inflection point for decreasing the overall procedural time for AxV cannulation was observed after patient 29 (Figure 2(b)), while a decreasing identification time was observed after patient 16 (Figure 2(c)).

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Table 2. Characteristics stratified by the CUSUM learning curve cutoff.

Variables	Group I (n = 29)	Group II $(n=31)$	p Value
Operating time (s)	1526 ± 134	1120 ± 96	< 0.001
Identification time (s)	110 ± 16	92 ± 4	< 0.001
First-attempt success rate n (%)	8 (27.6%)	30 (96.8%)	< 0.001
Number of needle attempts (4/3/2/1)	1/4/16/8	0/0/1/30	< 0.001

Values are mean ± standard deviation, number, or percentage of patients.

Distribution of perioperative factors between the early- and late-experience groups

Based on a LC-CUSUM cutoff of 29 procedures, the 60 patients were divided into two groups. The first 29 patients were included in group I, while the remaining 31 patients were included in group II. The baseline characteristics, including age, gender, ASA-PS classification, type of surgery, and presence of comorbid conditions, between the two groups were similar (Table 1). The mean procedural time was significantly longer (1526 s vs 1120 s, p < 0.001) and the first-attempt successful cannulation was higher (8, 27.6% vs 30, 96.8%, p < 0.001) in group I than those in group II. Moreover, the mean identification time (110s vs 92 s, p < 0.001) and number of needle attempts (4/3/2/1) (n) (1/4/16/8 vs 0/0/1/30, p < 0.001) were less in group I than those in group II (Table 2). Guidewire malposition was observed in one patient in group I, and none in group II (1, 3.5% vs 0, 0%, p=0.97).

Discussion

Ultrasound is increasingly utilized to enhance the safety and success of CVC cannulation.¹⁴ Since the subclavian vein is obscured by the clavicle, its use as a CVC site is now less common. AxV can be clearly visualized by ultrasound in the lateral infraclavicular position. 15 Furthermore, AxV cannulation has several potential advantages for patients undergoing cardiac surgery, including easier to nurse, less troublesome, and fewer occurrence of catheterrelated bloodstream infections. 16,17 Ultrasound in skilled hands may result in a high success rate and low risk of complications but requires sufficient training and experience for all practitioners.¹⁵ However, for inexperienced clinicians, a certain number of successful procedures are required to guarantee a safe and satisfactory procedural competency.¹⁸ Calculations from learning curves are useful for predicting the number of trials before a novice can safely perform ultrasound-guided AxV cannulation. Hence, this formal study was applied to investigate the learning curve of ultrasound-guided AxV cannulation and found that, for a single third-year resident who was trained in adult cardiac anesthesia, as experience increased, identification time for AxV, number of needle attempts, and the operating time of cannulation significantly decreased.

Furthermore, excellent experience can be obtained with a reasonable number of procedures performed by a novice anesthesiologist with experience in ultrasound-guided IJV cannulation.

CUSUM analysis is often used to quantitatively assess the learning curve of a procedure and precisely present the association between the number of cases performed and a practitioner's ability in a specific procedure. 8,9 In the present study, the CUSUM technique was used to determine the learning curve of ultrasound-guided AxV cannulation in terms of operating time, identification time, and puncture-related complications. Relatively often, the main challenge for new practitioners is the proper visualization of the target vessels both pre- and intra-procedurally. During the procedure, to achieve adequate, simultaneous visualization of the AxV and the needle, practitioners need to correct the orientation of the probe and the needle coordinately, which is difficult for novices.

A standardized clinical simulation curriculum might enhance the invasive procedures skills, which must help determining procedural safety and mastery. ¹⁸ In the present study, the resident studied the ultrasonic anatomy of the AxV in details through standard anatomy texts and viewed an instruction video regarding standardized ultrasound-guided AxV cannulation. Besides, the resident learned by watching the attending anesthesiologist performing AxV cannulation in five patients before commence operation. Based on the CUSUM data, we concluded that approximately 29 cases are required to gain proficiency in performing ultrasound-guided AxV cannulation for new practitioners.

The AxV, formed by the brachial and basilic veins, begins at the lower margin of the teres major muscle and terminates at the lateral margin of the first rib to become the subclavian vein. The anatomical location of the AxV allows for a relatively clear visualization by ultrasound. In addition, the AxV is on the thoracic cage, with no direct contact with the pleura, offering a potentially lower risk of pneumothorax. It was reported that ultrasound-guided AxV cannulation in 76 patients achieved a 100% success rate by experienced operators. In this study, the novice anesthesiologist safely placed 60 axillary lines with a total success rate of 92.3%. This may be attributed to his familiarity with ultrasound usage and his previous experience of IJV cannulation. During the initial training period, the

trainee approximately required 1629s to complete AxV cannulation. Gradually, his ability to complete AxV cannulation improved rapidly. By the end of the study, the mean time for cannulation was shortened to 1044s.

Although the operating time is a good parameter for measurement of the learning curve, adverse events are also important and essential. Only when the adverse events decreased significantly to a satisfactory level was the learning curve completed.²⁰ Our results showed that, after the required cases, not only the operating time but also the number of needle attempts and incidence of early and late puncture-related complications reduced significantly. In this study, although the first attempt success rate during the early training stage was 27.59%, it increased to 96.78% in the last stage. Previously, the first-attempt success rate varied among some studies and ranged from 75% to 95%, 21-23 which is similar to our results. The axillary artery, accompanying the vein, is most often parallel to it and can overlap with the vein.²⁴ Thus, complications such as AxV arterial puncture, hematomas, pneumothorax, and brachial plexus injury are frequent, especially in the early training stage of the procedures, even for anesthesiologists who are well experienced in performing CVC insertion. In the present study, two patients in the early stage encountered axillary artery puncture, but none of the patients experienced puncture when the trainee gained sufficient experience.

Although the CUSUM technique is certainly useful, it has certain limitations. First, all the procedures were performed by a single practitioner who was familiar with the ultrasound-guided IJV cannulation, but had never been exposed to AxV cannulation. The sole operator experience may be not representative to all who learning this procedure. This might limit the generalization of the present data to other operators, with a different degree of expertise in general sonography, who may, in practice, have a different learning curve. Secondly, criteria for novice or expert is not defined, and many factors may be associated with the time and number of procedures required to complete the learning process. Finally, this is a single-center clinical research; therefore, further investigations are needed to study the learning curve for ultrasound-guided AxV cannulation.

Conclusions

In conclusion, at least 29 successful cases are required to achieve an expertized manipulation in ultrasound-guided AxV cannulation for inexperienced novices. After adequate training, the overall procedural time, the first-attempt success rate, and puncture-related complications for ultrasound-guided AxV cannulation improved with increased experience. The LC-CUSUM for ultrasound-guided AxV cannulation can be used as the basis for performance-guided training and implementation at institutions not currently using this technique.

Author's note

All authors have completed the ICMJE uniform disclosure form.

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Author contributions

(I) Conception and design: Y Ni, L Chen; (II) Administrative support: LL Zhu, JM Zhu; (III) Provision of study materials or patients: CJ Gong; LJ Zhu; (IV) Collection and assembly of data: GJ Gong; LJ Zhu; (V) Data analysis and interpretation: LJ Zhu, L Chen; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Declaration of conflicting interests

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Ethical statement

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Institutional Ethics Committee of the 1st Affiliated Hospital of Nanjing Medical University (Nanjing, China) (No.: 2020-SR-104) and was registered in the Chinese clinical trial (NO.: ChiCTR2100042761). Written informed consent was obtained from all patients or their legal representative prior to enrollment in the study.

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