Evaluating Effectiveness of the Use of an Extremity Stabilization Device for Vascular Access Procedures in Pediatrics

Tricia Templet[1] Roger Rholdon[1] Ansley Bienvenu[2]

[1] Department of Nursing, University of Louisiana at Lafayette, Lafayette, Louisiana, United States
[2] SafeBoard™ Device, Lafayette, Louisiana, United States

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Address for correspondence Tricia Templet, DNP, APRN, CPNP-PC, FNP-C, Department of Nursing, University of Louisiana at Lafayette, Lafayette 70504, LA, United States (e-mail: tricia.templet@louisiana.edu).

Abstract

The purpose of this study is to evaluate the effectiveness of SafeBoard, a Food and Drug Administration–approved extremity stabilization device, as an assistive method in performing peripherally inserted central catheter procedures on children 0 to 3 years of age. This is a retrospective chart review ($n = 59$) of vascular access procedures where SafeBoard was utilized ($n = 32$) in comparison to those procedures which utilized a traditional approach to placement ($n = 27$). Statistical analysis demonstrated significant effect on length of procedure time, number of personnel needed for procedure, and success of placement when SafeBoard was utilized. Obtaining vascular access in pediatrics can be a challenging endeavor. Most young pediatric patients require procedural sedation and/or assistive personnel as a "holder" for successful vascular access placement to occur. An alternative option for extremity stabilization may provide improved workflow and improved placement success, which in turn may positively affect workflow.

Keywords
- vascular access
- extremity stabilization
- PICC placement
- pediatric

Introduction

For children requiring long-term intravenous (IV) access, peripherally inserted central venous catheters (PICCs) are a well-known and frequently utilized option, but placement can present the vascular access clinician with some challenges. In pediatrics, ultrasound-guided PICC insertions often require the use of supplemental resources including additional personnel and/or the use of medication for procedural sedation to ensure successful completion of the procedure.

One of the biggest challenges of pediatric ultrasound-guided PICC insertion is the inability of the patient to cooperate and maintain optimal extremity positioning and best practices have yet to be established.[1] The use of procedural sedation has often been a modality employed to facilitate successful procedure completion in pediatric patients, including PICC placements. Procedural sedation is not without its complications or its adverse events.[1–3] Up to 50% of pediatric patients were described to experience movement during PICC placement under procedural sedation.[1] Other risks associated with procedural sedation include respiratory depression, laryngospasm, apnea, and hypoxia, all requiring some level of respiratory support.[2,3]

Invasive pediatric procedures, both with and without the use of sedating medications, often require additional staff to provide patient distraction, pain management, monitoring of medication effects and patient response, and aiding the clinician with procedure completion as necessary. Ensuring staff availability for assistance can inhibit timely completion of PICC insertion. The largest barrier to the implementation of pediatric procedural sedation was physician and nursing shortages. The availability of a physician to perform pediatric procedural sedation at any time may be limited, with report

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of 24% availability at any given time.[4] Nursing availability for sedation monitoring was similarly reported as 28%.[4] Additional staff members may be required during PICC placement in infants and young children including a team member to stabilize the extremity and a team member such as a child life specialist to assist in soothing the infant or young child.[5,6] Staff availability to assist in providing any of the needed assistance may be limited due to inadequate staffing. Some units may not have these team members readily available when the vascular access clinician is presenting for placement, which may impact scheduling of other placement procedures and length of time required for successful placement on a pediatric patient and lead to treatment delays which can interfere with overall patient care.

The success of the PICC placement procedure has traditionally necessitated the use of ultrasound guidance,[7,8] though is not frequently utilized by vascular access clinicians for peripherally placed central venous catheters.[9] Ultrasound is utilized to view the tip of the needle as it enters and advances into the blood vessel in a technique known as dynamic needle tip positioning,[10] which assists in successful completion of the procedure as direct visualization guides the clinician.

SafeBoard (►**Fig. 1**) is an extremity stabilization device developed in 2017 by a vascular access clinician to address issues related to delays in treatment, unsuccessful placement, and increased risks and complications identified with the use of conscious sedation.[11] SafeBoard is classified as a Class 1, or low risk, medical device by the Food and Drug Administration (FDA). The device provides safe and efficient extremity stabilization without the need for an additional care team member, using their own force, to hold the patient's upper or lower extremity still for cannulation (►**Figs. 2** and **3**). The materials utilized include a three-dimensional printed acrylic board sized appropriate to the age of the patient with a nonabrasive grip applied on the underside of the board with an acrylic adhesive. A disposable, age-appropriate sized blood pressure cuff for either a small child or neonate functions as a papoose for the extremity and is inflated with a polyisoprene and natural rubber bulb. A urethane strap with a nylon buckle is used to secure the device to the bedframe for additional stability. Instructions for the use of this extremity stabilization device is provided in ►**Table 1**.

Fig. 1 SafeBoard extremity stabilization devices, depicted in various pediatric sizes. Copyright A. Bienvenu, 2021.

Fig. 2 SafeBoard extremity stabilization device in use on lower extremity, lateral view. Copyright A. Bienvenu, 2021.

Fig. 3 SafeBoard extremity stabilization device in use on lower extremity, anterior view. Copyright A. Bienvenu, 2021.

The device allows the vascular access clinician to properly position the extremity on to the board and position the board to the bed or gurney with minimal to no residual movement. It further allows ease of performance of the procedure with ultrasound utilization as the vascular access clinician can manipulate an ultrasound probe and cannulate the vein simultaneously, knowing the extremity is stable and immobile. Along with extremity positioning and stabilization, maximum comfort measures should be used on all patients appropriate to age and development including, but not limited to, topical anesthetics, oral sucrose, nonnutritive sucking, swaddling, and distraction.[4] Topical anesthetic is used local to the site of insertion to decrease pain and discomfort. Oral sucrose and nonnutritive sucking have been shown to help alleviate pain for newborns undergoing painful procedures[12] and should be utilized when indicated. Child life specialists were also utilized when available to help reduce distress in pediatric patients during medical procedures.[6] The purpose of this project was to evaluate effectiveness of the use of the FDA-approved and U.S.-patented SafeBoard extremity stabilization device in children 0 to 3 years of age undergoing ultrasound-guided PICC placement.[11]

Materials and Methods

Retrospective chart review was utilized to examine variables including the type of procedure technique utilized as either a traditional approach with procedural sedation or

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Table 1 Instructions for use of SafeBoard

Step 1	Position SafeBoard under patient's extremity with the curvature of the board toward the midline of the patient and the clear nonabrasive grip beneath the shoulder blade or bottom (whether you are using upper or lower extremity)
Step 2	Place blanket roll under the medial upper arm or medial upper leg to increase stabilization and create external rotation with a flat plane surface to better visualize vessels using ultrasound guidance
Step 3	Position and fasten cuff appropriately between wrist and antecubital region of the arm, or between the ankle and popliteal fossa of leg
Step 4	Slide cuff tubing into side clips and insert tubing connector into bulb connector
Step 5	Pump blue bulb to inflate cuff, within safe limits, until stabilized
Step 6	Apply strap around bedframe and adjust
Step 7	Perform procedure
Step 8	To deflate cuff, press and hold black release button
Step 9	Unfasten cuff from extremity
Step 10	Unfasten strap from bedframe
Step 11	Remove SafeBoard from beneath patient SafeBoard can be left in place, as the board is nonradiopaque, for postinsertion chest Xray with cuff minimally inflated
Important notes	1. Inflation time of cuff should be minimized as much as possible 2. Cuff should be deflated as soon as practical, even if only partially during procedure

the use of the SafeBoard device, number of documented attempts at PICC line placement, overall procedure success, length of time for procedure completion, and number of additional personnel needed at the bedside for procedure completion. Deidentified data were entered into Intellectus statistical software for descriptive and inferential statistical testing.[13]

Setting

Chart review was completed using medical records from a contracted local infusion therapy service in Southwest Louisiana. The contracted service company provides PICC, midline, and other IV access placement to one regional medical center that provides care for children and one women's and children's hospital in one city in the southern region of the United States. Hospital A serves a total of 334 beds with 6 dedicated inpatient pediatric beds and a 31-bed level II neonatal intensive care unit. Hospital B serves a total of 241 beds with 25 dedicated pediatric inpatient beds, a 12-bed pediatric intensive care unit, and a 76-bed level III neonatal intensive care unit.

Participants

Medical records from March 2014 to September 2020 were included in the review. Inclusion criteria were children 1 day to 3 years of age who underwent PICC line placement.

Procedure

After Institutional Review Board approval was deemed exempt, data collection via retrospective chart analysis was undertaken. The medical records of a total of 59 children, 1 day to 3 years of age who underwent PICC line placement, were evaluated for the aforementioned variables. The records of 27 patients were utilized as the control sample, with the documented procedures utilizing a traditional approach to PICC line placement utilizing conscious or deep sedation and additional staff at the bedside. The remaining 32 medical records evaluated utilized the SafeBoard extremity stabilization device as the intervention of study. The data sample was obtained from the population of children who received care for PICC placement within the past 6 years. PICC placement procedure was undertaken by a single board-certified vascular access clinician employed by a local infusion therapy service contracted by local hospitals for inpatient vascular access procedures.

Results

A point biserial correlation analysis was conducted for the type of technique and the number of documented attempts at PICC line placement, whether the procedure was successful, length of time the procedure lasted as documented in minutes, and number of additional personnel needed at the bedside during the procedure. A point biserial correlation is a special case of the Pearson's correlation. Cohen's standard was used to evaluate the strength of the relationships, where 0.1, 0.24, and 0.37 represent small, medium, and large effect sizes.[14] These effect size thresholds are based on the assumption that both values of the binary variable are equally likely to occur.[15,16] ►**Table 2** presents statistical results.

The result of the correlations was examined using Holm corrections to adjust for multiple comparisons based on an α set at 0.05. There was a significant negative correlation between the technique utilized and the documented number of attempts ($r_{pb} = -0.37$, $p = 0.008$, 95% confidence interval [CI] [−0.57, −0.12]). The correlation coefficient between the technique and the number of attempts was −0.37, indicating a moderate effect size. This indicates that moving from the standard of care to the use of the SafeBoard stabilization device is associated with a decrease in the number of attempts utilized for placement. Thus, the SafeBoard use category of technique tends to be associated with lower values in the category of number of attempts needed for successful PICC placement. There was a significant positive correlation between the technique and reported success of

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Table 2 Point biserial correlations for technique and number of attempts, successful, length of procedure time, minute, and additional personnel at bedside

Combination	r_{pb}	95% CI	*p*-Value
Technique–number of attempts	−0.37	−0.57, −0.12	0.008
Technique–successful	0.29	0.04, 0.51	0.024
Technique–length of procedure time, min	−0.60	−0.74, −0.41	< 0.001
Technique–additional personnel at bedside	−0.60	−0.74, −0.41	< 0.001

Abbreviation: CI, confidence interval.
Note: $n = 59$; Holm corrections used to adjust *p*-values.

PICC access placement ($r_{pb} = 0.29$, $p = 0.024$, 95% CI [0.04, 0.51]). The correlation coefficient between the documented technique and successful placement was 0.29, indicating a moderate effect size. This indicates that moving from the standard of care to the use of the SafeBoard stabilization device is associated with an increased chance of successful placement.

There was a significant negative correlation between the utilized technique and length of time for procedure completion ($r_{pb} = -0.60$, $p < 0.001$, 95% CI [−0.74, −0.41]). The correlation coefficient between the technique and the length of time for procedure completion was −0.60, indicating a large effect size. This indicates that moving from the standard of care to using the SafeBoard device is associated with a decrease in the length of time that was required for completion of the procedure. Finally, there was a significant negative correlation between the utilized technique and the number of additional personnel that were needed at the bedside ($r_{pb} = -0.60$, $p < 0.001$, 95% CI [−0.74, −0.41]). The correlation coefficient between the utilized technique and additional personnel at the bedside was also −0.60, again indicating a large effect size. This indicates that utilizing SafeBoard in replace of the standard of care is associated with a decreased in the number of personnel needed to assist in the procedure at the bedside. ►**Table 2** presents the results of the correlations.

Discussion

PICC line placement in pediatric and neonates can present challenges for health care providers. Strategies such as dedicated personnel have led to improvements in PICC line placement and outcomes.[17,18] Decreased number of attempts and successful insertion with the use of ultrasound guidance for PICC line placement has also been well documented in the literature.[19–21] However, to our knowledge, the use of a stabilization device in conjunction with ultrasound guidance for PICC line insertion has yet to be examined.

The use of an extremity stabilization device for ultrasound-guided PICC line insertion was found to be superior to a traditional approach with procedural sedation in relation to the length of time of procedure, success of placement, and number of assistive personnel needed at bedside. The statistically significant findings related to the use of this extremity stabilization device demonstrated shortened procedure completion time, improved rates of procedural success, and fewer attempts at vascular access placement. The use of the device allows a single vascular access clinician to complete PICC placement timely and efficiently regardless of the use of sedative medications.

Using the SafeBoard extremity stabilization device further reduces the need for additional staff assistance, allowing for procedure completion in a timelier manner. However, a gap in the literature exists on the importance of extremity stabilization or on the use of stabilizing devices in pediatric procedures. Staffing ratios may sometimes not allow for additional nurses to be at bedside during PICC placement procedures, impacting procedural safety and potential for success. SafeBoard use was demonstrated in this small sample to reduce the need for additional personnel to provide extremity stabilization which may positively impact nursing workflow.

Extremity stabilization for procedures involving PICC catheter placement is an important component for successful completion. Historically, procedural sedation has been utilized to optimize extremity positioning and patient compliance, as well as to decrease procedural discomfort.[22] With the use of SafeBoard, safety implications related to procedural sedation can potentially be minimized and medication intervention can be focused on pain reduction and anxiolysis instead of focusing on decreasing patient movement. Further, SafeBoard allows for the use of ultrasound guidance as the stabilized extremity does not require manipulation by the vascular access clinician and instead can place and hold the ultrasound transducer to visualize the vasculature and ensure cannulation. It is important to note that the use of this stabilization device does not negate the need for local anesthesia or pain or anxiety management.

Conclusion

Although this research adds to the body of knowledge in health care and demonstrates the effectiveness of the SafeBoard device, the study has some limitations. Using a small sample for retrospective analysis of procedural reports on children 0 to 3 years of age in a southern state may limit the generalizability of the study. Further, the device was utilized by a singular vascular access clinician contracted with two regional medical centers in Southwest Louisiana that provide care for children. Technique and experience of this singular nurse may play a role in success of placement and length of procedure time; placement technique was not evaluated as

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having an impact on placement success. Thus, further evaluation with additional vascular access clinicians is warranted to assist in assessing whether success of placement was clinician driven or a result of the use of the SafeBoard device. Furthermore, this study does not evaluate aspects of PICC care such as postprocedural phlebitis or catheter dwell time.[22] As these may be issues associated with procedure technique, additional research may be needed to quantify any postprocedural complications that may be affected by the use of the SafeBoard device.

Funding
None.

Conflict of Interest
A. B. was the developer of the SafeBoard device and is the nurse utilizing SafeBoard in all vascular access procedures utilized for this research. Rest authors declare no conflict of interest.

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