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The intracavitary ECG method for tip location of ultrasound-guided centrally inserted central catheter in neonates

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Abstract

Background: The correct position of the tip of a central venous access device is important in all patients, and especially in neonates. The traditional method of tip location (approximated intra-procedural length estimation + post procedural chest X-ray) is currently considered inaccurate and not cost-effective by most recent guidelines, which recommend the adoption of tip location by intracavitary electrocardiography (IC-ECG) whenever possible.

Methods: This study prospectively investigated the applicability, the feasibility, the accuracy, and the safety IC-ECG for tip location in neonates requiring insertion of ultrasound-guided centrally inserted central venous catheters (CICCs) with caliber 3Fr or more. All catheter tip locations were verified using simultaneously both IC-ECG and ultrasound-based tip location, using the Neo-ECHOTIP protocol.

Results: A total of 105 neonates were enrolled. The applicability of IC-ECG was 100% since a P wave was evident on the surface ECG of all neonates recruited for the study. The feasibility was also 100% since an increase of the P-wave was detected in all cases. The accuracy was also 100%, since a perfect match between IC-ECG based tip location and ultrasound-based tip location was found. There were no adverse events directly or indirectly related to the IC-ECG technique; no arrhythmias occurred.

Conclusions: When applied to ultrasound guided CICCs, tip location by IC-ECG is applicable and feasible in neonates, and it is safe and accurate.

Keywords

Techniques and procedures, neonatal intensive care, tip location, POCUS, intracavitary ECG

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Introduction

Central venous access devices (CVAD) are essential in the care of critical ill patients, both in adult patients and in children and neonates.

Current guidelines recommend that the tip of a CVAD inserted through the superior vena cava (SVC) should be preferably located in the proximity of the junction between the right atrium and the SVC (cavo-atrial junction = CAJ).[1] An inappropriate location of the tip of a CVAD may lead to several complications including thrombosis,[2] vein wall perforation, tip migration,[3,5] life-threatening arrhythmias, tricuspid valve dysfunction, atrial thrombosis,[4] pleural and pericardial effusion, and cardiac tamponade.[6]

Current guidelines[1] recommend that the proper tip location should be assessed during the procedure, preferably

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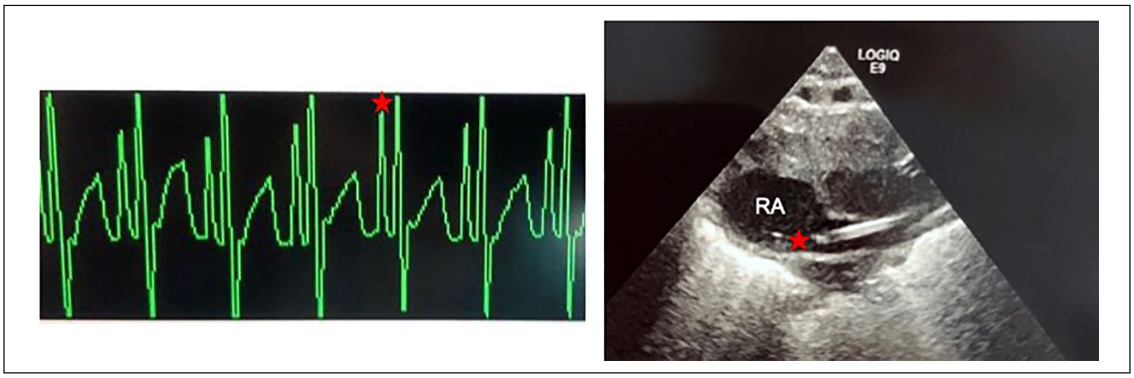

Figure 1. Intracavitary ECG pattern for correct tip location and corresponding US view.

using the intracavitary ECG method (IC-ECG) or—in some situations—ultrasound-based methods of tip location or—if strictly needed—fluoroscopy. Post-procedural tip location by chest X-ray is currently discouraged, for several reasons: (a) it is not accurate, as the CAJ is not directly visualized on the chest X-ray, but its location is only indirectly suggested by unreliable radiological landmarks such as for example the vertebral bodies, the cardiac silhouette, or the diaphragmatic contour; (b) it implies a delay in the starting of the use of the CVAD; (c) it requires exposure of the patient to ionizing radiation.

Among the intraprocedural methods of tip location currently available, IC-ECG and ultrasound should be preferred to fluoroscopy since they are more accurate, less expensive, easier to perform, and certainly safer than fluoroscopy, since they do not imply exposure to radiation.[1]

The intracavitary ECG (IC-ECG) technique for tip location was first described in 1949.[5] The precise position of the catheter tip inside the vasculature can be individuated by considering the catheter as an intracavitary electrode that replaces the right shoulder electrode of the standard surface ECG; when the catheter is connected to the ECG monitor, the height of the P wave reflects the position of the tip in relation to depolarizing atrial tissue (as the tip is at the CAJ, the P wave reaches its peak) (Figure 1). Due to its accuracy, safety, cost-effectiveness, and fast learning curve, IC-ECG is currently recommended for the intraprocedural assessment of tip location for any central venous access, in all patients regardless of the age. This technique of tip location has been used also in neonates, during placement both of umbilical venous catheters (UVC) and of epicutaneo-cava catheters (ECC).[7]

In the last decade, a new CVAD has been adopted in neonatal intensive care unit, that is, the ultrasound-guided centrally inserted central catheter (CICC). In neonates, it is possible to insert 3Fr-4Fr polyurethane catheters by real time ultrasound guided puncture and cannulation of the brachio-cephalic vein (or, less frequently, in the internal jugular vein). Little or no data are available in the literature about the use of IC- ECG for this type of neonatal central venous access. This prospective study was aimed to investigate the applicability, the feasibility, the accuracy, and the safety of the IC-ECG method for the CICC tip confirmation when placing CICCs via the brachio-cephalic vein.

Methods

The study was conducted over 24 months in the neonatal intensive care unit (NICU) of two different Italian hospitals: University Hospital Fondazione Policlinico Gemelli IRCCS in Rome and "Infermi" Hospital in Rimini. About 25 beds of admission were active in both NICUs (16 in Rome and 9 in Rimini) with a mean of 350 admissions per year of infants requiring intensive care.

The aim of this study was to evaluate the applicability, the feasibility, the accuracy, and the safety of IC-ECG for tip location in neonates admitted to two NICUs and requiring a CICC.

As the IC-ECG method is based on the variations of the amplitude of the P wave, we defined applicability as the proportion of neonates who had an identifiable and changing amplitude of the P wave with CICC advancement.

The feasibility included the evaluation of the method in technical and operational terms. Feasibility was therefore defined as the possibility of successfully bringing the procedure as described below to its conclusion; in other words, feasibility was defined as the percentage of cases where there was a clear identification of the peak of the P wave (corresponding to the CAJ).

The accuracy was assessed by comparing IC-ECG to our standardized ultrasound-based method for CICC tip confirmation as already described in a previous study.[8] Accuracy was calculated as percentage of the match or mismatch between the position of the tip as evaluated with IC-ECG versus ultrasound.

The safety of the method was evaluated considering the potential arrhythmogenic risk and the potential risk of electric hazard for the patient or for the operator.

All neonates admitted to one of NICUs, that required a CVAD were consecutively assessed for eligibility (eligible for a brachio-cephalic CICC insertion approach, normal native heart rhythm). Exclusion criteria were (a) infants with more than 28 days of life (if born at term); (b) infants with a postmenstrual age of 40 weeks (if born preterm). Informed consent was obtained from both parents before the procedure, as requires by Ethics Committee. We inserted power injectable polyurethane catheters, either 3Fr single lumen or 4Fr double lumen, adopting our insertion bundle for pediatric central lines,[9] which includes: pre-operative ultrasound scan of central veins (RaCeVA: Rapid Central Vein Assessment) so to choose the most appropriate vein for cannulation.[10]

- maximal barrier precautions.
- skin antisepsis with 2% chlorhexidine in 70% isopropilic alcohol.
- ultrasound guided venipuncture using modified Seldinger technique and a micro-introducer kit.
- ultrasound assessment of the direction of the guidewire into the vasculature (ultrasound-based tip navigation).
- tip location using simultaneously both IC-ECG and ultrasound-based tip location.
- anterograde tunneling of the catheter to the infraclavicular area.
- securement by subcutaneously anchored sutureless device.
- application of cyanoacrylate glue both for closing the puncture site and for sealing the exit site;
- coverage of the exit site with semipermeable transparent membrane.

All catheters were inserted by three operators (MP, VD, and GB) well trained in ultrasound guided venipuncture and cannulation.

As regards IC-ECG, the technique was performed using a standard ECG monitor. The II lead was set prior the procedure, verifying the presence of the P wave, and the AC filter (cutting off 60 Hz) was activated to avoid interferences. The speed of the ECG trace was set at 50 mm/s to facilitate the interpretation of the trace and the visualization of the P wave. The IC-ECG method was performed adopting exclusively the technique of the liquid column, connecting the catheter with the ECG monitor by means of a dedicated sterile cable (Vygocard, Vygon).

Our protocol for IC-ECG is as follows. After vein cannulation, the catheter was inserted into the vessel through a micro-introducer (modified Seldinger technique). At this time, the surface ECG is switched to the intracavitary ECG. As the catheter advances into the SVC, the P wave increases, reaching a peak at the CAJ; proceeding further, a progressive reduction of the P wave and/or the appearance of an initial negative component in the P wave occurs. To be sure that the peak of the P wave has been properly identified, the catheter was inserted further on, until the P becomes diphasic, then the catheter was withdrawn back to the maximum peak of the P wave. The catheter is secured in this position by subcutaneous anchorage.

After securement, tip location is also verified by ultrasound. According to the Neo-ECHOTIP protocol,[8] a small sectorial probe (7–8 MHz) was used and at least one of three different windows: the subcostal bi-caval view, the four-chamber apical view, and the long axis parasternal view of the SVC. In any of these views, a small flush of normal saline (0.5–1 ml) is used so to enhance the visualization of the tip of the catheter. Ultrasound-based tip location was performed by two neonatologists (GB and VD) with over 10 years of experience in neonatal ultrasound.

Sample size was calculated as follows. Tip location with ultrasound was considered the gold standard and therefore as able to correctly locate all catheters (100% of the cases). Calculations indicated a sample size of 105 patients to yield 80% power (with alpha = 0.05) for detecting a difference in diagnostic accuracy $>7\%$ using intracavitary ECG.

Sensitivity, specificity and accuracy of intracavitary ECG will be calculated using real time ultrasound as gold standard for tip location. Fisher exact test will be used to compare the percentage of catheter properly located using the two techniques. Continuous variables will be evaluated with descriptive statistics (mean, medium, standard deviation and interquartile range). Non continuous variables will be described as number and percentage. A p value <0.05 will be considered as statistically significant. The level of agreement among two neonatologists (GB, VD) was evaluated using Cohen's Kappa score.

Results

During the period of study 620 infants were admitted in NICUs. All infants eligible for CICC placement were enrolled from January 2018 to January 2020, and a total of 105 neonates were recruited; median age was 16 days (IQR 7–67 days). Table 1 summarizes the main characteristics of the patients.

The applicability of IC-ECG was 100%, since a P wave was evident on the surface ECG of all neonates recruited for the study.

The feasibility of IC-ECG was also 100%, since a peak of the P wave was identified during all procedures.

The match between IC-ECG based tip location and ultrasound-based tip location was optimal, since all catheters were properly located at the CAJ as judged by ultrasound. All catheter tips were identified at ultrasound tip location, using one or more of the windows as described above.

There was no complication reported during the procedure, and in particular no complication potentially related to the IC-ECG method, either directly or indirectly.

Table 1. Neonatal population and CICCs descriptive statistics. Values are expressed as median [IQR] or absolute number (percentage).

Population (*n*)	105
Gestational age (weeks)	32 [26–37]
Birth weight (g)	1890 [765–2845]
Age at time of insertion (days)	16 [7–67]
Weight at time of insertion (g)	2370 [1480–3140]
Indication at insertion (%)	Surgery disease 32 (30.4)
	respiratory distress syndrome 23 (21.9)
	BPD 21 (20)
	Prolonged parenteral nutrition 16 (15.2)
	Septic shock 9 (8.6)
	DIVAs >4 4 (3.8)
Reason for removal CICC (%)	Elective removal 85 (81)
	CRBSI 0.77/1000 line days
	Infective complications 11 (10.4)
	Mechanical reason 9* (8.6)

*Two CICCs were removed after a mean dwell time of 40 days; since these two preterm had fast growth therefore the two devices were found to be short (non-central position at subsequent ultrasound examination).

Out of the 105 CICCs, 85 (81%) were electively removed; 11 (10.4%) were removed for infective complications; 9 (8.6%) were removed for mechanical reasons (in most cases, malfunction due to fibroblastic sleeve). The overall incidence of catheter-related blood stream infections (CRBSI) was 0.77 per 1000 catheter days. No secondary malposition was reported. The rates of non-planned CICC removals were similar to those evaluated in the previous our database and previous studies.[9,11]

Discussion

Our results suggest that IC-ECG is 100% applicable, 100% feasible, 100% accurate, and 100% safe for tip location of ultrasound-guided CICCs in neonates.

In the past decades, post-procedural chest X-ray and intra-procedural fluoroscopy were considered the gold standard for assessing tip location of central venous access devices. It is now recognized that radiological methods of tip location have several limitations, including the inevitable exposure to ionizing radiation and an overall inaccuracy, since they may directly visualize the catheter tip, but they can locate the CAJ only indirectly.[12] Additionally, fluoroscopy is expensive and requires a specific setting (interventional radiology or operating room); on the other side, chest X-ray—as post-procedural assessment—it is associated with an inevitable delay before starting to use the central line.[12,13]

Both IC-ECG and ultrasound are validated as effective, inexpensive, and safe techniques for intra-procedural tip location in adults and children.[12,14,15] A good quality of evidence suggests that they should be adopted also in neonates.[8,16–18] Though, there are some relevant differences between IC-ECG and ultrasound-based tip location. In fact, the latter requires specifically trained operators, aware of the basic notions of standard echocardiography.[12,19] On the contrary, IC-ECG is particularly easy to learn and to teach, it is not operator dependent, and it is also extremely accurate.[12]

The extremely high accuracy of IC-ECG has been demonstrated in the adult population comparing tip location with IC-ECG versus X-ray, using as gold standard transesophageal echocardiography.[20–22] Many studies have proven the cost-effectiveness of IC-ECG if compared to radiological methods of tip location.[13,23]

The effectiveness and accuracy of IC-ECG in adult patients have been confirmed by many studies over the course of the last decade.[24–39] A good quality of evidence is also available in the pediatric population.[40–48]

On the other side, only few studies have been published about IC-ECG in neonates. This might be related to the fact that the most studies have investigated IC-ECG applied to UVC and ECC, the most common central vascular access devices used in NICU. Tip location of UVC and ECC by IC-ECG may not be efficient, if compared to ultrasound-based methods. IC-ECG has been shown to be safe and effective for tip location of UVC[49]; however, no study has suggested any advantage of IC-ECG for UVC if compared to real time ultrasound. As regards ECC, there is a growing evidence about the use of IC-ECG[50–52]; still, in these very small catheters (caliber <3Fr), the IC-ECG may be not easy and not always feasible, as the conductivity of the thin column of saline inside the catheter may impair the signal of intracavitary ECG.

On the contrary, the accuracy and the safety of the technique are not surprising, since they have been proven by many decades of clinical use in adults and children. The very high rate of applicability and feasibility in neonates is probably related to two main reasons: (a) the CICCs used are relatively large bore catheters (3 or 4 Fr), so that the technique of the column of saline can be performed easily; (b) abnormal rhythms—which may reduce the applicability of IC-ECG are very rare in the neonatal population.

Conclusion

Our data suggest that the IC-ECG method is a very effective for tip location of ultrasound-guided CICCs in the neonatal population. IC-ECG appears to be optimal in terms of applicability, feasibility, safety, and accuracy. It is as inexpensive as ultrasound-based tip location, but it carries the advantage of being easier to learn and easier to teach if compared to ultrasound methods. These results cannot be extended to other central venous access devices used in neonates (UVC and ECC), where ultrasound-based tip location plays a major role.

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