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Ultrasound guidance for internal jugular vein cannulation in PICU: a randomised controlled trial

Tiago Henrique de Souza,[1] Marcelo Barciela Brandão,[1] Thiago Martins Santos,[2] Ricardo Mendes Pereira,[1] Roberto José Negrão Nogueira[1,3]

[1]Deparment of Pediatrics, University of Campinas (UNICAMP), Campinas, Brazil
[2]Deparment of Emergency Medicine, University of Campinas (UNICAMP), Campinas, Brazil
[3]Department of Pediatrics, School of Medicine São Leopoldo Mandic, Campinas, Brazil

Correspondence to
Dr Tiago Henrique de Souza, Division of Critical Care, Department of Pediatrics, University of Campinas (UNICAMP), Campinas, SP 13083-887, Brazil; tiago.souza@hc.unicamp.br

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ABSTRACT

Objective We investigated whether ultrasound guidance was advantageous over the anatomical landmark technique when performed by inexperienced paediatricians.

Design Randomised controlled trial.

Setting A paediatric intensive care unit of a teaching hospital.

Patients 80 children (aged 28 days to <14 years).

Interventions Internal jugular vein cannulation with ultrasound guidance in real time or the anatomical landmark technique.

Main outcome measures Success rate, success rate on the first attempt, success rate within three attempts, puncture time, number of attempts required for success and occurrence of complications.

Results We found a higher success rate in the ultrasound guidance than in the control group (95% vs 61%, respectively; p<0.001; relative risk (RR)=0.64, 95% CI (CI) 0.50 to 0.83). Success on the first attempt was seen in 95% and 34% of venous punctures in the US guidance and control groups, respectively (p<0.001; RR=0.35, 95% CI 0.23 to 0.54). Fewer than three attempts were required to achieve success in 95% of patients in the US guidance group but only 44% in the control group (p<0.001; RR=0.46, 95% CI 0.32 to 0.66). Haematomas, inadvertent arterial punctures, the number of attempts and the puncture time were all significantly lower in the ultrasound guidance than in the control group (p<0.015 for all).

Conclusions Critically ill children may benefit from the ultrasound guidance for internal jugular cannulation, even when the procedure is performed by operators with limited experience.

Trial registration number RBR-4t35tk.

What is already known?

- Few data support the use of ultrasonography for central venous catheter placement in paediatric intensive care units.
- Studies published on this topic only included fellows who completed their residency programme in surgery or anaesthesia.
- Some studies showed that ultrasound-guided venous puncture did not have a lower failure rate or lower incidence of complications when compared with the anatomical landmark technique.

What this study adds?

- In contrast to other studies, this randomised controlled trial was conducted exclusively in a paediatric intensive care setting.
- The procedures were performed by newly graduated paediatricians who were enrolled in the paediatric intensive care residency programme.
- Even when performed by inexperienced operators, the ultrasound guidance technique might improve the quality of deep venous punctures.

INTRODUCTION

The central venous catheter (CVC) is often used in patients in intensive care units; its correct placement is particularly challenging in children.[1] For many years, the standard technique for catheterisation was guidance by an anatomical landmark, without direct visualisation of the vein and surrounding anatomical structures. This technique is still widely used as an alternative to ultrasonography (US), even in developed countries.[2 3] Due to anatomical differences in children and adults, paediatric patients are at higher risk of procedure-related complications such as arterial puncture, pneumothorax, nervous system injuries, thrombosis and haematomas. Furthermore, it has been reported that success rates were lower and the rate of complications higher when CVC placement was performed by resident physicians (ie, non-experienced operators).[4]

US guidance has been shown to provide a safe way to perform deep venous punctures; moreover, this technique might reduce complications and increase success rates.[5] Most studies on US guidance during CVC placement were conducted in adults; they consistently reported the benefits of the technique, including reduced procedure times and increased success rates on the first attempt, with a consequent reduction in the rate of complications.[6 7] However, the results of these studies cannot be extrapolated to paediatric patients. There is a paucity of pediatric-specific data related to US-guided CVC placement, and most existing literature is limited to infants undergoing cardiac surgery.[8] A meta-analysis in children and infants showed no advantages of US-guided venous puncture regarding failure rates and the incidence of complications when compared with the anatomical landmark technique.[9] However, it is important to note that most of the studies included in this meta-analysis analysed fellows who completed

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their residency programme in surgery or anaesthesia.[10–13] In the first systematic evaluation of the use of US guidance for CVC placement, specifically performed by paediatric intensivists, no improvement in success rates was reported when compared with the anatomical landmark technique.[14]

To date, there are no data supporting the US guidance technique for deep venous punctures when performed by paediatric intensive care residents. Thus, the aim of this study was to evaluate if real-time US guidance was advantageous over the anatomical landmark technique when performed by these inexperienced operators.

METHODS

Subjects and setting

This prospective randomised clinical trial was performed at the Paediatric Intensive Care Unit (PICU) of the Clinics Hospital of the State University of Campinas—UNICAMP (a tertiary care academic teaching hospital), Sao Paulo, Southeastern Brazil, between December 2014 and December 2015.Written informed consent was obtained from the legal guardians of the patients. The study was registered with the Brazilian Clinical Trials Registry (RBR-4t35tk).

All patients aged 28 days to <14 years who required central venous access (at the discretion of the attending physician) and who had been admitted to the PICU were approached for inclusion in the study. Patients with previous multiple line placements were screened for deep venous thrombosis using colour Doppler US. Children with internal jugular vein (IJV) thrombosis, coagulation disorders, tracheostomy and those who underwent cannulation of veins other than the IJVs were excluded.

Randomisation

The patients were randomised to the US-guided IJV access (US guidance) and landmark-guided IJV access (control) groups. Randomisation was performed case by case at the time of the procedure, using a simple coin toss in the presence of at least one of the researchers involved in this trial.

Procedures

All procedures were performed by newly graduated paediatricians who were enrolled in the paediatric critical care training residency programme. Their experience with central venous cannulation in children using the anatomical landmark technique was similar, with 20 supervised punctures performed prior to participating in this study.

The US training consisted of 1 hour of theory and 1 hour of practical training. During the practical training, the residents received instructions on the operation of the US device and were able to perform punctures on a handmade model that had been produced according to the instructions by Domenico *et al* (model A).[15] Then, each resident was trained in the use of the US guidance technique in five cases that were not related to this study.

Venipuncture was performed with the child under deep sedation, in the supine position, with a roll under the shoulders, and the head turned to the contralateral side. Punctures were preferably performed in the right IJV, except in cases of skin lesions, prior thrombosis or left lung injury (eg, intercostal thoracic drainage). All procedures were performed according to the Centers for Disease Control and Prevention (CDC) guidelines for the prevention of intravascular catheter-related infections.[16]

Anatomical landmark technique

The traditional anatomical landmark technique was used in patients randomised to the control group. This approach is based on the visualisation and palpation of external anatomical structures. All procedures were performed according to the instructions in the Rogers' Textbook of Pediatric Intensive Care.[17]

Ultrasound guidance technique

Two US devices (Toshiba Power Vision 6000, Tochigi, Japan and GE Healthcare Vivid Q, California, USA) that were equipped with linear transducers (6–11 MHz and 5–13 MHz, respectively) were used in this study. To avoid catheter-related bloodstream infections, the US probe was covered with a sterile cover, and a sterile conductive medium was used. In the transversal plane view, the artery and vein were visually distinguished by their relative position, compressibility of the vein and significant pulsation of the artery. After distinguishing between the two vessels, the central mark of the probe was aligned over the middle of the vein. The needle, aligned with the centre of the transducer, was then advanced into the vein directed by US visualisation.[12] The procedure was performed by one operator only.

Outcomes

The primary outcome was the success rate of central venous cannulation. Secondary outcomes included successful venipuncture on the first attempt, successful venipuncture within three attempts, puncture time, number of attempts required for success and complications such as haematomas, arterial puncture, pneumothorax and procedure-related infections.

We calculated the sample size that was required for evaluating the primary outcome. We estimated a 70% success rate for the control group, based on previous studies that reported success rates of 35%–64% for CVC placement when using the anatomical landmark technique. We further assumed that a clinically significant difference in the success rate using the US guidance technique should be at least a 25% increase when compared with the anatomical landmark technique. Based on these assumptions (success rates of 70% vs 95%), using a power of 0.85 and an alpha of 0.05 for the primary outcome, a sample size of 80 patients was calculated.

Data collection and statistics

Successful entry into the vein was recognised by the instantaneous aspiration of at least 1 mL of flash dark blood, followed by non-arterial pulsation after syringe disconnection.[10] After three failed attempts at the specified location, the operator was free to declare failure in the procedure. If carotid artery puncture and haematoma formation occurred, the puncture was abandoned at the site. However, if haematoma formation could be averted by applying pressure for at least 5 min, another attempt was made at the same site.

The time between the first needle insertion to the aspiration of blood was defined as the puncture time; it was measured by a stopwatch operated by the nursing staff. A single attempt was defined as needle insertion through a single skin puncture site. The requirement for a new skin puncture was defined as a new attempt. The presence of haematomas was clinically verified when masses or lumps occurred at the puncture site after ineffective blood reflux in the syringe. Arterial puncture was detected in the case of pulsatile light red blood reflux. Occurrence of a pneumothorax was verified by chest radiography that was performed after each procedure. Bacteraemia, which was considered a procedure-related infection, was confirmed with

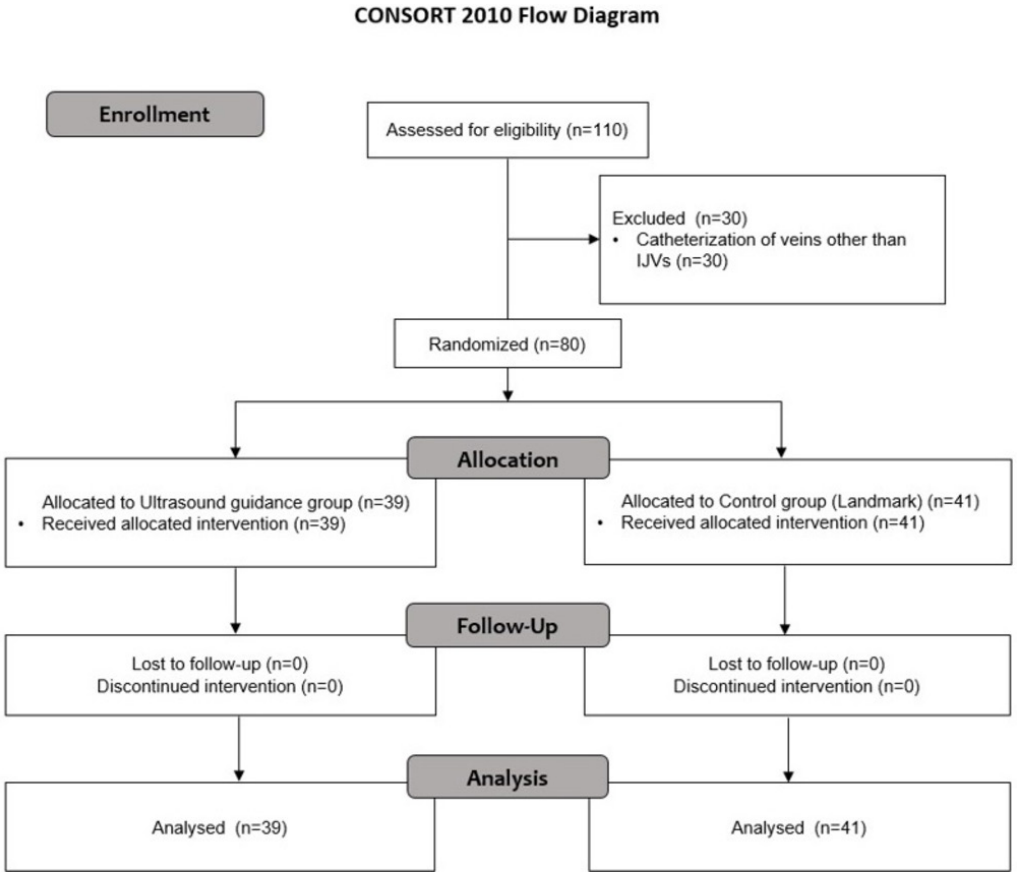

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

a blood culture within 7 days after CVC placement and was defined as being associated with signs of inflammation at the puncture site.

Continuous variables were asymmetrically distributed and are thus described as medians and IQR. Categorical variables are described as absolutes and relative frequencies. The Mann-Whitney U test was used to compare the medians between the groups and the Pearson's X^2 or Fisher's exact test to compare proportions. For categorical variables, the relative risks (RR) and 95% CI were calculated. All analyses were performed with IBM SPSS V.22.0. Significance was defined as $p<0.05$.

RESULTS

A total of 41 and 39 patients were randomly assigned to the control and US guidance groups, respectively (figure 1). The procedures were performed by six residents. The availability of the operators did not allow for an equal distribution of the procedures (22, 15, 13, 12, nine and nine punctures were performed by the six residents, respectively). The characteristics and clinical profile of the patients are shown in table 1. We observed no differences in sociodemographic characteristics between the two groups ($p=0.958$ and $p=0.365$ for age and weight, respectively).

The main results of this study are described in table 2. Successful venous puncture was achieved in 95% (37/39) and 61% (25/41) of patients in the US guidance and control groups, respectively (RR=0.64, 95% CI 0.50 to 0.83; $p<0.001$). Success on the first attempt was seen in 95% (37/39) and 34% (14/41) of venous punctures in the US guidance and control groups, respectively (RR=0.35, 95% CI 0.23 to 0.54; $p<0.001$). Fewer than three attempts were required to achieve success in 95% of patients (37/39) in the US guidance group but only 44% (18/41) in the control group (RR=0.46, 95% CI 0.32 to 0.66; $p<0.001$).

When considering only successful punctures, the median puncture time was significantly lower in the US guidance than in the control group (16 s, IQR 8–39 s vs 81 s, IQR 16–346 s, respectively; $p=0.003$, figure 2). We also identified a statistical difference in the number of required attempts for successful cannulation between the US guidance and the control group (one attempt, IQR 1–1 vs 1 attempt, IQR 1–3; $p=0.001$).

Neither pneumothorax nor procedure-related infections were reported in either group. The incidences of haematomas, the most frequent complication, were 2.6% (1/39) and 26.8% (11/41) in the US guidance and control groups, respectively (RR=0.73, 95% CI 0.61 to 0.89; $p=0.003$; table 1). The second most frequent complication was arterial puncture, which occurred in 2.6% (1/39) and 22% (9/41) of patients in the US guidance and control groups, respectively (RR=0.80, 95% CI 0.68 to 0.95; $p=0.015$).

DISCUSSION

Currently, few data support the use of US guidance for CVC placement in paediatric emergency departments and PICUs; this might contribute to low usage rates by paediatricians in practice.[8] Even in developed countries, the practice of using US guidance for CVC placement is not widespread among intensive care paediatricians. A survey in the UK showed that although 85% of physicians included in the study had access to US devices for the guidance of CVC placement, only 39% used them routinely.[2] To the best of our knowledge, this is the first prospective randomised study conducted in a PICU that evaluated paediatric

Table 1 Patient characteristics.

Variables	US guidance group (n=39)	Control group (n=41)
Age (months)	8 (3–14)	7 (3–16)
Weight (kg)	5.5 (3.4–8.8)	6.1 (4.5–11.2)
Respiratory failure	14	13
Bronchiolitis	4	3
Bacterial pneumonia	3	4
Cystic fibrosis and others chronic lung diseases with acute exacerbations	7	6
Heart failure	5	8
Congenital heart defects	4	6
Arrhythmia	0	1
Scorpion sting	1	0
Dilated cardiomyopathy	0	1
Kidney failure	1	2
Nephrotic syndrome	1	2
Liver failure	4	3
Extrahepatic biliary atresia	3	3
Transplant rejection	1	0
Sepsis	10	8
Meningitis	4	2
Pyelonephritis	1	0
Endocarditis	3	1
Peritonitis	1	3
Cryptogenic	1	2
Trauma	1	3
Elective catheterisations*	4	4

Data given as median (IQR) or n.
*Patients underwent internal jugular vein catheterisation in the intensive care unit without critical illness

residents using the anatomical landmark versus the US guidance techniques for deep venous punctures. Similar studies have been performed in surgical settings.[10–13 18–20]

Some randomised studies in children in surgical settings found comparable results to the present study.[10 12 18 20] Verghese *et al* compared the traditional landmark and US guidance techniques for IJV puncture in a prospective study of 95 children and found a significantly higher success rate for US guidance (100% vs 77%, respectively).[12] Similar results were reported by other authors.[10 18 20] The success rates for the landmark technique described by these authors were higher than that reported in our study (61%). We hypothesise that differences in operator

Table 2 Main results (p<0.05 for all).

Variables	US guidance group (n=39)	Control group (n=41)	
Success rate	37/39 (95%)	25/41 (61%)	RR=0.64 (95% CI 0.50 to 0.83)
Success in the first attempt	37/39 (95%)	14/41 (34%)	RR=0.35 (95% CI 0.23 to 0.54)
Success in <3 attempts	37/39 (100%)	18/41 (44%)	RR=0.46 (95% CI 0.32 to 0.66)
Haematomas	1/39 (2.6%)	11/41 (26.8%)	RR=0.73 (95% CI 0.61 to 0.89)
Arterial puncture	1/39 (2.6%)	9/41 (22%)	RR=0.80 (95% CI 0.68 to 0.95)
Time (s)	16 (8–39)	81 (16–346)	
Number of attempts	1 (1–1)	1 (1–3)	

Data given as n (%) or median (IQR).

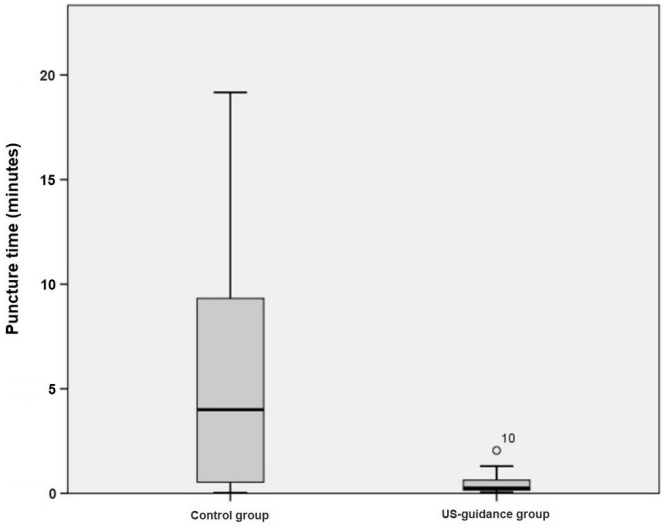

Figure 2 Time to successful puncture in the ultrasound guidance and control groups.

experience and patient characteristics (as the profiles of patients admitted to intensive care units differ from those admitted to surgical centres) likely caused the differences in the success rates seen for the anatomical landmark technique.

Some studies did not find lower rates of catheterisation failures for US guidance when compared with the anatomical landmark technique.[13 14 19] The only systematic evaluation of US guidance for CVC placement performed specifically by paediatric intensivists in critically ill or injured children reported no significant improvement in the success rate or time to successful placement.[14] Nevertheless, the use of US guidance was associated with fewer inadvertent arterial punctures and fewer attempts required for success.[14]

The median weight of the patients included in this study (around 6 kg) was very similar to the study published by Verghese *et al* that showed favourable results of the use of US guidance for venous punctures.[12] Two studies that did not find advantages of US guidance over the landmark technique included paediatric patients with a higher median/mean weight than that of our study.[14 19] When we restricted our analysis to patients with a weight below the median of the sample, we found a higher failure rate in the control than in the US guidance group (60% vs 8.7%, respectively; p<0.001). These data suggest that the use of US guidance for CVC placement may be especially important in smaller children.

In our study, the use of US guidance for CVC placement was associated with a shorter puncture time and fewer attempts required for success. It is crucial to minimise the number of attempts needed to reach catheterisation as the incidence of complications increases dramatically after three puncture attempts.[7 12 21] Reducing the number of attempts appears to be the clearest benefit of US guidance and has been reported in most published studies.[10–12 14 18 20] We found a surprisingly high success rate on the first attempt in the US guidance group (95%). Bruzoni *et al* studied surgeons and also found a significant difference in the success rate on the first attempt for US guidance when compared with the anatomical landmark technique (65% vs 45%, respectively)[10] ; however, the success rates were overall lower than those reported in our study.

Haematoma was the most frequent complication of IJV puncture observed in our trial, followed by arterial puncture; both had a low incidence in the US guidance group. The rates of

inadvertent arterial puncture with the landmark technique have been shown to range from 3% to 25%, depending on operator experience.[12 18 22–24] Inadvertent arterial puncture can result in major complications, including haematomas, haemothorax, pseudoaneurysm, arteriovenous fistulae, embolism and arterial cannulation.[5–7 10] As our study, other authors also reported a significant reduction in the rate of arterial punctures for US-guided CVC placement when compared with the anatomical landmark technique.[10 12 14 18 20] Only in one study, anesthesiologists reported a significant increase in the rate of arterial punctures for US guidance when compared with the anatomical landmark technique (11.9% vs 6.2%, respectively).[19] The authors assumed that the higher failure rates may have been related to the operators' inexperience using the US probe.

Simulation-based medical education has been shown to be associated with improved in-hospital performance of CVC insertion.[25] However, the tactile and anatomic differences between a manikin, phantom models and the authentic human body make the latter a more attractive training modality. In an attempt to improve the quality of the simulation, some authors have suggested the use of fresh cadavers for venous catheterisation training.[26] Perhaps, the greatest challenge of simulation training is to replicate the emotionally stressful environment of a medical emergency. The authors of this study believe that although simulation training is an important supporting tool for medical education, it is important for residents to experience the stressful environment related to medical emergencies during their training.

Our study has several limitations. This was a single-centre study with a small sample size. However, the intervention and control groups showed comparable baseline characteristics, and the statistical power for measuring differences between the two groups was 85%. Moreover, there were fewer punctures in children weighing ≤6 kg. The volemic status and disease severity of the patients were not considered in this study; these factors can affect the diameter of a deep vein.

CONCLUSION

In children admitted to the PICU, the use of US guidance for venous punctures by non-experienced operators might significantly decrease the failure rate, puncture time, required number of attempts and incidence of complications related to the procedure. Even when performed by residents with little experience in deep venous puncture techniques, the use of US guidance seems to be safe and effective. Further studies with larger sample sizes are necessary to support the mandatory use of US guidance in paediatric clinical practice.

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Contributors THdS, MBB and RMP conceptualised and designed the study and data collection instruments, coordinated and supervised data collection. THdS, TMS and RJNN wrote the manuscript and analysed data. RJNN revised the manuscript. All authors approved the final version of the manuscript.

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