Original Article

Comparison between marked versus unmarked introducer needle in real-time ultrasound-guided central vein cannulation: A prospective randomized study

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ABSTRACT

Introduction: Introducer needle tip is not clearly visible during the real-time ultrasound (US)-guided central vein cannulation (CVC). Blind tip leads to mechanical complications. This study was designed to evaluate whether real-time US-guided CVC with a marked introducer needle is superior to the existing unmarked needle. **Methodology:** Sixty-two critically ill patients aged 18–60 years of either sex were included in the study. The patients were randomized into two groups based on whether a marked or unmarked introducer needle was used. Both groups underwent real-time US-guided CVC by a single experienced operator. Aseptically, introducer needle was indented with markings spaced 0.5 cm (single marking) and every 1 cm (double marking). This needle was used in the marked group. Approximate depths (centimeter) of the anterior and posterior wall of the internal jugular vein, anterior wall of the internal carotid artery, and lung pleura were appreciated from the midpoint of the probe in short-axis view at the level of the cricoid cartilage. Access time (seconds) was recorded using a stopwatch. A number of attempts and complications such as arterial puncture, hematoma, and pneumothorax of either procedure were compared. **Results:** Both marked needle and unmarked needle groups were comparable with regard to age, gender, severity scores, platelet counts, prothrombin time, and distance from the midpoint of the probe to the vein, artery, and pleura and skin-to-guide wire insertion access time. However, an average number of attempts ($P = 0.03$) and complications such as hematoma were significantly lower ($P = 0.02$) with the marked introducer needle group. Pneumothorax was not reported in any of the groups. **Conclusion:** Our study supports the idea that marked introducer needle can further reduce the iatrogenic complications of US-guided CVC.

Received: 20-02-16
Accepted: 18-07-16

Key words: Central venous cannulation; Introducer needle; Ultrasound; Ultrasound education; Ultrasound-guided catheter insertion

INTRODUCTION

Ultrasound (US) guidance is now the recommended practice in central venous cannulation (CVC).[1] Real-time, US guidance has been reported to have lesser access time (skin to vein puncture), higher success rate, and lower mechanical complications.[1,2] However, even with US, mechanical complications (such as arterial puncture, hematoma, and pneumothorax) are still high (~4.6%).[3] The incidence of pneumothorax during real-time US-guided CVC is reported to be approximately 0.7%.[4] Furthermore, the incidence of carotid

Access this article online
Website: www.annals.in
DOI: 10.4103/0971-9784.191563
Quick Response Code:

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Cite this article as: Ghatak T, Singh RK, Baronia AK. Comparison between marked versus unmarked introducer needle in real-time ultrasound-guided central vein cannulation: A prospective randomized study. Ann Card Anaesth 2016;19:621-5.

and posterior wall venous puncture has been reported to be about 20% and 64%, respectively, in US-guided CVC even in human simulators.[5]

The poor visualization of the introducer needle tip in US is the primary reason for these complications. This blind spot can often occur in real-time US guidance for CVC in both short (transverse) and long (longitudinal) axis during needle advancement toward anticipated vein. To circumvent this, we incorporated a simple additional safety measure by indenting markings on the existing unmarked introducer needle. We further evaluated the marked against unmarked needle during real-time US-guided CVC in a prospective randomized pilot study.

MATERIALS AND METHODS

The study commenced after approval from the Institutional Ethical Committee. The study was registered in the Clinical Trial Registry India (CTRI/2015/04/005728). Written informed consent from first of kin of included patients was taken. Sixty-two critically ill adult patients (aged 18–60 years) of either gender admitted to the Intensive Care Unit were included in the study from among the 125 admitted patients during this period. Patients with age < 18 years, presence of skeletal deformities, features suggestive of raised intracranial tension, refusal of consent, and in whom subclavian catheterization was planned were excluded from the study. The patients were randomly allocated into two groups (marked and unmarked introducer needle) as per the computer-generated random number table.

Real-time ultrasound-guided cannulation

Both groups underwent real-time US-guided CVC. Portable US machine (Sonosite MicroMaxx® with a 7.5-MHz vascular probe) was used for imaging. A single operator with a minimum of 5 years of experience in CVC and more than 1 year experience in real-time US-guided CVC performed all the cannulations. One observer helped in recording the US data and access time (skin puncture to successful guidewire placement in the vein). All patients were sedated and mechanically ventilated (Servo-I ventilator; Maquet Inc., Bridgewater, NJ, USA). Internal jugular vein (IJV) was chosen as the standard vein for CVC in both groups. The selection of right or left IJV was as per feasibility. After placing the patient in the Trendelenburg position,[6] we aseptically prepared and draped the neck area with 2% chlorhexidine gluconate and 70% isopropyl alcohol. The target area was anesthetized with 1% lidocaine solution via a 22-gauge needle. Triple lumen central venous cannula set (Certofix Trio; B Braun, Germany) was used in both groups. Aseptically, the unmarked 18-gauge introducer needle from the same set was indented with markings spaced 0.5 cm (single marking) and every 1 cm (double marking) with the help of a sterile blade (available in the CVC set) and scale (predipped in cide × 15 min before the procedure) [Figure 1]. Henceforth, this needle was used as the marked introducer needle. The entire US vascular probe was cleaned with the help of sterile gauze soaked in 2% chlorhexidine gluconate and 70% isopropyl alcohol after which footprint of the probe was covered with sterile Tegaderm (10 cm × 12 cm). The sterilizing solution was used as US gel for viewing. The operator held the probe in a transverse (short-axis) plane to the IJV to be cannulated in the diversion of sternocleidomastoid muscle at the level of the cricoid cartilage. Approximate depths of the anterior and posterior wall of the IJV, anterior wall of the internal carotid artery, and lung pleura (where possible) were appreciated from the midpoint of the probe in this short-axis view [Figure 2]. Then, under real-time US guidance, the operator inserted the introducer needle directing it straight toward the vein. After skin penetration, long-axis was used to see the path of the needle. In unmarked group, the strict vigilance of the needle path in US was done. While in marked group, the strict vigilance of the needle path in US along with its markings over needle outside skin was ensured. The needle was thus forwarded toward vein. The venous puncture was confirmed by aspiration of the free flow of venous blood. Then, guide wire was placed from the side port of introducer needle. The time required from skin puncture to successful guidewire placement (access time) using a stopwatch was recorded. After placement of guidewire, US long-axis view of the vein with the movement of the guidewire within the vein was checked to confirm placement. Rest of the procedure of CVC was performed as per Seldinger technique. Carotid artery puncture was noted by the forceful pulsatile expulsion of bright red blood from the needle. In patients where the first attempt of

Figure 1: Ghatak-Singh-Baronia's marked introducer needle. Single marking in every 0.5 cm and double marking in every 1 cm length

introducer needle placement or guidewire placement failed, the same operator performed the second attempt in the same vein. In case if the vein was not punctured at the same depth as estimated previously by US, the operator reverified the depth by repeat US. However, any such reconfirmation was also counted as a second attempt. The access time of the repeat attempt was then noted. A check US was done to review hematoma and pneumothorax after all the procedures.

Data collection

Demography (Age, gender, illness [sepsis as defined by SCCM 1992 definition],[7] severity scores [Acute Physiology and Chronic Health Evaluation (APACHE-II) and Sequential Organ Failure Assessment (SOFA)], coagulation [platelet count and International Normalized Ratio (INR)], US variables [distances (centimeters) from the midpoint of the probe to the anterior and posterior wall of IJV, anterior wall of the internal carotid artery, and lung pleura] and procedural variables [access time (seconds), number of attempts, and complications (arterial puncture, hematoma, and pneumothorax)]) of both groups were recorded.

Statistical analysis

Statistical analyses were performed using SPSS for Windows 21.0 (SPSS Inc., Chicago, IL, USA). Data expressed as mean (± standard deviation) and proportion (%) as appropriate. Independent sample *t*-test and Chi-square test were used for comparison of continuous and categorical variables, respectively. A two-tailed value of $P < 0.05$ was considered statistically significant.

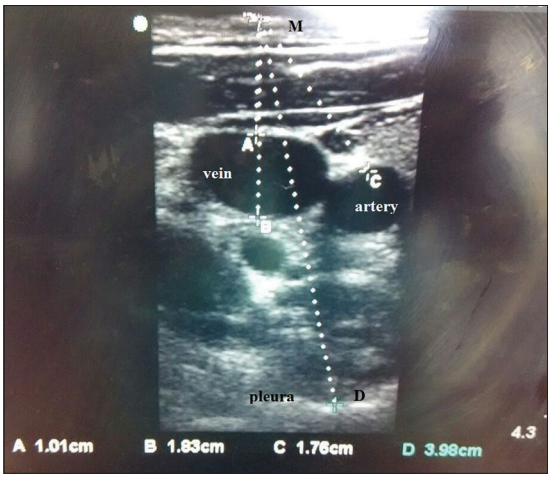

Figure 2: Distance from the midpoint (M-needle entry point) to the anterior wall of internal jugular vein (A), posterior wall of internal jugular vein (B), anterior wall internal carotid artery (C), and lung pleura (D)

RESULTS

There were 31 patients in the marked and unmarked needle groups. Demographic variables (age, gender, and illness) and prognostication (APACHE II and SOFA) scores and coagulation variables (platelet counts and INR) were comparable between the two groups [Table 1].

US variables of approximate depths from the midpoint of the probe to the anterior/posterior wall of IJV, anterior wall of the internal carotid artery, and lung pleura were comparable in either group. Access time (skin puncture to successful guide wire placement), though slightly higher in marked group (177.97 ± 54.10 vs. 168.77 ± 64.73; $P = 0.55$), was not found to be significant [Table 1].

The average number of attempts for CVC was higher in unmarked group compared to marked group (1.26 ± 0.51 vs. 1.03 ± 0.18). This difference was statistically significant ($P = 0.03$) [Table 2].

Complications such as hematoma were significantly lower (3.2% vs. 22.5%; $P = 0.02$) with the marked introducer needle group. There was a single arterial puncture (3.2%) in unmarked group while none in marked group. Pneumothorax was not reported in any of the groups [Table 2].

Table 1: Baseline characteristics of the study population

Variables	Marked needle group (*n*=31)	Unmarked needle group (*n*=31)	*P*
Age years	40.45±15.62	41.68±15.12	0.75
Gender male:female	17:14	11:20	0.13
Severity scores			
APACHE II	14.61±4.18	14.52±4.03	0.93
SOFA	7.35±3.04	6.90±2.89	0.55
Type of illness *n* (%)			
Sepsis:nonsepsis	12 (39):19 (61)	8 (26):23 (74)	0.28
Platelet count ×10^3	118.45±76.65	133.65±56.11	0.38
PT-INR ratio	1.30±0.11	1.54±0.70	0.07
Site of IJV			
Right:left	27:4	28:3	1.0
Distance from midpoint (cm)			
Anterior wall IJV	1.19±0.09	1.17±0.10	0.58
Posterior wall IJV	1.51±0.12	1.49±0.09	0.60
Arterial wall ICA	1.97±0.34	1.83±0.27	0.08
Lung pleura	3.87±0.34	3.80±0.33	0.40

Data measurements are in mean±SD unless specified.
SD: Standard deviation, APACHE II: Acute Physiology and Chronic Health Evaluation, SOFA: Sequential Organ Failure Assessment, PT-INR: Prothrombin time-international normalized ratio, IJV: Internal jugular vein, ICA: Internal carotid artery

Table 2: Outcome measures in the marked group versus the unmarked group

Outcome variables	Marked needle Group (*n*=31)	Unmarked needle Group (*n*=31)	*P*
Number of attempts	1.03±0.18	1.26±0.51	0.03
Access time (s) (skin-to-guide wire insertion)	177.97±54.10	168.77±64.73	0.55
Number of complications (*n*)			
Arterial puncture	0	1	0.31
Hematoma	1	7	0.02
Pneumothorax	0	0	
Procedure abandoned	0	0	

Data measurements are in mean±SD unless specified.
SD: Standard deviation

DISCUSSION

Our study shows that provision of a simple safety measure like marked introducer needle significantly reduces the number of attempts and mechanical complications such as hematoma during real-time US-guided CVC.

In real-time US, the operator sees the reflected view of the slender US beam (0.2–1.2 mm).[8] In this view, the operator actually visualizes the area near the needle tip rather than the actual needle tip. In short-axis view, the cross-sectional area near the needle tip can cause needle tip effect. The long-axis view cannot resolve this problem, and the needle tip may pierce the sidewall of the vein.[9] To address this issue, an echogenic vascular cannula (VascularSono, Pajunk, GmbH, Medizintechnologie, Geisingen, Germany), with "Cornerstone" reflectors near the tip, was evolved.[10] However, the use of this costly echogenic vascular cannula has not reduced the incidence of mechanical complications.[10] Moreover, for beginners, the real needle tip and echogenic reflectors in the shaft can be confusing.[10]

Our present study was in continuation to a published case of successful CVC using marked introducer needle in an obese hepatic encephalopathy patient.[11] In our study, we performed a static short-axis US view to measure the approximate depth of target IJV, carotid artery, and pleura (where ever possible) before the use of marked needle. The long-axis view for US-guided CVC was used since it provides a better imaging of the needle path, vein, and guidewire placement than the short-axis view.[9]

Access time in our study is the time between skin puncture and guidewire placement as against other studies (study with echogenic needle versus nonechogenic needle) where it is between skin to vein puncture.[11] Higher access time in our study in marked needle group may also be due to overcautious vigilance toward markings on the needle. The lesser number of attempts for CVC in marked introducer needle group may be due to similar cause. As the distance from needle entry point to the anterior and posterior wall of the vein is known, one should be overcautious in putting the needle beyond the expected distance.

We found a less number of hematoma formation during the procedure in marked needle group (3.2% vs. 22.5%; $P = 0.02$). The study using echogenic cannula reported similar results (0% vs. 10%). The cause of a more number of hematoma in unmarked group is due to posterior and lateral walls of the vein and arterial puncture by the blind tip.

Limitations and future plans

Our sample size is small. A sample size of 60 patients per group would be required to detect an intergroup difference of at least 20% ($\alpha = 0.01$, two-sided, power = 90%). The power of our study with the existing sample size is around 60%. Blinding, though desirable was not possible, as a readymade marked introducer needle is not available anywhere. Correlation between US depth and actual depth will be attempted on a larger sample in future.

CONCLUSION

Our study supports the idea that a small modification of existing introducer needle, i.e., marking the introducer needle can reduce the number of attempts and the iatrogenic mechanical complications associated with CVC. A simple modification of the existing introducer needle along with a prior assessment of depth of the vein, artery, and pleura can be another step toward zero CVC complications.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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