Evaluation of a Magnetic Tracking and Electrocardiogram-based Tip Confirmation System for Peripherally Inserted Central Catheters in Pediatric Patients

Nina Rosche, MSN, RN, PNP, VA-BC • Wolfgang Stehr, MD, MBA, FACS

ABSTRACT

The purpose of this study was to investigate whether a magnetic tracking and electrocardiogram-based tip confirmation system (TCS) (Sherlock 3CG Tip Confirmation System; Bard, Covington, GA) permits safe and correct placement of a peripherally inserted central catheter (PICC) in the pediatric population. A total of 144 PICCs were placed using the TCS. After excluding participants for various reasons, 112/121 (92.56%) of PICCs were appropriately placed using the TCS. The TCS confirmed tip location an average of 7 to 18 minutes faster than radiographic imaging. There were no complications associated with the insertion of the PICCs using the TCS.

Key words: electrocardiogram central line confirmation, improving patient care, pediatric, PICC, Sherlock 3CG Tip Confirmation System, technology

Peripherally inserted central catheters (PICCs) are an integral part of inpatient pediatric care. PICCs provide vascular access for pediatric patients with a history of difficult intravascular access, clinical instability, or a complex infusion regimen. PICCs are also used for invasive hemodynamic monitoring, long-term infusion therapy, and intravascular therapy with an irritant/vesicant or high-osmolality infusion.[1] Optimal position of the central catheter is paramount to reduce complications, such as catheter migration and associated infiltration/extravasation, mechanical phlebitis, thrombus formation, heart perforation, arrhythmia, fibrin sleeve formation, and endothelial damage.[2-9] Despite the importance of optimal position, national organizations disagree on its definition. The Infusion Nurses Society states that the central vascular access device tip location with the greatest safety profile in adults and children is the cavoatrial junction.[1] Other organizations speaking specifically about pediatric populations, such as the pediatric special interest group of the Association for Vascular Access, recommend that the catheter tip be positioned in the superior vena cava (SVC) or at the cavoatrial junction.[10] In contrast, the National Kidney Foundation defines optimal long-term central vascular catheter tip location to be in the right atrium (RA).[11]

Currently, PICC placement in the pediatric population is commonly verified by using radiographic imaging, such as x-ray or fluoroscopy. Conventional x-rays and fluoroscopy-technology use ionizing radiation, which is a form of radiation that has enough energy to potentially cause damage to DNA and increase a person's lifetime risk of developing cancer.[12] Exposure to radiation is particularly concerning for the pediatric population because pediatric patients are more radiosensitive than adults (the cancer risk per unit dose of ionizing radiation is higher), and they have a longer expected lifetime for any effects of the radiation exposure to manifest as cancer.[12] Fluoroscopy, which exposes a patient to continuous x-ray beams, allowing for real-time monitoring

Authors' Affiliation: *University of California, San Francisco (UCSF) Benioff Children's Hospital, Oakland, California (Ms Rosche and Dr Stehr).*

Nina Rosche, MSN, RN, PNP, VA-BC, *is interested in new technologies in advancing vascular access care delivery for pediatric patients. She has been a pediatric nurse practitioner for 4 years and is currently a vascular access nurse practitioner specializing in the insertion, maintenance, and quality improvement of vascular access devices.* **Wolfgang Stehr, MD, MBA, FACS**, *is focused on patient safety, operational improvement, and resource utilization. For the past 6 years Dr Stehr has engaged in the Toyota lean operational improvement process and is physician-champion of the vascular access team.*

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Corresponding Author: *Nina Rosche, MSN, RN, PNP, VA-BC, Pediatric Nurse Practitioner, UCSF Benioff Children's Hospital Oakland, 747 52nd Street, Oakland, CA 94609 (nrosche@mail.cho.org; nrosche@gmail.com).*

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of a procedure, can result in relatively high radiation doses, especially for procedures such as catheter insertions.[12] At the facility where the study took place, bedside PICC insertions are confirmed using portable x-ray machines; insertions occurring in the operating room or interventional radiology suite use fluoroscopy. However, PICCs inserted without additional imaging guidance have a high rate of catheter malpositions on initial radiographic imaging (23%-85.8%).[13] Catheter complications, such as sluggish blood return, may be the only indication that the PICC is not in the desired location, resulting in repeated radiation to correct PICC placement. Given the vulnerability of pediatric patients to ionizing radiation, alternatives to radiation should be explored and examined whenever possible.

In addition to the risk of radiation exposure, studies have shown that multiple factors can result in erroneous interpretations of radiographic imaging and that there is significant interreader variability.[14,15] Factors that complicate radiographic interpretation include motion artifact, patient position, parallax effect, respiratory phase, and the use of different landmarks when interpreting central catheter tip location.[14-16] These factors are important to consider when working with pediatric patients because there is a smaller margin of error between a catheter tip in the SVC versus the RA as body habitus decreases. The ability to follow commands is also variable based on age and developmental appropriateness and can cause movement during imaging. Popular radiographic imaging landmarks used by providers include the distance in centimeters below the right tracheobronchial angle, the number of vertebral body units below the carina, and positioning at the fifth or sixth thoracic vertebrae or slightly inferior to the right superior border of the heart (right atrial appendage).[17-20] However, these studies are based on adult populations, and these similar landmarks are not always reliable in patients with a significantly smaller anatomy. Studies using transesophageal echocardiograms to assess the accuracy of bedside chest radiographs have determined that x-rays alone do not accurately identify intraatrial central vascular catheter tip location.[21] There is concern about how well radiographic image landmarks correlate to the anatomical junction location and the limited data in the neonatal and pediatric population.[15,19,22]

Nonradiologic technology for confirmation of tip location, such as an intravascular electrocardiogram (ECG), has been shown to be effective and to improve overall patient care by reducing procedure duration, allowing for immediate correction of malpositions, and being economically favorable compared with radiographic imaging.[23-31] One particular ECG-guided tip confirmation system (TCS) available in the United States is the Sherlock 3CG Tip Confirmation System (Bard; Covington, GA). The device has 2 components to help guide the catheter into the desired location: magnetic tracking capabilities and intravascular ECG capabilities. Studies reviewing this particular TCS product have concluded its accuracy and utility in the adult population but are lacking evidence in the pediatric population.[29,31,32] This is the first study of this combined technology in the pediatric population and an important topic to investigate, as the routine use of radiographic imaging for catheter placement may be harmful for pediatric patients because of increased radiation exposure and duration under general anesthesia or sedation.[33]

Nonradiologic methods for PICC tip confirmation are potentially advantageous and should be studied further in pediatric patients. The purpose of this study was to investigate whether the magnetic tracking and ECG-based TCS is a safe and valid alternative to confirm the acceptable placement of a PICC in pediatric patients.

DESIGN AND METHODS

Research Design

The team collected data on 144 patients who had an upper extremity PICC inserted September 2016 through July 2017 at a pediatric acute care hospital and American College of Surgeons-verified level 1 trauma center. This study was approved by the institutional review board (study number 2016-51). An additional informed consent was not required for this study because of the noninvasive nature of the catheter guidance technology and the established medical indication for the PICC placement.

Methods and Procedures

Pediatric patients (0-18 years) who required an upper extremity PICC for their medical care at the hospital were included in the study. The vascular access team, which comprised pediatric nurse practitioners (PNPs), inserted all PICCs. There were no changes in the insertion technique or patient population during the period of the study. Ultrasound was used initially to scan the patient's upper extremity vessels to locate a suitable vein for insertion and to measure vessel diameter to choose an appropriate catheter size. The desired location for the insertion site was marked with a surgical marker. The Y-shaped magnetic sensor of the TCS and the external ECG electrodes were placed on the patient's chest and abdomen before insertion. The baseline ECG waveform was evaluated by the inserter to ensure that a distinguishable P wave was present (Figure 1). A catheter compatible with the TCS and the appropriate size for the patient's vessel was then selected. The length of the catheter was determined using anatomical landmarks and sterilely trimmed. Once all equipment was prepared and the insertion site prepared for sterile procedure, a catheter was inserted into the vessel using ultrasound guidance. The PICC was inserted using the modified Seldinger technique.

The TCS-compatible PICC is designed with a magnetic-tipped stylet inside the lumen, which was kept level with the catheter tip. Using the Y-shaped magnet tracking display of the TCS, the catheter was advanced slowly. With the assistance of the magnetic tracking capabilities, the operators were able to determine the general direction in which the catheter had advanced and whether the catheter was advancing as desired toward the SVC or in a wrong location (eg, up the neck or to the contralateral side). The ECG capability of the TCS was then used to determine how far to advance the catheter by determining the location at which the P wave was at its maximum amplitude without a preceding deflection (Figure 1). The catheter was left at this point of maximal P wave voltage while an x-ray or fluoroscopy technician was called for imaging, according to routine procedure. Once the imaging was available for review, the inserter would verify initial catheter tip location. If the PICC needed to be adjusted based on the inserter's interpretation of the radiographic image, the inserter would do this immediately before dressing the catheter with a transparent semipermeable dressing.

All PICC placements in the pediatric intensive care unit (ICU) and neonatal ICU were performed at the bedside with the assistance of sedative and/or pain medication, according to standard hospital practice. Patients on acute units went to the operating room for PICC placement under general anesthesia, based on factors such as age, condition, and developmental ability to cooperate with the procedure. Older patients who were able to tolerate PICC placement without sedation underwent the procedure at the bedside with appropriate comfort measures, including child life specialists and, when appropriate, premedication with pain and/or anxiety medication.

Only PICCs inserted while 2 vascular access team members were available were collected for the study, given the necessity for extra support to ensure that data were collected accurately while the other member performed the procedure. Patients with an abnormal or absent P wave or a known cardiac anomaly, and those requiring urgent PICC placement or lower extremity PICCs, were excluded from the study.

All PICC placement radiographic images were retrospectively reviewed by an experienced pediatric radiologist at the hospital. One radiologist was assigned to interpret all study participants' images given the known interreader variability when interpreting x-ray/fluoroscopy images. The radiologist was asked to review the first radiographic image taken for the PICC placement procedure, which correlated with the catheter placement determined to be acceptable according to the magnetic tip and ECG-guidance technology. This official radiology reading was used for data analysis and comparisons.

Data Collection

The team defined acceptable PICC tip placement as mid to low SVC cavoatrial junction (SVC/RA junction) or high RA. The team collected the following data: the frequency of repositioning attempts using the magnetic tracking technology, the frequency of correct PICC placements using the TCS, any complications that arose from the PICC, and time until confirmation by TCS and x-ray and/or fluoroscopy. During the study period, a new x-ray machine was introduced to the facility. The hospital transitioned from using a portable x-ray machine that required the technician to transport the film to the radiology department before the image became available for interpretation by the inserter to another portable x-ray machine that allowed for instant review of the x-ray film by the bedside on an electronic screen. This transition occurred on January 5, 2017. As a result, the time difference between TCS confirmation of the tip location and x-ray confirmation of the tip location was analyzed in 2 groups: before January 5, 2017; and January 5, 2017, and after.

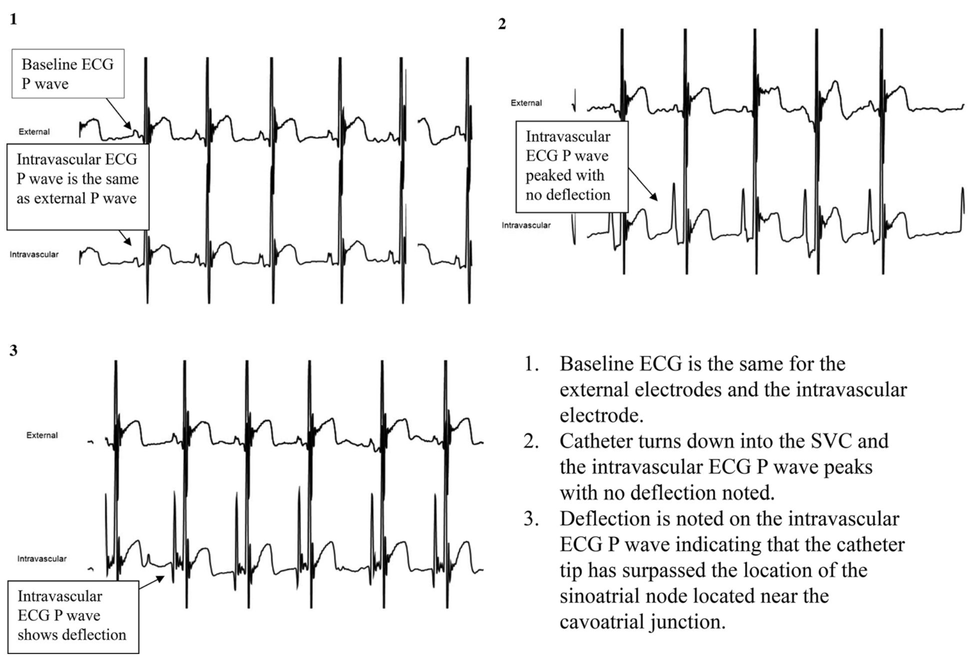

Figure 1 Electrocardiogram tracing as peripherally inserted central catheter approached cavoatrial junction. *Abbreviations: ECG, electrocardiogram; SVC, superior vena cava.*

Statistical Analysis

Descriptive statistics were computed to include frequencies, means, and measures of variability for each of the variables measured. An analysis of variance model was used, followed by Tukey's method of multiple comparisons to examine the differences in weight between the radiology readings. A significance value of $P = .05$ was used for all statistical analyses.

RESULTS

A total of 144 PICCs were placed using the TCS. Twenty-three of 144 (15.9%) were excluded for reasons such as difficulty interpreting the ECG waveform (9/23), radiographic imaging errors (6/23), user error in the technology and data collection process errors (5/23), and others (3/23). As a result, data statistics were performed on 121 patients. Of the 121 patients, the youngest patient was 5 days old and the oldest was 18 years (mean = 6.7 years). The minimum and maximum weights in kilograms (kg) were 2.8 kg and 105.8 kg with a mean of 29.05 kg (standard deviation = 23.5). More detailed demographic information addressing gender, radiographic technology use, and implications for the PICC can be found in Table 1.

Based on the team's definition of acceptable PICC tip location, 112/121 (92.56%) of PICC placements were appropriately placed using the TCS (Table 2). Radiographic imaging identified 8/121 (6.6%) in the RA and only 1/121 (0.8%) in the high SVC (Table 2). There was no statistically significant difference in patient weight in those with acceptable versus nonacceptable PICC tip location. Although the team had excluded RA placement as a definition of an acceptable tip location in the population, the National Kidney Foundation recommends this placement for some central catheters. Had the team included this definition in the data analysis, the success rate for appropriate PICC tip placement using the TCS would have increased to 99% (120/121). There were no gross malpositions identified, such as catheter tip location in the subclavian vein, jugular vein, brachiocephalic vein, azygous vein, or right ventricle. An average of 1.52 repositioning attempts using the magnetic tracking technology (as many as 12 for 1 patient) were required to achieve correct placement. There were no complications such as death, catheter malfunction, catheter malposition, infiltration/extravasation, central line-associated bloodstream infection (CLABSI), or arrhythmia associated with the placement of the PICCs using the TCS (Table 3).

Fluoroscopy imaging added an average of 7.13 minutes to the procedure. X-ray imaging with the older x-ray machine

TABLE 2

Peripherally Inserted Central Catheter Tip Placement as Identified on Radiographic Image (N = 121)

Radiology Reading	n	%
SVC/RA junction	84	69.42
Low SVC	7	5.79
Mid SVC	10	8.26
High RA	11	9.09
RA	8	6.61
High SVC	1	0.83

Abbreviations: RA, right atrium; SVC, superior vena cava.

TABLE 1

Demographic Information

Participants (N = 121)	n (%)
Female	56 (46.3%)
Male	65 (53.7%)
Radiographic technology	
Fluoroscopy	46 (38%)
X-ray	75 (62%)
PICC implications	
Long-term infusion therapy	49 (41%)
Vesicant/high-osmolality drug infusion (eg, chemotherapy, TPN)	28 (23%)
Access for complex infusion regimen	41 (34%)
Inadequate SPC access for therapy	3 (2%)

Abbreviations: PICC, peripherally inserted central catheter; SPC, short peripheral catheter; TPN, total parenteral nutrition.

TABLE 3

Peripherally Inserted Central Catheter Complications

Complications	n	Occurrence of Event (Average Days After Placement)
Arrhythmia	0	n/a
Central line-associated bloodstream infection	1	11.0
Death	0	n/a
Infiltration/extravasation	0	n/a
Catheter accidently pulled out	2	5.0
Catheter malfunction	2	20.5
Occlusion defective catheter (pinhole in catheter hub)	1	14.0
Catheter malposition	2	3.5

Abbreviation: n/a, not applicable.

before January 5, 2017, added an average of 18.23 minutes to the procedure. One outlier was excluded from the time collected for x-rays taken with the newer x-ray machine on or after January 5, 2017. These data were excluded because circumstantial events restricted the ability to perform the imaging in a timely manner. With the outlier excluded, x-rays taken on or after January 5, 2017, added an average of 15.08 minutes to the procedure (Table 4).

DISCUSSION

Summary

This study aimed to investigate the safety and validity of a magnetic tracking and ECG-based TCS to confirm the placement of PICCs in pediatric patients. The TCS yielded a high rate of acceptable PICC tip placements, and no complications were associated with the use of the TCS. The use of this technology allowed for real-time feedback, nearly eliminating the need for repeat radiographic imaging because of catheter tip malposition. The time to confirm tip location was reduced when relying on the TCS technology compared with chest radiography. If radiographic studies could be eliminated as part of routine PICC placement procedures in pediatric patients, it would reduce radiation exposure, time to intravenous treatment initiation, length of time under general anesthesia or sedation, and costs related to operating room occupancy and obtaining multiple x-ray/fluoroscopy images.

Rationale for Various Tip Placements

The decision was made to include the mid-SVC as an acceptable PICC tip location because catheters were found in this location, often as a result of the catheter being trimmed short based on external anatomical measurements (40% of mid-SVC placements). The inserter concluded that a PICC tip in this location did not warrant a PICC replacement procedure, given the PICC indication for the patients and the benefit-risk analysis of increasing the patient time under general anesthesia or sedation. One patient's catheter tip was located in the high SVC as a result of measurement errors with catheter trimming. Again, it was not deemed medically appropriate to replace the PICC. The high RA was also included as an acceptable PICC tip location. The team determined that the high RA radiographic reading was safe in the population, based on the known role of interreader variability in radiographic image readings and the extent of PICC movement with arm positioning.

For the 8 patients with a catheter tip identified in the RA, there may have been user error with ECG waveform interpretation. This is supported by the decrease in the incidence of RA placement as the providers' experience with the technology increased. As mentioned in the Results section, if an RA placement had been included in the definition for acceptable catheter tip placement, the success rate would have increased to 99%. The team did not include this placement in the definition because they believed it would not be safe, given the rare, but reported, cases of cardiac perforation that have occurred in neonates. However, an RA placement may be safe and appropriate for older pediatric patients, if they do not show signs of complication such as arrhythmia.

Decrease in Radiation Exposure

Information about the hospital's baseline x-ray and fluoroscopy use for PICC tip confirmation is not available. However, the vascular access team members reported that repeat x-ray needs were common without the use of a tip guidance technology. Inserters reported that brisk blood return was not an accurate indication of appropriate PICC tip location. There were cases of PICCs having brisk blood return even in a malpositioned location, such as the internal jugular vein or contralateral subclavian vein. The blind approach of advancing the catheter often resulted in more than 1 x-ray and/or fluoroscopy imaging and added time to the procedure.

The TCS is unique because it provides 2 modes to identify the location of the tip: magnetic tracking and ECG. When both technologies were used correctly, there was a high level of success in appropriate catheter tip placement. The magnetic tracking presented visual clues to the placement of the catheter tip that an inserter might have missed

TABLE 4

Difference in Time[a] to Confirmation Between TCS and Radiographic Imaging

Confirmation Method	n	Mean	SD	Min	Max
Fluoroscopy	46	7.13	4.13	1	16
X-ray before January 5, 2017	26	18.23	5.96	2	30
X-ray on or after January 5, 2017[b]	48	15.08	5.78	8	33

Abbreviations: Max, maximum; Min, minimum; SD, standard deviation; TCS, tip confirmation system.
[a]Time measured in minutes.
[b]One outlier was excluded from the time collected for x-rays taken with a newer x-ray machine on or after January 5, 2017. This table reflects the data with the outlier excluded.

without this guidance. For example, when a catheter began to loop in the SVC, the tracking device suddenly lost track of the catheter. The team would reasonably suspect that the catheter was not in a desirable place if it did not see the catheter follow the expected course of the vessel anatomy, did not have consistent laminar descension on the tracking screen, noted intermittent detection of the catheter, or observed a P wave that did not gradually increase with advancement of the catheter. These instances were resolved by retracting the catheter to the axilla or distal subclavian region and then advancing again as usual. A number of patients required 1 to 12 repositioning attempts that were identified using the magnetic tracking technology. Had the team attempted placement without magnetic tracking guidance in these patients, it would have exposed the children to multiple radiation attempts to correct the location of the catheter. Although there was an average of 1.5 repositioning attempts among study participants, the team was able to limit x-ray/fluoroscopy to 1 attempt in most of the patients because the grossly malpositioned tip location would be corrected before capturing an image. This technology is a safe and noninvasive method that reduced radiation exposure and did not increase the incidence of complications.

Complications

There were no complications associated with the use of the TCS for PICC tip confirmation. The team observed no instances of death, arrhythmia, or infiltration/extravasation as a result of the PICC. All but 3 PICCs continued to function properly for the duration of treatment. Of the 3 cases of PICC malfunction, 2 PICCs were occluded 20 and 21 days after catheter placement, and 1 PICC had a pinhole fracture at the hub of the catheter 11 days after placement. There were 2 cases of catheter malposition that occurred several days after placement, even though the initial radiographic image showed the tip to be in an appropriate location. PICCs are known to migrate up and down the SVC with arm movement. PICCs have also been noted to malposition into the internal jugular vein or contralateral subclavian vein, if there are any increases in the intrathoracic pressures. These migrations are seen when catheters are placed using only radiographic imaging for tip confirmation; therefore, the team concluded that this was not a result of using the TCS. One CLABSI occurred in a single study participant. This occurred 11 days after insertion. At the University of California, San Francisco, infections occurring 1 week after insertion are not linked to a breach in sterility during the insertion procedure. All complications the team observed in study participants were complications that historically have been seen in PICC placements without the use of the TCS. There were no complications linked directly to the technology used to assist in the placement of the PICCs.

Limitations and Implications

The technology was relatively simple to learn but required initial training, provided by the manufacturer's representative, on the correct use and interpretation of the technology. The TCS also required several placements to gain confidence and skills in the technology. Various circumstances occurred during the data collection phase that required exclusion of study participant data.

Some patients were excluded from the study because of the inserter's difficulty interpreting the ECG waveform (6%). When that occurred, the inserter obtained the x-ray or fluoroscopy image to identify the tip location. Examples of radiographic imaging errors (4%) included the first image not being saved (5/6) and 1 case in which the image was not clear enough for the radiologist to identify the tip location retrospectively. User and process errors in the technology (3%) included instances when the inserter did not readvance the stylet so it would be flush with the catheter tip before interpreting the ECG waveform; the catheter tip was left where the ECG waveform showed a P wave deflection; and 1 case in which an anesthesiologist urged the inserter for the fluoroscopy image before determining appropriate placement using the TCS.

Other exclusion reasons mentioned in the broader category of "other" in the Methods section included 2 catheters that would not enter the SVC based on the TCS technology (later confirmed by radiographic image), and 1 patient who had ectopic beats before first imaging. In the latter case, the catheter was retracted and an image that correlated with ECG-guided placement was not captured. Although some of these instances were out of the team's control, other errors were made as a result of a lack of experience with the device. As the team gained more confidence with the device, user error in the technology decreased. Radiographic imaging can always be performed to confirm PICC placement when the magnetic tracking and ECG technology malfunctions. However, given the accuracy of the TCS, this noninvasive alternative should be used before considering routine chest radiation in PICC insertions for pediatric patients.

The TCS typically saved between 7 and 18 minutes to PICC tip confirmation, compared with fluoroscopy and x-ray imaging, once the outlier was excluded from the data. In the case of the single outlier, the fluoroscopy machine was not available in the operating room, and an x-ray had to be captured in the unit after the patient's return from the procedure. For this patient, the x-ray was obtained 521 minutes after the PICC placement was verified by the TCS. During this time, the PICC could not be used by the staff because the radiographic image had not been obtained to confirm placement. Once obtained, the image showed the catheter to be positioned appropriately. If institutions could move away from routine radiographic imaging and rely more on the TCS for PICC placement, they would save valuable resources, such as radiology technician time and occupancy of the x-ray/fluoroscopy machine.

Eliminating x-rays and/or fluoroscopy may be challenging for various reasons, especially if current protocols regarding total parenteral nutrition and chemotherapy administration require catheter verification by radiographic imaging.

This would need to be addressed with adjusted protocols. Documentation of the tip position in the patient's electronic medical record needs to be established to allow the responsible provider to be able to view the method by which the catheter placement was verified. This transition will require acceptance by key stakeholders. Given the results of this study—showing the method to be safe and beneficial for patients, as well as a way to save time, reduce radiation, and lower cost for everyone involved in the PICC placement procedure—the team expects that the technology will be embraced widely.

CONCLUSION

The combined magnetic tracking and ECG-based TCS is a safe, noninvasive alternative for PICC tip location verification in pediatric and neonatal populations. PICCs were correctly placed in a majority of patients, with no incidence of gross malposition or increased complications. The technology was successful in accurately placing catheters in an acceptable location in very small patients. Time taken for the procedure also was significantly reduced.

If a facility could move away from routine use of radiographic imaging for PICC placements, the implications for children would be paramount. The technology would reduce exposure to radiation; duration of general anesthesia and procedural sedation in vulnerable patients; time to treatment initiation; and costs associated with the use of valuable resources, such as operating room occupancy, anesthesiologists' time, the number of x-ray and fluoroscopy machines used, and radiology technicians' time.

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