

# The intracavitary electrocardiography method for positioning the tip of epicutaneous cava catheter in neonates: Pilot study

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Antonella Capasso<sup>1</sup>, Rossella Mastroianni<sup>1</sup>, Annalisa Passariello<sup>2,3</sup>,  
Marta Palma<sup>2</sup>, Francesco Messina<sup>4</sup>, Antonella Ansalone<sup>1</sup>,  
Italo Bernardo<sup>1</sup>, Daniela Brescia<sup>1</sup>, Francesco Crispino<sup>1</sup>,  
Carolina Grassia<sup>1</sup>, Attilio Romano<sup>1</sup> and Gaetano Ausanio<sup>1</sup>

## Abstract

**Purpose:** The neonatologists of Sant’Anna and San Sebastiano Hospital of Caserta have carried out a pilot study investigating the safety, feasibility, and accuracy of intracavitary electrocardiography for neonatal epicutaneous cava catheter tip positioning.

**Patients and methods:** We enrolled 39 neonates (1–28 days of postnatal age or correct age lower than 41 weeks) requiring epicutaneous cava catheter in the district of superior vena cava (head–neck or upper limbs). Intracavitary electrocardiography was applicable in 38 neonates.

**Results:** No significant complications related to intracavitary electrocardiography occurred in the studied neonates. The increase in P wave on intracavitary electrocardiography was detected in 30 cases. Of the remaining eight cases, six malpositioned catheters tipped out of cavoatrial junction–target zone (chest x-ray and echocardiographical control) and two were false negative (tip located in target zone). The match between intracavitary electrocardiography and x-ray was observed in 29/38 cases, and the same ratio between intracavitary electrocardiography and echocardiography was detected.

**Conclusion:** We conclude that the intracavitary electrocardiography method is safe and accurate in neonates as demonstrated in pediatric and adult patients. The applicability of the method is 97% and its feasibility is 79%. The overall accuracy is 76% but it rises to 97% if “peak” P wave is detected.

## Keywords

Epicutaneous cava catheter, intracavitary electrocardiography, neonates, peripherally inserted central catheter, target zone, tip position

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## Introduction

The use of peripherally inserted central catheter (PICC) is widespread in neonatal intensive care units (NICUs). A central catheter provides an ideal access for successful treatment in critically ill newborns. The epicutaneous cava catheters (ECCs), the most used catheter in neonatal age, are very thin; they are necessarily positioned through a superficial vein. These characteristics distinguished the ECCs from children’s and adult’s central catheters. The correct position of the tip of central venous catheter (CVC) is crucial in neonates. The ideal position has been said to

<sup>1</sup>Neonatal Intensive Care Unit, Hospital Sant’Anna and San Sebastiano, Caserta, Italy

<sup>2</sup>Department of Translational Medical Science, University of Naples “Federico II,” Naples, Italy

<sup>3</sup>Department of Pediatric Oncology, Santobono-Pausilipon Hospital, Naples, Italy

<sup>4</sup>Neonatal Intensive Care Unit, “Villa Betania” Evangelical Hospital, Naples, Italy

### Corresponding author:

Gaetano Ausanio, Neonatal Intensive Care Unit, Hospital Sant’Anna and San Sebastiano, Palasciano Street, Caserta 81100, Italy.  
Email: ausanio1961@libero.it

be between the lower third of the superior vena cava (SVC) and the upper third of the right atrium (RA), but the only guidelines available specifically related to the pediatric patient are issued by the Great Ormond Street Hospital and the Pediatric Special Interest Group of AVA (Association for Vascular Access). The positioning of a CVC can lead to increased side effects if the tip is located in the wrong position. If the tip is placed too low in the RA, there may be a risk of myocardial infiltration and arrhythmias; if the tip is placed too high in the SVC, there may be a risk of venous thrombosis and pericarditis. Regarding late cardiac tamponade (LCT), it has been described as secondary both to perforation of the RA and to perforation of the SVC; thus, a clear correlation between LCT and tip position is not established.<sup>1-8</sup> In neonates, chest radiography has been regarded as a practical standard for the verification of correct tip location after catheterization. The interpretation of radiological images is difficult because the validity of radiological landmarks is debated. In fact, even in recent studies,<sup>9-11</sup> the carina has been recommended in children as a landmark to guide the CVC placement; in neonates, the carina is not always located above the pericardium, as it is in adults; therefore, the carina is not an appropriate landmark for CVC placement.<sup>12</sup>

In addition, post-procedural assessment of tip position can lead to more radiation exposure if a reposition is required for a malpositioned catheter. Ultrasonography is an alternative method in assessing PICC tip position but this technique needs specific skills. Actually, new methods are being investigated such as the intracavitary electrocardiography (IC-ECG) for real-time monitoring and verification of CVC tip placement.<sup>13-15</sup> A recent multicenter study conducted by GAVeCeLT (the Italian Group for Venous Access Devices) has already demonstrated the safety and feasibility of IC-ECG in pediatric patients and has confirmed its accuracy compared with postoperative chest x-ray.<sup>16</sup> But newborns and ECCs are not included in this study. ECCs placement with ECG-IC in neonates should be more widespread, since the evaluation of the length of insertion of the catheter from the puncture site to the target zone is more difficult.<sup>16</sup> However, few studies have been reported about ECC placement with IC-ECG in neonates<sup>17,18</sup> and the studies performed included late preterm or term neonates who weighed more than 900 g. The aim of our pilot study was to verify the safety, feasibility, and accuracy of IC-ECG in the positioning of ECCs in any newborn, independent of weight, gestational age, and catheter size.

## Methods

This is a prospective observational study conducted by neonatologists from Sant'Anna and San Sebastiano Hospital of Caserta.

Similarly, as reported by Rossetti et al.<sup>16</sup> in their study protocol, we have evaluated the following:

1. *The applicability of the method.* As the IC-ECG is based on the variations of the shape of the P wave, we defined applicability as the percentage of neonates who had a visible P wave on the surface ECG and thus were eligible for the IC-ECG.
2. *The feasibility of the method in technical and operational method terms.* "Feasibility" was defined as the possibility of successfully bringing the procedure described below the "Conclusion" section, which is the proper identification of the "peak" P wave corresponding to the passage between the SVC and RA.
3. The safety of the procedure in terms of potential arrhythmogenic risk or other types of risks for the patient or for the operator.
4. The accuracy of the method was defined in comparison with two methods widely used in clinical practice: the radiological and echocardiographical verification of the tip position at the end of procedure. Accuracy was calculated as the match or mismatch between the position of the tip as assessed by IC-ECG during the procedure ("peak" P) and the position of the tip assessed at the end of the procedure by chest x-ray and echocardiography. As the radiography has a wide margin of variability in detecting the actual tip position, it was absolutely important to define precise criteria for the interpretation of the radiological image (see below). Furthermore, as the posture of patient affects the position of the tip, we chose to have the post-procedural radiological control in a supine position.

The study protocol was examined and approved by the Ethics Committee of Campania Nord, Italy (12 July 2017), and parents or guardians of all enrolled patients provided written informed consents.

## Patients

From February 2016 to July 2017, the neonates who underwent ECC placement in the district of SVC (head-neck or upper limbs) were enrolled. Inclusion criteria were term and preterm neonates with postnatal age 1-28 days or correct age lower than 41 weeks and parental informed consent for positioning the ECC using IC-ECG method. Exclusion criteria were correct age greater than 41 weeks, previously diagnosed severe and complex congenital heart disease, coagulation disorders, and neck and chest deformities.

We have divided the patients into two groups, based on caliber catheter instead of their weight:

- *Group 1.* Patient cannulated with catheter 28G—overall, 27 neonates.
- *Group 2.* Patient cannulated with catheter 24G—overall, 11 neonates.

## ECCs

The ECC was chosen according to the venous heritage of the neonates between 28G (Premicath 1Fr/28G; Vygon, Aachen, Germany) and 24G (Nutriline 2Fr/24G; Vygon) ECCs. Allowed districts were arm veins (cephalic or basilica vein), hand veins, axillary veins, and external jugular or temporal veins.

For the purpose of this study, all ECCs the tips of which were within a target zone corresponding to the lower third of the SVC, or at the cavoatrial junction (CAJ), or in the upper area of the RA (see below for the definition of this area with ECG and radiological criteria) were considered as positioned correctly.

## Intra-procedural verification of tip position by IC-ECG

In the IC-ECG method for positioning of the tip, the catheter itself is used as an intracavitary electrode and this can be obtained by two different techniques: either the intracavitary electrode is a metallic guide inserted inside the catheter or the intracavitary electrode is a liquid column (saline hypertonic solution, see below) which fills in the catheter itself. Within this study, only the technique of the liquid column was considered, as it is safer with regard to possible arrhythmias that can be triggered by a wire which comes out of the catheter and may come in contact with the atrial walls. This methodology required a device specifically designed for the IC-ECG.

We used Vygonard (Vygon) for easy shifting from surface ECG tracing to intracavitary ECG tracing. We used the defibrillator Defigard 5000 (DG5000, Schiller Medical, Wissembourg) as an ECG monitor.

Three electrodes were used: yellow—left shoulder, red—right shoulder, and green—left flank. The IC-ECG focused on lead II (red to green), which is ideal for the visualization of the P wave. Whenever the P wave is evident on surface ECG on lead II, the IC-ECG is applicable. After having registered basal ECG, the red electrode is detached from the shoulder and connected with special Vygonard clip. After that, we begin to position the catheter. We used surface landmark for estimating the length of insertion of catheter from puncture site. The catheter is threaded further on into the venous system; when the tip is 2 cm before the optimal measured position, the catheter is filled with saline hypertonic solution and attached to the connector of the transducer. The surface ECG is switched to the intracavitary ECG, and by watching the variation of the shape of P wave on the intracavitary lead II, it is

possible to infer the position of the catheter tip. As the catheter proceeds slowly into the SVC, the P wave gets higher, reaches its peak at CAJ, and proceeding further gradually decreases to become diphasic. To ensure that the tip is well-positioned, it is appropriate to insert the catheter until the P wave becomes diphasic and then pull it back until the P wave is at its peak (positioning that will correspond to the CAJ).

The variation of P wave may be influenced by many factors such as the electrode position, the choice of the voltage most appropriate for the display of the monitor, and the interference from other electromedical devices operating in proximity to the patient.

## Post-procedural radiological control

The radiological control at the end of procedure was carried out through standard chest x-ray. All the patients were studied in one projection (anteroposterior (AP) view), in the same position: supine position and arms along the body, in consideration that the t position of the tip may significantly change with variation arm movements. We have decided to use the carina as radiological landmark for the radiological verification of the position of the tip. The target position of the tip was from 1cm above the carina until 2cm maximum under the carina, related to weight of the neonate because, according to the literature, this is the usual CAJ position at least in children,<sup>16</sup> but it is not sure in neonates.<sup>12</sup>

## Post-procedural echocardiographical control

As the radiological landmark in neonates is unreliable, and based on statistics, we used echocardiography as the second and more reliable verification of the tip position. All the patients were studied with a 5-Mhz semiconvex probe, in most cases with a subcostal bicaval projection. The target position for the tip was lower third of SVC, CAJ, and upper third of RA.

## Collection and analysis of the data

For each insertion, we considered the following data: underlying disease, maternal risk factors, and presence of visible P wave at the surface basal ECG:

1. *ECC data.* External diameter (G) and total length;
2. *Insertion data.* Vein punctured and cannulated, side of insertion (right or left);
3. *IC-ECG data.* Identification of the peak of the P wave during the maneuver; final position of the tip (lower third of the SVC=P wave at about half to one-third of the maximum amplitude, CAJ=peak of the P wave, upper portion of the RA=wave decreasing in amplitude, and/or with an initial

negative component); intraoperative complications potentially related to IC-ECG (arrhythmias, bleeding, etc.);

4. *Radiological data.* Type of projection (AP or lateral (LL) view), modality of execution (if different from what that previously described in the protocol), classification of the tip position are as follows: mismatch between IC-ECG and x-ray: tip not within the target zone (specifying the distance from the carina) and a good match between IC-ECG and x-ray: tip within the target zone (specifying the distance in centimeters from the carina).
5. *Echocardiographical data.* Other types of projection (subcostal bicaval projection or other types of projection) and classification of the tip position are as follows: mismatch between IC-ECG and echocardiography: tip not within the target zone (specifying the position and the distance from the target zone) and a good match between IC-ECG and x-ray: tip within the target zone.

Both Rx interpretation and echocardiographical study were performed by the same two specialists (a radiologist and a neonatologist with cardiological experience).

All data were collected in a software-based database for statistical analysis. Quantitative variable (gestational age, weight, age at procedure, etc.) was expressed by average value  $\pm$  standard deviations and in one case with Fisher's exact test. Qualitative variables (size of ECCs, site of access, etc.) were described in terms of percentages.

## Results

A total of 39 neonates were enrolled for this study. They were 30 males and 9 females, of which are 2 term neonates and 37 preterm neonates, with mean gestational age  $29.41 \pm 3.04$  (range: 25–40) weeks. Median age for first catheterism was  $12.30 \pm 3.58$  days. Mean birth weight was  $1213.97 \pm 456.71$  (range: 670–2.750)g.

In 1 of 39 neonates, the P wave was too high on the surface ECG (due to pulmonary hypertension) so that IC-ECG could not be performed. This corresponded to an applicability of 97%.

IC-ECG was performed in 38 patients. In eight cases, no elevation of the P wave could be detected on the IC-ECG (so overall feasibility was 79%).

Of these eight negative cases, seven were in group 1 and one was in group 2, but the result of Fisher's exact test was not significant at  $p < 0.05$ , between two groups. Table 1 shows the distribution of the patients.

In the majority of cases, the tip was in the CAJ in 39.4%, in the lower third of SVC in 28.9%, and in the upper third of RA in 15.7% (Table 2). In six cases, the tip was malpositioned (the tip of the catheters was in subclavian veins in five cases and in jugular veins in one case).

**Table 1.** Patients' distribution—applicability and feasibility.

Total	39
Sex (male/female)	30/9
Gestational age, mean $\pm$ SD (range) (weeks)	$29.41 \pm 3.04$ (25–40)
Weight, mean $\pm$ SD (range) (g)	$1.213 \pm 456$ (670–2.750)
Group 1 (catheter 1F)	26
Group 2 (catheter 2F)	12
Not applicability	1 (3%)
Not feasibility	8 (21%)

SD: standard deviation.

**Table 2.** Tip location.

CAJ	15 (39.4%)
SVC	11 (28.9%)
Upper 3° RA	6 (15.7%)
Malpositioned	6 (15.7%)
Total	38

CAJ: cavoatrial junction; SVC: superior vena cava; RA: right atrium.

The concordance between the tip verification by the IC-ECG method and by the radiological methods was mildly high: the overall match, that is, tip correctly located both according to IC-ECG and according to x-ray, was observed in 29 of 38 cases (76%) but it rises to 97% (29/30 cases) if peak P wave is detected.

The percentage of concordance between IC-ECG and echocardiography was the same as IC-ECG and x-ray.

With regard to the safety of the maneuver, it was virtually 100%, with no complications during the positioning.

The natremia was measured at time of insertion and after 1 and 3h, finding no single case with significant value.

## Discussion

To our knowledge, this is the first pilot study investigating the IC-ECG method in neonates requiring ECC in the district of SVC, independent of weight, gestational age, and catheter size. In fact, even in the work by Zhou and colleagues,<sup>17,18</sup> they refer to larger catheters (almost double: 1.9F vs 1F) and in parallel with neonates of higher gestational age and weight (mean gestational age and mean birth weight of 35.4 years and 2629g vs 29.4 years and 1213g, respectively). Furthermore, until now, this is the first study comparing the efficacy of IC-ECG and ultrasonography on the catheter's tip position on neonatal age.

ECCs were excluded by other pediatric studies on IC-ECG because their caliber was too small and so inappropriate to take over P wave when filled with saline solution and when intracavitary electrode was used. We have



demonstrated that it is possible to observe a P wave using hypertonic solution (Na solution 4%) alternative to saline solution (Na solution 0.9%) to fill the smallest ECC (1F). The hypertonic solution is obtained in NICU. The nurse prepares the hypertonic solution diluting 1 mL of NaCl at 12% with 2 mL of distilled water. The volume used corresponds to the priming volume of catheter (0.09–0.12 mL, respectively, for 28G and 24G catheters) plus the filling volume of the Vygonard (0.2 mL). The overall feasibility (79%, apparently low) is correlated to difficulties related to cannulation with ECC catheter and not to IC-ECG method; if catheter does not proceed through the venous system to the heart, it is not possible to realize P-wave peak. It is necessary to clarify that in all the cases studied, there were three (8%) in particular which demonstrated a mismatch between IC-ECG and x-ray (one case) and between IC-ECG and echocardiography (two cases).

In one case of false positivity, we obtained optimal P-wave peak to IC-ECG but the ECC was malpositioned.

In x-ray and post-echocardiography control, the catheter tip had ended in the correct position but the ECC had looped in the RA. This mismatch (false positive) can be easily avoided if operator introduces the ECC to distance (calculated as centimeters from point of insertion) not too different from external measure based on anthropometric dates. In this case, the operator obtained P-wave peak above 6 cm from external measures.

On the contrary, in the two cases of mismatch between IC-ECG and x-ray and IC-ECG/echocardiography, although P-wave peak was not detected, the x-ray and echo revealed tip catheter in target zone.

There can be various causes for the two false-negative cases: mechanical ventilation, electrical interference, and the need to stop the procedure for clinical complications.

## Conclusion

In conclusion, although referred to only 39 neonates, we believe that IC-ECG method is applicable to ECCs too, independent of weight and gestational age and catheter size.

The combined use of IC-ECG and echocardiography for tip location is ideal because of the following reasons:

1. It allows you to establish exactly the tip of the catheter in the target zone (CAJ), thus reducing the incidence of malpositions and complications caused by them.
2. It leaves little or no space to x-ray, which can be limited to selected cases, and so reduces newborn's exposure to x-ray.
3. It reduces the costs because the IC-ECG use-related products are easily available and very cheap. Our study is a pilot study on a small number of newborns. More experience, in particular, in

very-low-birthweight neonates is to be accumulated in the future.

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