

# Ultrasonography-Guided Peripheral Intravenous Access in Children

## A Randomized Controlled Trial

### ABSTRACT

A prospective, randomized controlled trial compared the success of peripheral venipuncture in pediatric patients using vascular ultrasound and standard landmark methods and the occurrence of infiltration and phlebitis. The sample was composed of 382 venipunctures; 188 (49.2%) were performed with vascular ultrasound, and 194 (50.8%) were performed using the standard landmark method. No significant difference ( $P = .059$ ) was found between either method in the success of peripheral venipuncture. A higher frequency of infiltration was found ( $P = .025$ ) in the vascular ultrasound group.

**Key words:** child, patient safety, pediatric nursing, peripheral venous catheterization, ultrasound

Obtaining peripheral vascular access in pediatric patients is a complex, time-consuming procedure that is particularly difficult in small children.<sup>1,2</sup> Young children, including infants and toddlers, have more subcutaneous tissue than older children and adults. In addition, their veins are a smaller caliber and are difficult to visualize and palpate, which contribute to a low rate of insertion success on the first attempt.<sup>2,3</sup> Studies conducted with children have shown failure rates for the procedure that range from 9% to 36%, result in several attempts, and in some cases, contribute to related complications, such as hematoma and stress.<sup>1,4-9</sup>

Pediatric nurses, who are responsible for achieving better results during peripheral catheter insertion in children, strive to improve practice.<sup>10</sup> One potential innovation for increasing successful venipunctures could be the use of vascular ultrasound, which has already proved efficacious for central vascular access.<sup>11</sup>

Only a few studies have examined the use of ultrasonography for peripheral vascular access in children, and the results differ with regard to success rates.<sup>4,12-14</sup> Two randomized trials were performed in children with a history of difficult access or of previous unsuccessful attempts at insertion using the traditional standard landmark method. The first study was unable to demonstrate a clinically important benefit in a static, ultrasound-aided catheter insertion technique,<sup>12</sup> but the second study concluded that ultrasonography-guided catheter insertion improved overall success rates by 16% compared with the standard landmark method. However, no significant difference in success rates ( $P = .208$ ) was observed in children with difficult access.<sup>4</sup>

Two nonrandomized studies concluded that ultrasonography-guided peripheral venipuncture in children could be a significant benefit, reducing the number of insertions and potentially reducing insertion-related pain and the risk of infection.<sup>13,14</sup> This study analyzed whether the use of ultrasound during the

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routine insertion of peripheral catheters and site identification would increase the insertion success rate and reduce the incidence of infiltration and phlebitis compared with the standard landmark method for catheter insertion.

## METHODS

### Study Design

A prospective, randomized controlled trial was performed in a 25-bed pediatric surgical unit in a teaching hospital in Brazil, following the approval of the ethical merits of the research by its institutional review board. The study, “Peripheral Intravenous Puncture Guided by Vascular Ultrasound,” is registered with [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (#NCT00930254).

The aims, methods, benefits, discomforts, and potential risks of the interventions were described to all subjects and their parents or guardians, according to the framework of the World Medical Association’s Declaration of Helsinki.<sup>15</sup> Written informed consent was obtained from all parents/guardians and subjects 12 years of age and older who agreed to participate in the research.<sup>16</sup>

### Selection of Participants

All children admitted to the pediatric surgical unit who required peripheral vascular access were eligible for the study with the exception of patients who were younger than 24 hours old or older than 18 years, as well as patients who needed emergency treatment. Consent was obtained from all of the 335 children who met the inclusion criteria and their parents or guardians.

The method of venipuncture was assigned randomly to 1 of 2 groups by a computerized randomization program. For the experimental group (EG), venipuncture was guided by ultrasound. In the control group (CG), the venipuncture was performed using the standard anatomical landmark technique with venous palpation and visualization.

The sample comprised 382 insertions—188 (49.2%) in the EG and 194 (50.8%) in the CG—performed in 335 children between 12 days and 17 years of age who met the study’s inclusion criteria. The insertions were completed in the presence of parents or guardians.

Before data collection, nurses were trained in the standards for peripheral vascular access, catheter maintenance, assessment of the insertion site, and ultrasound use. Introduction of ultrasound use into nursing practice, equipment operation, and image interpretation training was provided to all pediatric nurses in the unit by a group of experts in infusion therapy and ultrasonography.<sup>17</sup>

Before the procedure, all of the children and their parents took part in an orientation about venipuncture and ultrasound, using an educational manual and toy therapy and simulated ultrasound equipment.

### Intervention

Portable equipment with a 25-mm linear transducer operating at a frequency of 10 MHz was used for ultrasonographic imaging. One nurse operated the equipment and examined vessels in transverse and longitudinal directions with a 90-degree angle of the transducer, then chose the vein to be used. Another nurse performed skin antisepsis and the catheter insertion, analyzing the image on the screen.

In the EG venipunctures, the catheter was inserted and visualized by real-time imaging during its advance into the vein (Figure 1). Insertions among the children in the CG group were accomplished using the standard landmark method. Venous access and the insertion of the catheter were clinically evaluated with inspection and palpation.<sup>18</sup> Two nurses carried out the procedure; 1 performed the insertion and the other provided the required support.

In both groups, routine assessments of the catheter insertion site were performed 4 times a day and when there was a complaint of pain.<sup>18</sup> The assessment of complications in the EG, including visualization of the intravessel catheter position to obtain images that might suggest infiltration or phlebitis in the insertion and surrounding areas, was performed by positioning the transducer on the transparent catheter dressing. Clinical evaluations were performed in the CG, including inspection, palpation, and attention to any complaints.

### Outcome Measures

The main outcomes of interest were the success of the insertion and the incidence of infiltration and phlebitis. The success of the insertion was defined as blood reflux through the catheter followed by the administration of 2 mL 0.9% NaCl solution with no complaints of pain and without any signs of complications in the insertion area.<sup>6,19,20</sup>



**Figure 1** Longitudinal ultrasound image of a peripheral IV catheter in the vein. Abbreviation: IV, intravenous.

**TABLE 1**

## Baseline Characteristics of the Sample

Characteristics	EG (n = 188)	CG (n = 194)	P
Age, median (Q1-Q3), y	8.2 (4.8-12.5)	7.2 (3.9-10.6)	.028 <sup>a</sup>
Male gender	105 (55.9)	107 (55.2)	.891 <sup>b</sup>
Nutritional condition			.698 <sup>b</sup>
Eutrophic	156 (83.0)	160 (82.5)	
Malnutrition	22 (11.7)	20 (10.3)	
Overweight	10 (5.3)	14 (7.2)	
1 or more clinical predispositions to venipuncture failure or complications	70 (37.2)	79 (40.7)	.485 <sup>b</sup>
1 or more therapeutic risk factors for venipuncture failure and complications occurrence	47 (25.0)	44 (22.7)	.595 <sup>b</sup>
Previous infusion therapy	145 (77.1)	150 (77.3)	.964 <sup>b</sup>
History of complications	33 (17.6)	30 (15.5)	.582 <sup>b</sup>

<sup>a</sup>Using the Mann-Whitney test.

<sup>b</sup>Using the  $\chi^2$  test.

Abbreviations: EG, experimental group; CG, control group; Q1, first quartile; Q3, third quartile.

Infiltration was defined as the escape of solutions into the extravascular area, the presence of cold skin around the insertion site, dependent edema, or an absent or slow continuous infusion rate.<sup>21,22</sup> Phlebitis was defined as a vein inflammation at the catheter insertion site resulting in rigid or tortuous veins, heightened sensitivity, pain, and occasionally, purulent drainage.<sup>21,22</sup> Identification of such adverse events was performed by following the Infusion Nurses Society's (INS') *Infusion Nursing Standards of Practice*.<sup>21</sup>

### Data Analysis

Data were analyzed by using IBM SPSS 16 software for Windows. The associations between categorical variables were evaluated using the  $\chi^2$  test and the Fisher exact and the Fisher exact test. Numerical variables were evaluated by the Mann-Whitney test. All associations considered a *P* value < .05 to denote statistical significance.

## RESULTS

Table 1 shows that subjects were for the most part school aged, male, and eutrophic; had undergone previous infusion therapy without complications; and did not exhibit clinical conditions capable of compromising venipuncture success (ie, chronic illness, prematurity, infection, vascular disease, extended infusion therapy) or therapeutic risk factors (ie, pH < 5 or > 9, osmolar-

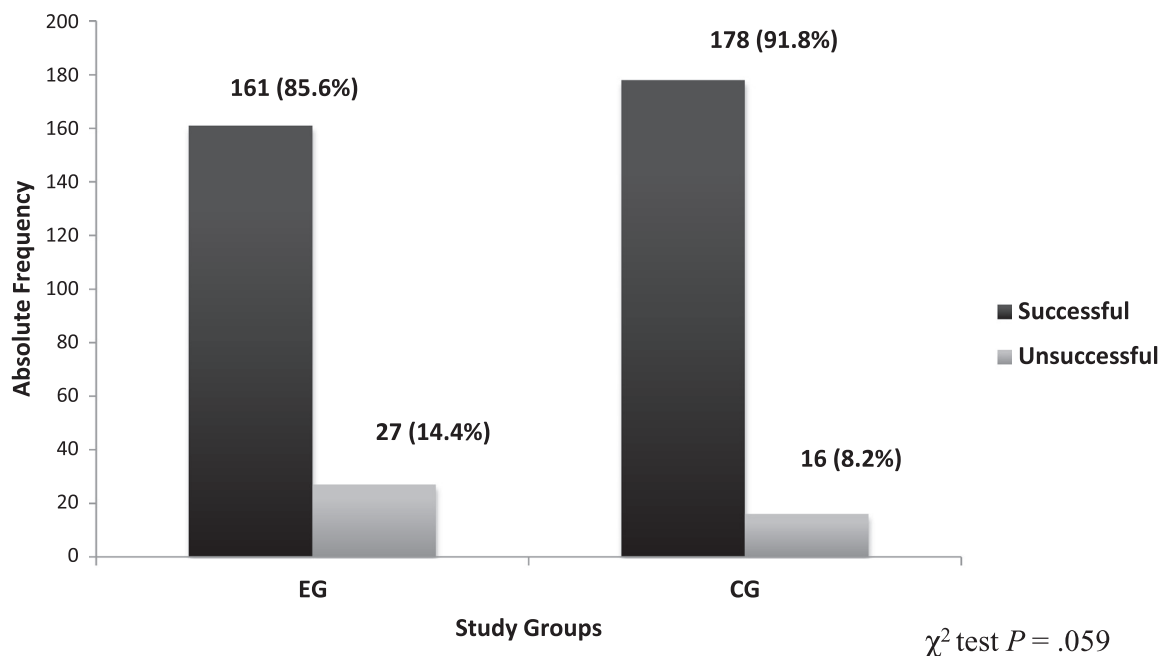
ity higher than 350 mOsm/L, risk of developing complications described by the manufacturers of the solutions or drugs), which would predispose the patient to insertion failure and complications.

Table 1 also shows there were no significant differences between the groups, although the median age in the EG was higher than in the CG (*P* = .028). Successful catheter placement was more frequent in the CG than in the EG, with no significant differences between the groups (Figure 2). The procedure failed in 43 of the 382 insertion attempts, with 161 (85.6%) successful insertions in the EG and 178 (91.8%) in the CG.

Complementary analysis of the use of ultrasound with the peripheral catheter insertions was conducted. Table 2 shows that a higher placement success rate occurred when good visualization of the vessel by ultrasound was possible, with a statistically significant correlation. A good visualization of the catheter progression in real time was not related to a significant improvement in peripheral vascular access.

The characteristics of the infusion therapy—the catheter insertion site, limb immobilization, method of fluid administration, and the infusion of solutions or drugs with therapeutic risk factor—had similar distributions between the studied groups. However, catheter readjustment, or back and forward movement, was more frequent in the EG and differed significantly compared with the CG (Table 3).

Catheter lengths used were 24 ga × 0.75 in (0.7 × 19 mm) and 22 ga × 0.75 in (0.9 × 19 mm), with a predominance of 24-gauge catheters used in both study groups (EG = 155, 82.4%; CG = 162, 83.5%). The



**Figure 2** Success of peripheral IV puncture according to studied groups. Abbreviations: EG, experimental group; CG, control group; IV, intravenous.

22-gauge catheters were used in 33 (17.6%) children from the EG and in 32 (16.5%) children from the CG. There was no significant difference between the groups ( $P = .783$ ).

The age of the children differed significantly between the groups, as shown in Table 1. Table 4 presents the analysis of the influence of age and the success of the catheter insertion, demonstrating better results related to ultrasound use in adolescents but without significant correlation.

Of the 339 catheters successfully inserted, 228 (67.3%) were removed because infusion therapy was discontinued, and 111 (32.7%) were removed as the result of adverse events, with statistically similar

distributions between the studied groups ( $P = .948/\chi^2$ ). Infiltration was identified in 57 (16.8%) patients and phlebitis in 9 (2.6%).

With regard to the complications observed, the incidence of infiltration differed significantly between the groups ( $P = .025$ ), occurring more frequently in the EG. Phlebitis occurred nearly 4 times more frequently in the CG, but no significant difference was observed (Table 5).

## DISCUSSION

No significant influence of ultrasound was found in the successful catheter insertions performed in the sample

**TABLE 2**

## Evaluation of the Ultrasonographic Images by Nurses and Successful Peripheral Venous Insertion

Ultrasonographic Evaluation	Successful f (%)	Unsuccessful f (%)	P
Vessel visualization			.009 <sup>a</sup>
Yes	150 (93.2)	21 (77.8)	
No	11 (6.8)	6 (22.2)	
Catheter insertion visualization			.059 <sup>b</sup>
Yes	48 (29.8)	3 (11.1)	
No	113 (70.2)	24 (88.9)	

<sup>a</sup>Using the  $\chi^2$  test.

<sup>b</sup>Using the Fisher exact test.

**TABLE 3**

## Characteristics of Infusion Therapy

Characteristics	EG (n = 161)	CG (n = 178)	P
Catheter insertion site			.669 <sup>a</sup>
Upper limbs	159 (98.7)	177 (99.4)	
Limb immobilization	97 (60.2)	118 (66.3)	.249 <sup>a</sup>
Catheter readjustment	60 (37.3)	46 (25.8)	.023 <sup>b</sup>
Method of infusion administration			.260 <sup>a</sup>
Continuous	94 (58.4)	91 (51.1)	
Intermittent	31 (19.2)	47 (26.4)	
Continuous and intermittent	36 (22.4)	40 (22.5)	
Solutions or drugs with therapeutic risk factor	133 (82.6)	142 (79.8)	.506 <sup>b</sup>

<sup>a</sup>Using the Fisher exact test.<sup>b</sup>Using the  $\chi^2$  test.

Abbreviations: EG, experimental group; CG, control group.

of children studied. The rate of phlebitis was statistically similar between groups; infiltration was significantly higher in the ultrasound group.

These results are consistent with those obtained in a randomized study showing that ultrasound did not improve insertion success rate in children.<sup>12</sup> In another randomized study, the authors concluded that ultrasonography-guided peripheral catheter insertions in children improved overall success rates. However, they did not find a significant difference in success rates ( $P = .208$ ).<sup>4</sup> Observational studies carried out with adults have reported as much as a 97.0% increase in the success of insertion with ultrasound guidance.<sup>23-25</sup>

Such findings indicate notable differences between peripheral vascular access and ultrasound use in children and adults. Technical, biological, and behavioral aspects could be studied to address the evidence to support these findings and promote advances.

The results of this study may have been affected by several factors, including (1) the introduction of a new technology into daily practice and (2) the inclusion of children with different levels of venous access difficulty and different ages and behavior that may have influenced their cooperation with the procedure. These variables also could have influenced the assessment of the ultrasound images and catheter insertions in real time. The use of ultrasonography to peripheral vascular access by nurses was not usual before the study beginning. We believe that the early development of technical skills and interpretation of the images may have contributed to the identified results.

**TABLE 4**

## Success of Peripheral Venous Insertion by Age

Age	EG (n = 161)	CG (n = 178)	P <sup>a</sup>
< 2 years	13 (36.1)	23 (63.9)	.148
2   - 7 years	50 (46.7)	57 (53.3)	.848
7   - 12 years	51 (45.1)	62 (54.9)	.538
12   - 18 years	47 (56.6)	36 (43.4)	.055

<sup>a</sup>Using the  $\chi^2$  test.

Abbreviations: EG, experimental group; CG, control group.

It should be noted that most of the studies with a higher success rate of peripheral catheter insertions with ultrasound were conducted in adults with difficult venous access and that none of that studies were randomized controlled trials.<sup>19,20,26-28</sup>

A prospective, nonrandomized study of the frequency of successful insertions in infants and adolescents without the use of ultrasound demonstrated that of 249 procedures, 91.0% of insertions were successful.<sup>7</sup> These results are similar to those obtained in this study (91.8%), suggesting that the pediatric nurses in this study were qualified and prepared to perform the procedure successfully.

Appraisal of the ultrasonographic image by professionals showed a statistically significant relationship ( $P = .009$ ) between successful insertions and vessel visualization (93.2%). The relationship observed between the ultrasonographic image visualization of the catheter insertion and the success of insertion (29.8%) may have been reduced because of the size of the infants' vessels,

**TABLE 5**

## Incidence of Infusion Therapy Complications: Infiltration and Phlebitis

Complications	EG (n = 161)	CG (n = 178)	P
Infiltration	34 (73.9)	23 (51.1)	.025 <sup>a</sup>
Phlebitis	2 (4.3)	7 (15.6)	.090 <sup>b</sup>

<sup>a</sup>Using the  $\chi^2$  test.<sup>b</sup>Using the Fisher exact test.

Abbreviations: EG, experimental group; CG, control group.

the catheter gauge, the sensitivity and size of the equipment transducer, and the children's cooperation.

The child's cooperation is necessary to identify the ultrasonographic image. Any movement causes loss of the image. In general, the older the child, the greater the rate of insertion success ( $P = .055$ ) (Table 4). In situations in which the child did not cooperate, the vessel image was analyzed, and the professional had to memorize the intended site of insertion because of the impossibility of completing the puncture in real time. Vessel visualization and catheter insertion is easier in older children and adolescents who cooperate during the procedure because venous access procedures are a significant source of distress for young children.<sup>12,29</sup>

Another factor that may have influenced these findings is the size of the limb that enables adequate transducer positioning, a variable identified by other researchers. A randomized, clinical trial performed in children younger than 7 years demonstrated that the limited physical space in the extremities of small children does not allow for the accommodation of the transducer during venipuncture because of the transducer's size. Instead, a static ultrasound technique was used in which the vessel was identified and the overlying skin was marked with a pen tip.<sup>12</sup>

Because a child's cooperation during the procedure is essential for ultrasound use in real time, an evaluation of the anxiety level, activity, and potential need for sedation must guide nursing decisions before the procedure, which should be supported by a multidisciplinary practice.<sup>28</sup> During data collection, sedatives for insertions were not used, which could have affected the results. In Brazilian clinical practice, the use of conscious sedation for children who undergo insertions is not routine.

In another randomized study conducted by the research team, in which children were sedated during insertion of a peripherally inserted central catheter guided by ultrasonography, the success in the first attempt was higher ( $P = .003$ ) in the ultrasound group (90.5%) than in the control group (47.6%).<sup>30</sup> Children with difficult venous access could be considered candidates for the use of conscious sedation to allow the use of ultrasound.

Complication rates for ultrasonography-guided peripheral catheter insertions have been studied only in adults at the moment of the venipuncture or immediately following it, including arterial punctures, hematomas, and nerve pain.<sup>31,32</sup>

In this investigation, 66 children exhibited infiltration or phlebitis, which, according to several studies, are the most common peripheral infusion complications.<sup>33-36</sup>

Prospective and observational studies of complications in ultrasonography-guided insertion in 75 adult patients identified infiltration (28%), inadvertent dislodgment of the catheter (11%), and phlebitis (4%) as the most common causes of peripheral vascular access failure. The authors described the absence of a control group as the study's major limitation.<sup>32</sup>

In this study, infiltration was more frequent than phlebitis. The predominance of infiltration and its significantly higher rate in the EG compared with the CG could possibly be related to catheter readjustment. Although the ultrasound allowed the nurse to view the vessel and attempt to position the catheter properly, readjustment can contribute to vessel transfixing and consequent infiltration. Therefore, while using ultrasound, it would be better to use an indirect method of vein access to prevent catheter readjustment in regions too close to the blood vessel wall. Another factor to consider is that nurses were unable to visualize the catheter insertion in some situations, which made the successful positioning of the catheter in the vessel impossible.

A previous study reported that 58% of the children exhibited some infiltration, an incidence 3 times greater than that identified in this research.<sup>37</sup> In a study with Brazilian children, 73.4% of 113 adverse events were infiltrations.<sup>35</sup>

The overall incidence of phlebitis was lower (2.6%) than that suggested by INS, which reports 5% as the maximum rate accepted for the incidence of phlebitis in any population of patients.<sup>21</sup> However, it is important to underscore that when evaluating the phlebitis frequency separately in the 2 study groups, the EG experienced lower rates (15.6% of the CG was above INS recommendations, compared with 4.3% of the EG).

To the best of the authors' knowledge, no studies have simultaneously evaluated the influence of ultrasound on the success of peripheral venous access and infusion therapy complication rates in children. The lack of such studies makes it difficult to compare this study with others. Moreover, direct comparisons between adults and children may be made increasingly complex because of a lack of scientific evidence regarding the differences and the diverse characteristics inherent to the pediatric group.

Innovation in clinical practice is an essential component of the evolution of nursing science. This study may encourage other investigations on this subject and the enhancement of nursing care provided to children undergoing infusion therapy.

## LIMITATIONS OF THE STUDY

The limitations of the study include sample size, the age differences among the children, the introduction of new technology into nursing practice, and the recent professional achievement of skills and competencies.

## CONCLUSION

The use of ultrasound guidance in peripheral catheter insertion in children promotes successful insertions and

complication rates of infusion therapy that are statistically similar to those achieved using the standard landmark method, with the exception of the incidence of infiltration, which was statistically higher in the ultrasound group.

The findings of this study provide unique, preliminary data on the use of ultrasound in a large group of children who participated in a randomized controlled analysis of peripheral access. Little or no innovation has been observed recently in the techniques used by nurses for peripheral insertion. The development of new methods that could improve skills should be studied, analyzed, and adjusted to improve clinical outcomes. Future research should address issues such as the influence of the type of ultrasound on the success of peripheral insertion and the incidence of complications of infusion therapy in children, in addition to how to improve nursing skills in the use of ultrasound with this population.

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