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Skin Transillumination Improves Peripheral Vein Cannulation by Residents in Neonates: A Randomized Controlled Trial

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Neonatology · Training · Venous access

Abstract

Introduction: Establishing peripheral vein access is challenging for pediatric residents and a painful procedure for neonates. We assessed the efficacy of a red light-emitting diode transilluminator during peripheral vein catheter insertion performed by pediatric residents. ***Methods:*** Patients were stratified by current weight (≤1,500 g, >1,500 g) and randomized to the transillumination or the control group. The first three attempts were performed by pediatric residents, followed by three attempts by a neonatologist. The primary outcome was success at first attempt. Secondary comparisons included time to successful insertion and overall success rates of residents and neonatologists. ***Results:*** A total of 559 procedures were analyzed. The success rate at resident's first attempt was 44/93 (47%) with transillumination versus 44/90 (49%) without transillumination ($p = 0.88$) in the strata ≤1,500 g and 103/188 (55%) with transillumination versus 64/188 (34%) without transillumination in the strata >1,500 g ($p < 0.001$). The overall success rate for residents was 86% in the transillumination versus 73% in the control group in the strata >1,500 g ($p = 0.003$) but not different in the strata ≤1,500 g (78/93 [84%] vs. 72/90 [80%], $p = 0.57$). There was no effect when the experience level of residents exceeded 6 months. Neonatologists' overall success rate and time to successful cannulation did not differ significantly in both weight strata. ***Conclusion:*** Transillumination improves the first-attempt success rate of peripheral vein cannulation performed by pediatric residents in neonates >1,500 g, while no benefit was found in infants ≤1,500 g.

Introduction

Term and preterm neonates undergoing intensive care medicine frequently require peripherally inserted vein catheters (PIVCs) [1]. Multiple puncture attempts in this population is associated with pain exposure and

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potentially increased risk of complications such as hematoma and nerve damage, increased staff requirements, and in emergency scenarios, may delay life-saving treatment [2–7]. As a consequence, the American Academy of Pediatrics states that the number of painful procedures in neonates should be reduced [8]. Effective cannulation of peripheral veins therefore represents a major goal in neonatal medicine. However, first-attempt success rates of PIVC insertion in clinical trials are non-satisfying and reported to be only 45–59% in neonate-specific study populations [9, 10]. To improve the PIVC placement success rate in children, different technical devices facilitating vein visualization were evaluated in several clinical studies [11–19]. Primary success rates in these trials are equivocal with some studies demonstrating improvements, while others found no benefit or even lower success rates [11, 20]. The studies differ substantially in terms of included study subjects (neonatal, pediatric, or mixed populations), experience level of the operators, and technical devices used. These differences might have mitigated potential benefits of the intervention in the neonatal population. The primary goal of this randomized controlled trial (RCT) is to assess the effect of a red light-emitting diode (LED) transilluminator on the first-attempt PIVC insertion success rate compared to the standard procedure and pediatric residents as the primary operator in a weight-stratified neonatal study cohort.

Fig. 1. LED-based transilluminator.

Methods

Design and Study Population

This non-blinded single-center RCT was conducted in a German perinatal level III center between July 2018 and January 2021. The study is registered at the German Clinical Trial Registry (DRKS00015181) and was approved by the local Institutional Review Board prior to study start (AZ 61/18). Subjects were eligible if they met the following inclusion criteria: all preterm and term neonates admitted to the neonatal unit requiring nonemergency PIVC insertion. Infants were ineligible (or not randomized in cases of available informed consent) if emergency intravenous access was required, if hemodynamically unstable (defined as mean arterial blood pressure < gestational age [GA]) or considered too sick to participate as decided by the responsible neonatologist.

Study Procedure and Intervention

Infants meeting the inclusion criteria were randomly allocated to receive one of the two following interventions: in infants randomized to the transillumination group, a red LED-based transilluminator (ASTODIA®, Stihler Electronic GmbH, Stuttgart, Germany) was used to visualize the veins (shown in Fig. 1) with the surrounding light dimmed. In infants allocated to the control group, no device to visualize veins for PIVC insertion was permitted. The primary operator in each study group was a pediatric resident as they perform PIVC insertion routinely in Germany. Before participating in this trial, each pediatric resident attempted a minimum of six explanatory and supervised PIVC insertions (standard and transillumination, respectively). The transillumination device has been implemented for study purposes only and has not been routinely used in daily clinical practice. Within both study groups, the PIVC insertion followed a standardized protocol: a neonatal nurse was responsible for comforting the infant, and oral administration of 20% dextrose 1–2 min prior to the vein puncture was given. Time measurement was recorded by a neonatal nurse using a stopwatch and started when the pediatric resident was ready to start scanning for available veins. After effective skin disinfection (30 s), PIVC insertion was performed using either 24-gauge (BD Insyte® catheter, Becton Dickinson, UT, USA) or 26-gauge (Klinijject® catheter KLINIKA, Usingen, Germany) catheters as considered appropriate by the operator. Successful insertion of the PIVC was confirmed by flushing the intravenous catheter with normal saline, and timing was stopped when no visible extravasation occurred. After three nonsuccessful attempts by the pediatric resident, a neonatologist performed up to three further attempts using the initially allocated intervention. After the study procedure, the operator noted relevant demographic variables and outcome data on a hard-copy case report form.

Randomization and Blinding

Study subjects were stratified by actual body weight at the time of randomization (≤1,500 g and >1,500 g). Randomization was single-sequence-based, and infants were allocated to the transillumination group or control group using sealed opaque envelopes generated by the research team. The participants were enrolled by the research team and the performers and randomly assigned to their group by the performers. Participating study subjects could be enrolled multiple times during their hospital stay if repeated PIVC insertion was necessary. Therefore, study subjects were allowed to switch weight strata with increasing body weight, and for every new required PIVC, patients were re-randomized. Crossover after allocation was not permitted. Due to the nature of the intervention, blinding of operators and participating staff members was not possible.

Study Outcomes

The primary outcome was successful PIVC insertion on first attempt performed by a pediatric resident. Secondary outcomes included success rate within two or three attempts by pediatric residents, success rate at first and within two or three attempts by neonatologists, and time to successful PIVC insertion at resident's first attempt. Patient and operator demographic variables (GA at birth, GA at randomization, birthweight, weight at randomization, sex, ethnicity, catheter size, reason for PIVC insertion, experience level of the resident in months of residency training, and puncture site) were documented as well.

Sample Size

The success rate at first attempt in a previous study with a neonate-specific population was 45% [9]. Assuming that the LED transilluminator increases the success rate at first attempt from 50% to 65%, this would lead to a number needed to treat of 7 and was considered as a clinically important difference. Based on an alpha of 0.05 and a power of 80%, 170 patients per arm are needed to detect the 15% increase in first-attempt success. To account for potential dropouts, the sample size was increased by approximately 10% (190 procedures per study arm). Because body weight at the time of randomization may have a significant impact on the primary outcome, we a priori determined two different weight strata (strata 1 ≤1,500 g and strata 2 >1,500 g). The final calculated sample size for each weight strata was therefore 380 procedures.

Statistical Analysis

All statistical analyses were performed using IBM® SPSS® Statistics (Version 25, SPSS Inc., Chicago, IL, USA), the statistical software R (Version 4.1.1, 2021), and Microsoft® Excel® 2013 (Version 15.0.5423.1000, Redmond, WA, USA). For statistical comparisons of categorical variables (PIVC insertion success rate, sex, catheter size, reason for PIVC insertion, and puncture site), a two-sided Fisher's exact test was applied, and the Mann-Whitney-U test was used to compare numerical variables (time to successful PIVC insertion at first attempt, GA at birth, GA at randomization, birthweight, weight at randomization, experience level of the resident in months). Data are presented as median and interquartile range (IQR) for numerical variables and percentage for categorical variables. For the primary and secondary outcomes, the unadjusted absolute increase in success rates between the two study groups was calculated and presented with 95% confidence interval based on Wald's statistic. The number needed to treat to avoid failure at placement was calculated. A p value of <0.05 was considered statistically significant. A logistic regression model was calculated with success at first attempt as the primary outcome, taking the experience level of the resident or puncture site into account as a possible confounder. Post hoc Tukey tests with adjustment for multiple comparisons were performed if appropriate using the emmeans R package (Version 17.7.5, 2022). Time to successful PIVC insertion was analyzed using a Mann-Whitney U-test as data show a skewed distribution. All analyses were performed as per the intention-to-treat principle. An interim analysis after reaching a sample size of 50% within each weight strata was performed.

Results

Study Population and Randomization

Between July 2018 and January 2021, custodians of 473 eligible neonates were approached for consent. We received consent for 405 (86%) neonates. A total of 127 patients were excluded as they had no need for a new PIVC insertion. Because study subjects could be re-enrolled, 570 PIVC insertions (190 ≤1,500 g, 380 >1,500 g) were performed in 278 neonates in this study. A total of 559 cases were included in the intention-to-treat analysis (183 ≤1,500 g; 376 >1,500 g), and 11 case report forms got lost during daily clinical routine (shown in Fig. 2). After the results of the interim analysis in March 2020, recruitment in the strata ≤1,500 g was stopped after randomization of 190 procedures due to a change of peripheral vein access policy in our unit and an insignificant difference regarding the primary outcome (47 in the transillumination vs. 49% in the control group). From this interim analysis, it seemed unlikely that ongoing recruitment would have affected the study results in a significant manner.

Baseline Characteristics

Demographic variables and baseline characteristics are presented in Table 1. Except for the experience level of the residents in the strata ≤1,500 g and the primary puncture site in the strata >1,500 g, demographics were comparable in both groups. The median experience level in the strata ≤1,500 g was 20 months (IQR 12–30) in the transillumination group and 16 months (IQR 7–22) in the control group (p = 0.001). In logistic regression analysis, this difference did not affect the primary outcome (estimated log-odds change by using transillumination = 0.7975, p = 0.395).

PIVC Insertion Success Rate and Time to Successful PIVC Insertion

Neonates ≤1,500 g

The first-attempt success rate in neonates ≤1,500 g performed by pediatric residents was not significantly different between the transillumination and the control

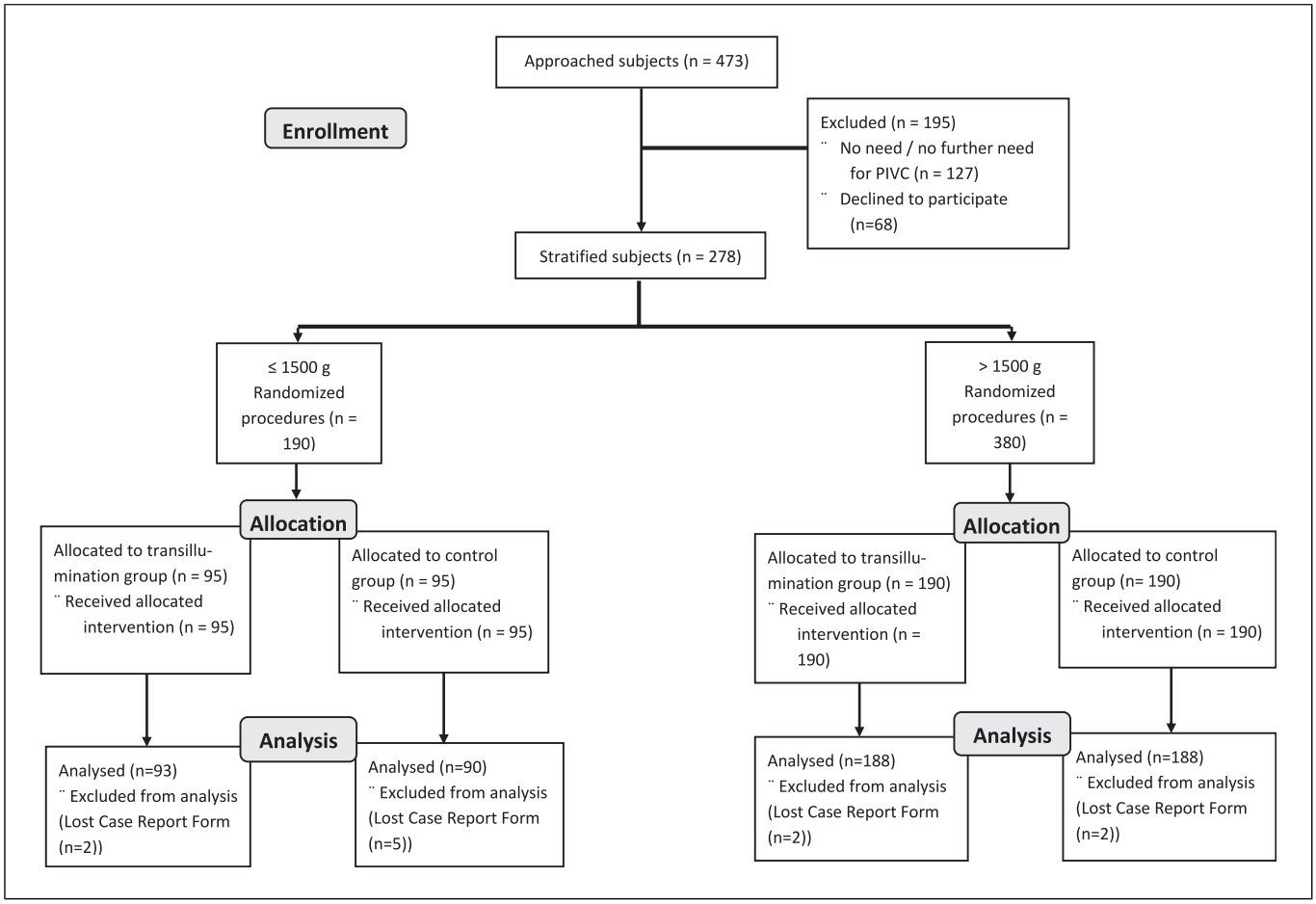

Fig. 2. CONSORT flow diagram.

group (47 [44/93] vs. 49% [44/90], $p = 0.88$, Table 2). The success rates within two and three attempts by pediatric residents were also comparable (Table 2). When the procedure was performed by a neonatologist, there were no significant differences between both groups in the success rate (Table 2). Time to successful PIVC insertion at resident's first attempt was comparable between the groups (Table 3).

Neonates >1,500 g

When an LED transilluminator was used, the first-attempt success rate by pediatric residents was significantly higher at 55% (103/188) compared to the standard procedure at 34% (64/188) (number needed to treat: 5, $p < 0.001$, Table 2). The success rate within two and three attempts by pediatric residents was also significantly higher in the transillumination group. Neonatologists' success rate was not significantly affected by the study intervention (Table 2). Time to successful PIVC insertion at resident's first attempt was comparable between the groups (Table 3).

Success Rate in Relation to the Clinical Level of Experience

The LED transilluminator significantly improved the success rate at first and within three attempts for pediatric residents with experience of up to 6 months. This effect became less pronounced with increasing clinical experience. There was no significantly improvement when the experience level of residents exceeded 6 months (Table 4).

Discussion

This RCT assessed the effect of an LED transilluminator on the first-attempt PIVC insertion success rate in a neonatal study population that was further segregated

Table 1. Neonatal and pediatric residents' baseline characteristics

	Strata							
	≤1,500 g				>1,500 g			
	overall (*N* = 183)	transillumination group (*N* = 93)	control group (*N* = 90)	*p*[a]	overall (*N* = 376)	transillumination group (*N* = 188)	control group (*N* = 188)	*p*[a]
Neonatal baseline characteristics								
GA at birth, median [IQR], weeks	28+0 [26+1–30+0]	27+3 [26+0–30+0]	28+4 [26+1–30+0]	0.40	36+3 [30+6–39+5]	36+0 [30+0–39+4]	37+5 [30+6–39+6]	0.22
GA at randomization, median [IQR], weeks	29+5 [28+3–31+3]	29+4 [28+2–31+3]	29+6 [28+4–31+2]	0.58	40+1 [36+2–41+6]	39+5 [36+3–41+4]	40+4 [36+0–42+1]	0.30
Age at randomization, median [IQR], days	5 [3–18]	5 [3–19]	6 [3–18]	0.78	12 [4–52]	12 [3–56]	12 [4–51]	0.85
Birthweight, median [IQR], g	900 [660–1,155]	900 [660–1,180]	905 [690–1,172]	0.60	2,650 [1,570–3,380]	2,340 [1,440–3,350]	2,774 [1,600–3,480]	0.21
Weight at randomization, median [IQR], g	1,090 [900–1,300]	1,080 [900–1,300]	1,100 [890–1,300]	0.82	3,170 [2,345–3,788]	3,135 [2,252–3,662]	3,215 [2,490–3,900]	0.23
Sex				0.24				0.66
Male, *n* [%]	87 [48]	40 [43]	47 [52]		258 [69]	127 [68]	131 [70]	
Female, *n* [%]	96 [52]	53 [57]	43 [48]		117 [31]	61 [32]	56 [30]	
Diverse, *n* [%]	0 [0]	0 [0]	0 [0]		1 [0]	0 [0]	1 [1]	
Ethnicity				0.20				0.58
Afro-American, *n* [%]	7 [4]	2 [2]	5 [6]		7 [2]	3 [2]	4 [2]	
Asian, *n* [%]	2 [1]	2 [2]	0 [0]		12 [3]	8 [4]	4 [2]	
Caucasian, *n* [%]	174 [95]	89 [96]	85 [94]		357 [95]	177 [94]	180 [96]	
Reason for peripheral vein catheter insertion				0.70				0.78
Antibiotic therapy, *n* [%]	47 [26]	24 [26]	23 [26]		214 [57]	105 [56]	109 [58]	
Parenteral nutrition, *n* [%]	84 [46]	39 [42]	45 [50]		104 [28]	55 [30]	49 [26]	
Antibiotic therapy and parenteral nutrition, *n* [%]	36 [20]	19 [20]	17 [19]		22 [6]	10 [5]	12 [6]	
Transfusion, *n* [%]	11 [6]	7 [8]	4 [4]		14 [4]	6 [3]	8 [4]	
Sedation, *n* [%]	1 [1]	1 [1]	0 [0]		10 [3]	4 [2]	6 [3]	
Antibiotic therapy and transfusion, *n* [%]	0 [0]	0 [0]	0 [0]		1 [0]	1 [1]	0 [0]	
Antibiotic therapy and misc., *n* [%]	0 [0]	0 [0]	0 [0]		2 [1]	1 [1]	1 [1]	
Misc. (antimycotics, drugs, contrast agents), *n* [%]	4 [2]	3 [3]	1 [1]		8 [2]	6 [3]	2 [1]	
Missing data, *n* [%]	0 [0]	0 [0]	0 [0]		1 [0]	0 [0]	1 [1]	
Catheter size				0.55				0.38
24 gauge, *n* [%]	141 [77]	71 [76]	70 [78]		364 [97]	183 [97]	181 [96]	
26 gauge, *n* [%]	30 [16]	14 [15]	16 [18]		9 [2]	5 [3]	4 [2]	
26 and 24 gauge used within 3 attempts, *n* [%]	12 [7]	8 [9]	4 [4]		3 [1]	0 [0]	3 [2]	

Table 1 (continued)

	Strata							
	≤1,500 g				>1,500 g			
	overall (*N* = 183)	transillumination group (*N* = 93)	control group (*N* = 90)	*p*[a]	overall (*N* = 376)	transillumination group (*N* = 188)	control group (*N* = 188)	*p*[a]
Puncture site of primary puncture				0.06				0.02
Hand, *n* [%]	126 [69]	64 [69]	62 [69]		302 [80]	157 [84]	145 [77]	
Foot, *n* [%]	38 [21]	15 [16]	23 [26]		59 [16]	24 [13]	35 [19]	
Forearm, *n* [%]	14 [8]	11 [12]	3 [3]		6 [2]	4 [2]	2 [1]	
Leg, *n* [%]	4 [2]	3 [3]	1 [1]		2 [1]	2 [1]	0 [0]	
Head, *n* [%]	0 [0]	0 [0]	0 [0]		5 [1]	0 [0]	5 [3]	
Missing data, *n* [%]	1 [1]	0 [0]	1 [1]		2 [1]	1 [1]	1 [1]	
Pediatric residents' baseline characteristics								
Experience level of the resident, median [IQR], months	18 [8–27]	20 [12–30]	16 [7–22]	0.001	12 [5–20]	14 [5–24]	12 [5–18]	0.38

IQR, interquartile range. [a]Fisher's exact test or Mann-Whitney U test as appropriate.

into two weight strata (≤1,500 g and >1,500 g, respectively) and different levels of experience of pediatric residents as the primary operators. We found a significant improvement in first attempt and overall success rate in the strata >1,500 g when the LED transilluminator was used by pediatric residents.

Of interest, the primary success rate of pediatric residents in the strata ≤1,500 g did not differ significantly between the study groups. This is in line with the findings by Phipps et al. where benefits of vein visualization were most clearly seen in more mature neonates [10]. The most obvious explanation for the improved success rate in more mature neonates could be the higher amount of subcutaneous fat, a condition where transillumination most effectively visualizes subcutaneous veins. Another possible explanation is the more difficult handling of the transilluminator in infants ≤1,500 g due to the disproportionally smaller size of the limbs compared to the size of the transilluminator.

Skills of the operator have been identified as one key determinant for successful venous puncture [2]. Our data support this finding and demonstrate that the use of the transilluminator can significantly improve success rates for less experienced staff (Table 4).

Phipps et al. [10] assessed a near-infrared-based vein visualization device for the placement of peripheral inserted central venous catheters and found no difference on the success at first attempt but an improved overall success rate within three attempts. Comparison of their outcome data with our study results is difficult. First, the device used in their trial uses near-infrared technology that directly visualizes hemoglobin parts of the flowing or non-flowing blood inside or outside the superficial veins, while the transillumination technique rather directly visualizes the anatomical vein structure and may more effectively allow the differentiation of the vein from the surrounding transilluminated tissue. Second, the primary operator in their trial were members of an expert neonatal nurse practitioners/registered nurses PICC-line team, and although no particular experience level was reported, we presume a higher level of operator experience compared to the performing residents in our trial [10].

The success rates of the primary operator without vein visualization in our study are below those reported in other studies [21]. The most likely explanation is the lower level of experience of the pediatric residents (Table 4).

Strengths of our study include an adequate sample size that allows confirmatory interpretation of our study results, particularly in the weight strata >1,500 g. The clear

Table 2. Success rate in % (ratio/total) and absolute increase in success rates with a 95% confidence interval in both groups

	Transillumination group, % [ratio/total]	Control group, % [ratio/total]	Absolute increase in success rate percentage point [95% confidence interval]	p^a
≤1,500 g				
Success rate at first attempt by pediatric residents	47 [44/93]	49 [44/90]	−2 [−16 to 13]	0.88
Success rate within two attempts by pediatric residents	69 [64/93]	70 [63/90]	−1 [−15 to 12]	0.87
Success rate within three attempts by pediatric residents	84 [78/93]	80 [72/90]	4 [−7 to 15]	0.57
Success rate at first attempt by neonatologists	60 [9/15]	72 [13/18]	−12 [−45 to 20]	0.49
Success rate within two attempts by neonatologists	87 [13/15]	78 [14/18]	9 [−17 to 35]	0.66
Success rate within three attempts by neonatologists	93 [14/15]	78 [14/18]	16 [−7 to 39]	0.35
>1,500 g				
Success rate at first attempt by pediatric residents	55 [103/188]	34 [64/188]	21 [11–31]	<0.001
Success rate within two attempts by pediatric residents	78 [146/188]	63 [118/188]	15 [6–24]	0.002
Success rate within three attempts by pediatric residents	86 [162/188]	73 [138/188]	13 [5–21]	0.003
Success rate at first attempt by neonatologists	58 [15/26]	48 [24/50]	10 [−14 to 33]	0.48
Success rate within two attempts by neonatologists	73 [19/26]	68 [34/50]	5 [−16 to 26]	0.79
Success rate within three attempts by neonatologists	88 [23/26]	76 [38/50]	12 [−5 to 30]	0.24

[a]Fisher's exact test.

Table 3. Time to successful peripheral vein catheter insertion at resident's first attempt in median (IQR) in both groups

Strata	Transillumination group		Control group		p^a
	median [IQR]	*N*	median [IQR]	*N*	
≤1,500 g	174 s [120–252]	44	172 s [120–270]	43	0.94
>1,500 g	180 s [114–278]	103	161 s [100–244]	64	0.28

One successful procedure in the transillumination group was not timed. IQR, interquartile range. [a]Mann-Whitney U test.

definition of the primary operator is another strength of this trial, and we were able to collect important performance data on the success rate of pediatric residents. The primary success rate of pediatric residents (representative for all less experienced staff members and trainees) in the control group of only 34% requires action and should prompt supervisors to seek for improved teaching strategies, including the use of skin transillumination. This strategy may further help to improve first-attempt success and, as a consequence, reduce procedure-related pain in this vulnerable population [7, 8]. However, our study also has limitations. Due to the nature of the intervention, blinding within this trial was not possible. Earlier termination in the low-weight strata due to a change in our vein access policy was mainly based on the observation of very short longevity of peripheral vein catheters in infants ≤1,500 g and the consecutive high PIVC insertion exposure. We therefore shifted toward the use of peripheral inserted central vein catheters in this study population. However, since there were no differences after 190 randomized procedures, we believed that it was unlikely that ongoing recruitment would have affected the study results in a significant manner.

Table 4. Success rate in % (ratio/total), absolute increase in success rates with a 95% confidence interval, and the number needed to treat with a 95% confidence interval according to the level of experience across both weight strata

	Transillumination group, % [ratio/total]	Control group, % [ratio/total]	Absolute increase in success rate percentage point [95% confidence interval]	Number needed to treat [95% confidence interval]	p[a]
<6 months					
Success rate at first attempt	56 [44/79]	28 [24/87]	28 [14–43]	4 [3–8]	<0.001
Success rate within two attempts	77 [61/79]	52 [45/87]	26 [12–40]	4 [3–9]	0.001
Success rate within three attempts	85 [67/79]	66 [57/87]	19 [7–32]	6 [4–16]	0.005
6–12 months					
Success rate at first attempt	49 [18/37]	34 [20/58]	14 [−6 to 34]	8 [−17 to 3]	0.20
Success rate within two attempts	70 [26/37]	66 [38/58]	5 [−14 to 24]	22 [−7 to 5]	0.66
Success rate within three attempts	78 [29/37]	76 [44/58]	3 [−15 to 20]	40 [−7 to 6]	0.81
12–18 months					
Success rate at first attempt	52 [30/58]	50 [29/58]	2 [−17 to 20]	58 [−7 to 6]	1
Success rate within two attempts	78 [45/58]	79 [46/58]	−2 [−17 to 13]	−58 [−6 to 8]	1
Success rate within three attempts	86 [50/58]	88 [51/58]	−2 [−14 to 10]	−58 [−8 to 10]	1
18–24 months					
Success rate at first attempt	55 [26/47]	54 [15/28]	2 [−22 to 25]	58 [−5 to 4]	1
Success rate within two attempts	81 [38/47]	82 [23/28]	−1 [−19 to 17]	−78 [−6 to 6]	1
Success rate within three attempts	89 [42/47]	82 [23/28]	7 [−10 to 24]	14 [−11 to 5]	0.49
>24 months					
Success rate at first attempt	48 [29/60]	43 [20/47]	6 [−13 to 25]	18 [−8 to 5]	0.56
Success rate within two attempts	67 [40/60]	62 [29/47]	5 [−13 to 23]	21 [−8 to 5]	0.68
Success rate within three attempts	87 [52/60]	74 [35/47]	12 [−3 to 27]	9 [−34 to 4]	0.14

[a]Fisher's exact test.

In conclusion, the use of a red LED-based transilluminator significantly increased the success rate of first attempts of PIVC insertion in the neonatal population with an actual weight >1,500 g for pediatric residents, and this effect was most pronounced for unexperienced pediatric residents. Vein visualization therefore is a very useful tool to increase success rates of PIVC insertion and to reduce the overall pain burden and the risk for other procedure-related complications associated with PIVC insertion in this vulnerable population.

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Statement of Ethics

This study protocol was reviewed and approved by the Medical Ethics Committee of the Justus-Liebig-University of Giessen, approval number AZ 61/18. Written informed consent was obtained from the parents of the participants to participate in the study.

Conflict of Interest Statement

The other authors have no conflicts of interest to disclose.

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Author Contributions

Samantha Hinterstein: methodology, investigation, data curation, formal analysis, writing – drafting the initial manuscript, and writing – review or editing of the manuscript. Prof Harald Ehrhardt: conceptualization/design, investigation, and

writing – review or editing of the manuscript. Prof Klaus-Peter Zimmer: conceptualization/design, supervision/oversight, resources, and writing – review or editing of the manuscript. Dr. Anita Windhorst: methodology, formal analysis, and writing – review or editing of the manuscript. Dr. Judith Kappesser: conceptualization/design and writing – drafting the initial manuscript. Prof Christiane Hermann: conceptualization/design, methodology, and writing – review or editing of the manuscript. Dr. Rahel Schuler and Dr. Markus Waitz: conceptualization/design, methodology, investigation, supervision/oversight, formal analysis, writing – drafting the initial manuscript, and writing – review or editing of the manuscript. All the authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Data Availability Statement

The data that support the findings of this study are not publicly available due to containing information that could compromise the privacy of research participants but are available from the corresponding author (Rahel Schuler, Rahel.Schuler@paediat.med.uni-giessen.de) upon reasonable request.

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