

# Veinlite Transillumination in the Pediatric Emergency Department

## *A Therapeutic Interventional Trial*

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**Objectives:** We hypothesized that transillumination would increase peripheral intravenous (IV) insertion success rates in pediatric emergency department patients. Primary outcome was success in first attempt, and secondary outcome was success within 2 attempts.

**Methods:** We evaluated IV insertion by pediatric emergency department physicians and nurses using the Veinlite (TransLite, Sugar Land, Tex). Patients who required nonemergent IV insertion were enrolled if younger than 3 years or aged 3 to 21 years with a history of difficult access. Participants were randomly assigned to transillumination or nontransillumination. Analyses were performed using a mixed-effects logistic regression model adjusting for provider effect.

**Results:** We evaluated 240 patients. After adjusting for significant covariates (safety catheter [ $P = 0.008$ ], visibility [ $P = 0.01$ ], and palpability [ $P = 0.03$ ]) and controlling for provider effect, IV placement was more likely successful in first attempt in transilluminated patients ( $P = 0.03$ ; odds ratio, 2.1 [95% confidence interval, 1.1–3.9]). After adjusting for significant covariates (safety catheter [ $P < 0.001$ ], location [ $P = 0.005$ ], and palpability [ $P = 0.05$ ]) and controlling for provider effect, IV placement was more likely successful within 2 attempts in transilluminated patients ( $P = 0.01$ ; odds ratio, 3.5 [95% confidence interval, 1.4–8.9]). Intraclass correlation for random effect of provider was 10% in first attempt and 16% within 2 attempts.

**Conclusions:** After adjusting for multiple significant covariates and controlling for random effect of provider, our results indicated a benefit in the use of Veinlite transillumination for IV insertion in first attempt and within 2 attempts. This technique seemed to facilitate nonemergent IV placement in pediatric patients compared with standard practice.

**Key Words:** transillumination, peripheral intravenous insertion, IV

In 1998, Frey<sup>1</sup> reported peripheral intravenous (IV) insertion success rates for admitted patients, at a large urban children's hospital, of 23% for physicians, 44% for staff registered nurses (RNs), and 98% for IV nurse clinicians. The number of attempts ranged from 1 to 10 on a single patient, and the average time required per IV start was 20 minutes, with an estimated average cost of \$24. In 1992, Friedland and Brown<sup>2</sup> reported a 74% success rate in the first IV attempt in 214 children in an emergency department (ED) by registered nurses.

Kuhns et al<sup>3</sup> described the use of transillumination of an extremity to facilitate infant venipuncture in 1975. They noted that venipuncture in infants could be difficult because superficial veins were often too small to palpate and were difficult to see with ambient light. The use of the initial transillumination devices required caution because of production of heat and iatrogenic second-degree burns.<sup>4,5</sup> The development and improvement of fiber optic lights has resulted in transilluminators that illuminate veins without danger of thermal injury when used appropriately.<sup>5–9</sup>

In a pediatric ED, IV insertion is often a difficult experience for patients, parents, and medical providers. Increased dexterity is required in the cannulation of infants, and children and adolescents with chronic medical conditions. When unsuccessful, alternatives include intraosseous infusion, central venous access, and venous cutdown. These more invasive procedures require greater skill and are associated with increased morbidity.<sup>10–13</sup> Therefore, techniques that optimize peripheral line placement are essential. We know of no published prospective randomized controlled trial comparing the success of IV placement with and without transillumination in a pediatric ED.

Our hypothesis was that transillumination would increase IV success rates in pediatric ED patients younger than 3 years and in those aged 3 to 21 years with a history of difficult access. We studied IV placement by 4 pediatric emergency medicine fellows (MDs) and 4 pediatric ED RNs, using the Veinlite (TransLite, Sugar Land, Tex). Our primary outcome was success rate of IV placement in the first attempt and our secondary outcome was success rate of IV placement within 2 attempts. We planned enrollment of 240 patients to detect a difference of 20 percentage points in IV success rates, with 80% power using a 2-sided test.

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## METHODS

Providers included 4 MDs with experience placing IVs in a pediatric residency and pediatric emergency medicine fellowship and 4 RNs with 4 to 12 years experience placing IVs in a pediatric ED setting. Their prestudy success rates during a 4-week period were 56% in the first attempt and 85% within 2 attempts. Their success rate in the first attempt was similar to success rates reported in the literature.<sup>1,2,14</sup>

This study was a prospective, unblinded, randomized, open, therapeutic interventional trial. Parental or guardian written informed consent was obtained and, when appropriate, assent or consent from the participant. All study parameters and forms were approved by the hospital's institutional review board.

Enrollment occurred at a large, freestanding, urban, tertiary-care pediatric teaching hospital ED from September 2002 to May 2004. The hospital has a pediatric emergency medicine fellowship program and an annual ED volume of approximately 50,000 visits.

We enrolled a convenience sample of children younger than 3 years who presented to the ED and required non-emergent IVs. In addition, we recruited patients aged between 3 and 21 years, with a history of chronic illness, who previously required IV insertion and were identified as having difficult access by their caregivers. Patients who required emergent IV placement were excluded.

Participating MD or RN providers approached parents or guardians and patients on whom they were to attempt IV placement if they satisfied eligibility requirements. In addition, the primary investigator enrolled eligible patients. Participants were randomly assigned to the Veinlite group or standard of care nontransillumination group (Fig. 1). Randomization was stratified by provider type, MD or RN. A computerized random number generator was used to prepare sealed opaque randomization envelopes by a researcher in the institution's Clinical Research Program. Consecutive randomization envelopes were opened by the provider or primary investigator only after signed consent was obtained.

TransLite (Sugar Land, Tex) provided Veinlite transilluminators to the study hospital ED but did not participate in the conception, design, or conduct of this study or in the development of the analysis plan or interpretation of the data. The Veinlite consists of a halogen light source with a variable intensity control and a fiber-optic cable that is

attached to either a small or a large C-shaped ring. This transilluminator is a cold light source that uses the transmission transillumination method or a patented side transilluminating method to visualize veins. In the transmission transillumination technique, the Veinlite ring is placed under an extremity, and the light is transmitted through that extremity. In the side transillumination technique, the Veinlite ring is placed on the skin and a ring of bright fiber-optic light is directed at an angle into the skin and focused under the skin. Side transillumination provides uniform illumination within the open area of the C-shaped ring and allows for imaging of veins without shadows (Figs. 2–4).<sup>15</sup>

Providers received standardized directions on the safe and correct use of the Veinlite and demonstrated their proficiency before the initiation of the study. Methods to improve venous cannulation including tourniquet application and swabbing with alcohol were done as per routine. An assistant to help immobilize patients was available as needed. The initial provider was responsible for the first and second IV attempts. A 22- or 24-gauge cannula was used for children younger than 3 years and a 20-, 22-, or 24-gauge cannula in older participants. All supplies necessary to insert and secure the IV were prepared before attempt at access.

The IV placement was considered successful only if 10 mL of isotonic sodium chloride solution could be infused without evidence of local infiltration. After confirmation of placement by infusion, if an IV was "lost" during immobilization, the attempt was considered successful. If the initial 2 attempts failed, a new provider could be asked to obtain venous access. This was considered an unsuccessful intervention. The new clinician did not have to be a study provider. Use of transillumination for subsequent attempts was at the provider's discretion regardless of randomization.

Data were collected on all enrolled patients until final outcome for every placement attempt. Baseline data forms were completed before attempted IV placement. Procedure data forms were completed after attempted IV placement. These data collection forms included information on demographics and possible confounders such as age, race, dehydration, chronic medical condition, provider type (MD or RN), location of attempt, gauge of cannula, and use of a safety catheter. They were completed by the same participating ED provider who was responsible for the initial 2 IV placement attempts. Database input into an SPSS 11.0 for

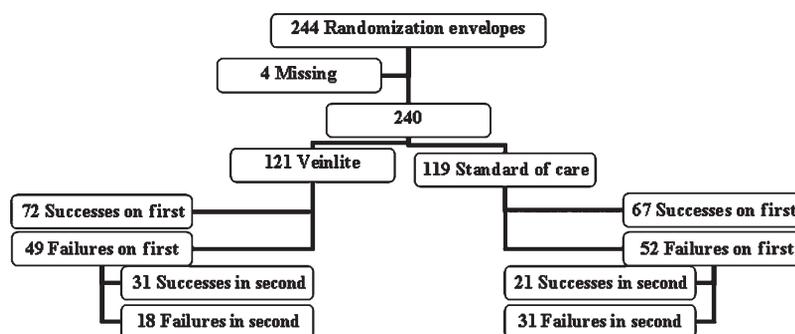


FIGURE 1. Flowchart.

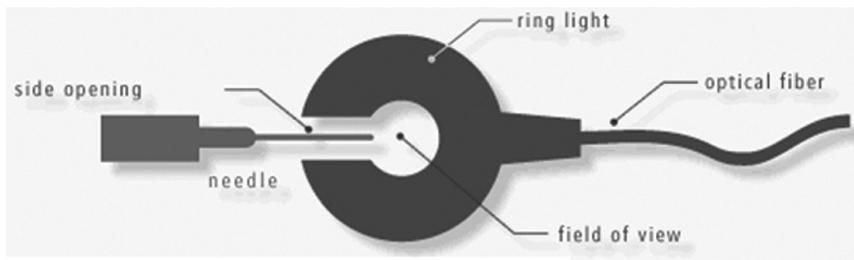


FIGURE 2. Veinlite schematic.

Windows (SPSS Inc, Chicago, Ill) file was completed by the primary investigator.

The primary outcome measure was the success rate of IV placement in the first attempt, and the secondary outcome measure was the success rate within 2 attempts.

The intention to treat principle was applied, and analyses was done assuming adherence to randomized assignment of Veinlite transillumination or standard of care treatment group. Data on 240 observations were used in the mixed-effects logistic regression model.

The primary predictor was Veinlite transillumination or standard of care treatment group; and age, location of attempt, gauge of cannula, use of a safety catheter, and provider type (MD or RN) were investigated as covariates. Race, dehydration, and a chronic medical condition were considered to be confounders. By the nature of the study design, patients were clustered within provider, and this was accounted for using a random effect for provider.

A mixed-effects logistic regression model adjusting for provider effect was developed. Race was recoded to be white or nonwhite. Because of the large number of potential covariates relative to the sample size, data reduction techniques were used. Backward elimination was applied to the full model, and nonsignificant variables were removed one at a time with the least significant being the one removed each time. In addition to the covariates and confounders previously stated, sex, location of attempt, visibility, palpability, and use of an assistant were explored.

For the secondary outcome, covariates were coded according to first attempt data if that attempt was successful; otherwise, they were coded according to second attempt data. A mixed-effects logistic regression model was developed using the same strategy as for the primary outcome.

All data analyses were conducted using SAS software version 9.1 (SAS Institute, Inc, Cary, NC), and conclusions were made at a 0.05 level of significance. Success in the first attempt and success within 2 attempts were binary outcomes and were modeled as generalized linear mixed models using the SAS macro GLIMMIX, version GLMM800, with a logit link function. Within-provider correlations were modeled using a compound symmetry structure.

### RESULTS

There were 244 randomization envelopes used, 122 each for the MD and RN provider types. Randomization envelopes and data collection forms were retrieved on 240 patients. There were 4 randomization envelopes missing, 3 MD envelopes and 1 RN envelope. No corresponding data collection forms were found. There were 121 patients assigned to Veinlite transillumination and 119 patients were assigned to standard of care nontransillumination (Fig. 1).

Patients ranged in age from 5 days to 15 years, with a mean age of 1 year 4 months and a median age of 10 months. Of those enrolled, 228 (95%) were younger than 3 years, and 12 (5%) were 3 years or older. Subject self-report of race was 166 (69.2%) white, 42 (17.5%) black, 10 (4.2%) Asian, and 22 (9.2%) other. There were 133 (55.4%) male patients. Providers reported that 176 (73.3%) of the patients were dehydrated, and 72 (30%) had a chronic medical condition. The 2 randomized groups differed significantly in use of a 24-gauge catheter ( $P = 0.02$ ), use of a safety catheter ( $P = 0.05$ ), visibility ( $P < 0.001$ ), and palpability ( $P < 0.001$ ) (Table 1).



FIGURE 3. Veinlite photograph.



FIGURE 4. Veinlite side transillumination technique.

**TABLE 1.** Characteristics and Comparison of Randomization Groups

Characteristics	Veinlite (n = 121)	Standard (n = 119)	P
Mean (SD)			
Age (yrs)	1.33 (1.89)	1.33 (1.74)	1.00
Weight (kg)	9.9 (7.0)	9.4 (5.1)	0.60
Frequency (%)			
Male sex	68 (56)	65 (54)	0.81
White race	89 (74)	77 (65)	0.14
Hispanic/Latino ethnicity	24 (20)	34 (29)	0.11
Provider MD	58 (48)	61 (51)	0.61
Dehydrated	88 (73)	88 (74)	0.83
Chronic medical condition	35 (29)	37 (31)	0.71
Dorsum of hand, first attempt	102 (84)	89 (75)	0.07
24-Gauge, first attempt	116 (96)	104 (87)	0.02*
Safety catheter, first attempt	102 (84)	110 (92)	0.05
Visible, first attempt	59 (49)	95 (80)	<0.001
Palpable, first attempt	47 (39)	74 (62)	<0.001
Assistant to immobilize patient, first attempt	117 (97)	113 (95)	0.54*

Means were compared using *t* test, and frequencies were compared using  $\chi^2$  test or Fisher exact test (indicated by \*) not controlling for the random effect of provider.

In the first attempt, providers described 154 (64.2%) of the veins at the site as visible and 121 (50.4%) as palpable. The location of the initial attempt was the dorsum of the hand in 191 (79.6%), antecubital fossa in 41 (17.1%), dorsum of the foot in 7 (2.9%), and saphenous in 1 (0.4%). In 220 (91.7%) first attempts, a 24-gauge catheter was used, and a 22-gauge catheter was used in 20 (8.3%). A safety catheter was used in 212 (88.3%) of the initial attempts.

In the first attempt, there was a 3.2% difference in success rates, with Veinlite transillumination 59.5% and standard of care 56.3% (Table 2). In univariate analysis, controlling for the random effect of provider only, Veinlite use did not predict success in the first attempt ( $P = 0.53$ ). Significant covariates included use of a safety catheter ( $P = 0.01$ ), visibility ( $P = 0.01$ ), and palpability ( $P = 0.02$ ).

The first attempt final mixed-effects logistic regression model included randomized group, visibility, palpability, and use of a safety catheter. After adjusting for significant covariates and controlling for provider effect, Veinlite use did predict success in the first attempt ( $P = 0.03$ ). In patients randomized to use of Veinlite, IV placement was 2.1 times more likely to be successful in the first attempt (odds ratio [OR], 2.1; 95% confidence interval [CI], 1.1–3.9). Sig-

nificant covariates included use of a safety catheter ( $P = 0.008$ ), visibility ( $P = 0.01$ ), and palpability ( $P = 0.03$ ). Intraclass correlation for random effect of provider was 10%, which means that 10% of the variation in the model for the first attempt was attributable to the providers.

In the second attempt, providers described 59 (57.8%) of the veins at the site as visible and 44 (43.1%) as palpable. The location of the next attempt was the dorsum of the hand in 59 (57.8%), antecubital fossa in 26 (25.5%), dorsum of the foot in 12 (11.8%), and saphenous in 5 (4.9%). In 95 (93.1%) second attempts, a 24-gauge catheter was used, and a 22-gauge catheter was used in 7 (6.9%). A safety catheter was used in 84 (82.3%) of the second attempts.

Within 2 attempts, there was an 11.1% difference in success rates, with Veinlite transillumination 85.1% and standard of care 74.0% (Table 2). In univariate analysis, controlling for the random effect of provider only, Veinlite use did predict success within 2 attempts ( $P = 0.01$ ). Significant covariates included use of a safety catheter ( $P < 0.0001$ ), location ( $P = 0.0009$ ), sex ( $P = 0.03$ ), and palpability ( $P = 0.02$ ).

The within 2 attempts final mixed-effects logistic regression model included randomized group, palpability, location of attempt, and use of a safety catheter. After adjusting for significant covariates and controlling for provider effect, Veinlite use did predict success within 2 attempts ( $P = 0.01$ ). In patients randomized to use of Veinlite, IV placement was 3.5 times more likely to be successful within 2 attempts (OR, 3.5; 95% CI, 1.4–8.9). Significant covariates included use of a safety catheter ( $P < 0.001$ ), location ( $P = 0.005$ ), and palpability ( $P = 0.05$ ). Intraclass correlation for random effect of provider was 16%, which means 16% of the variation in the model within 2 attempts was attributable to the providers.

No adverse outcomes were reported with the use of the Veinlite transilluminator during the study period.

## DISCUSSION

The use of a randomized controlled study design minimizes bias and confounding while allowing for detection of a small, but clinically significant, treatment effect. Data were collected on multiple variables that we anticipated may affect our outcomes. In this study, we tried to ensure that the IV placement procedure was standardized except for the use of Veinlite transillumination. The details of the procedure were specified, and we attempted to limit provider variability by selecting participants that were experienced in pediatric IV insertion. Eight providers were selected to facilitate patient enrollment and study completion. As a result of this relatively large number of providers, each

**TABLE 2.** Results

Randomization	Success on First Attempt	Success on Second Attempt	Success Within 2 Attempts
Veinlite	72/121 (59.5%)	31/49 (63.3%)	103/121 (85.1%)
Standard of care	67/119 (56.3%)	21/52 (40.4%)	88/119 (74.0%)
Total	139/240 (57.9%)	52/101 (51.5%)	191/240 (79.6%)

individual provider made a limited number of IV attempts, and their data were analyzed in aggregate (Tables 2 and 3).

Our statistical analysis plan was to perform multiple logistic regression analyses to estimate an association between the use of Veinlite transillumination and IV success while adjusting for potential confounding effects of other covariates. As the study was conducted, it became apparent that even among experienced MDs and RNs, there was an observable variability in poise, proficiency, and persistence of providers during IV placement. The difference between providers themselves was not of interest in this study. The analysis plan was modified to include the random effect of provider to capture this variability among providers and to not wrongly attribute it to either the use of the Veinlite or any other patient-level predictors.

Prerandomization limitations that affect the generalizability of this study included the choice of the providers as well as the source population, the eligibility criteria, and the portion of those who accepted recruitment. Participants were enrolled from a hospital that is a level 1 pediatric trauma center and a primary teaching hospital that serves a diverse patient population. Nevertheless, only patients who required nonemergent IV insertion were eligible, 69.2% of enrolled patients were white, and our sample size was insufficient to determine the effects of any specific acute or chronic illness. All patients younger than 3 years or those aged 3 to 21 years with a history of difficult access were eligible for enrollment. However, only 5% of patients enrolled were 3 years or older, and a history of difficult access was subjective and elicited from the patient's caregiver(s). Data on the number of patients who were eligible but not approached during the study period were not collected. The number of patients who refused enrollment was also not tracked.

This was an unblinded open trial with the potential for selection bias because most enrollment was done by the same providers responsible for IV placement. However, randomization was maintained by allocation concealment, and both providers and the primary investigator were unaware of treatment assignment until after signed consent was obtained. There were 4 randomization envelopes missing in our study. We could not determine if they were misplaced prerandomization or postrandomization with all of the corresponding data collection forms.

Postrandomization limitations included observational bias, recall bias, and performance bias. No measure of interobserver reliability in the identification of veins was used. Data collection was done by self-report, and participating providers were asked to complete baseline data forms before attempted IV placement and procedure data forms after each attempt. Nonetheless, in a busy ED setting, it is likely that these instructions were not always adhered to and that forms were completed at the providers' earliest convenience. Providers were also asked to prepare all supplies before IV insertion and use uniform methods in their IV insertions; but systematic differences in the care provided to the participants other than transillumination was possible. In addition, a safety catheter was introduced after initiation of this study and may have affected study results. Two MD providers had previous experience with the safety catheter. The RN providers received an in-service in the use of the new catheter before its introduction. The original catheter type was sometimes still available and may have been used preferentially for patients perceived to be more difficult. All providers expressed a subjective proficiency in the use of both catheter types.

There were 3 identified cases of compliance failure in which providers or parents of participants either withdrew from the study after treatment assignment or did not follow assignment. In the first, the Veinlite was used in 2 unsuccessful attempts on a patient randomized to standard of care. In the second, the transilluminator was not used on a successful second attempt on a patient randomized to use of Veinlite. In the third, after an unsuccessful first attempt, a patient randomized to use of Veinlite refused transillumination on a second attempt that was successful. Nevertheless, all analyses was done assuming adherence to randomization according to the intention-to-treat principle.

Prior studies have shown that when previous attempts at IV placement without transillumination were unsuccessful, the subsequent use of a transilluminator was helpful.<sup>14,16</sup> Interestingly, in our study, there was a 22.9% difference in success rates in IV placement in the second attempt alone, with Veinlite transillumination 63.3% and standard of care 40.4%. (Table 2). There were only 101 second attempts (Fig. 1; Table 2). Analyses of the second attempt data, excluding those that succeeded in the first attempt and adjusting only for the random effect of provider, indicated that IV placement was 2.9 times more likely to be successful (OR, 2.9; 95% CI, 1.24–6.77) in patients randomized to use of Veinlite transillumination. No covariates were significant in this model, nor did adding covariates improve the significance of the randomized group in the model. It is possible that "easy" initial sites with visible and palpable veins were used for the first attempt resulting in a more difficult second attempt. However, the intracluster correlation for random effect of provider was 48%, which indicates that almost half of the variation in the model for second attempts was attributable to the providers. This indicates that provider skill was a very important factor in determining successful cannulation.

As with all new modalities, there is a comfort level and learning curve associated with transillumination devices.<sup>3</sup>

**TABLE 3.** Subjects Treated by Provider

Provider	No. Subjects Treated	%
MD 1	40	16.7
MD 2	39	16.3
MD 3	21	8.8
MD 4	19	7.9
RN 1	40	16.7
RN 2	40	16.7
RN 3	24	10
RN 4	17	7.1

An increased familiarity and dexterity with the Veinlite may have resulted in a larger benefit. The IV placement in a more difficult subset of patients, such as those with dark skin tone, high body mass index, or severe dehydration, may also have resulted in a larger relative benefit. In our study, data on skin tone and level of dehydration were not collected. Weight but not height data were collected, and the effect of body mass index could not be evaluated.

There are previous reports of modified fiber-optic light sources being used to facilitate arterial and venous cannulation, but uniform acceptance or availability of such devices does not exist.<sup>3,6,14,16–18</sup> Our intent was to show that transillumination increased success rates in routine IV placement and should not only be used as an adjunct after previous attempts have failed. An increased success rate should decrease the anxiety, pain, time, and cost associated with IV insertion. Preventing more invasive attempts at access or less optimal therapeutic interventions would also facilitate medical care.

Our results only indicated a benefit in the use of Veinlite transillumination for peripheral IV insertion in first attempt and within 2 attempts after adjusting for multiple significant covariates and controlling for provider effect. Although our study has many limitations, this technique seemed to facilitate nonemergent IV placement in pediatric patients who were cared for in a children's hospital ED. An increased success rate would support increasing the availability and use of this and similar devices that facilitate IV cannulation.

A repeat study with both a larger sample size and a larger number of providers may better illustrate the efficacy and use of Veinlite transillumination, especially given the differences in vein visibility and palpability in our 2 randomized groups and the amount of variation attributable to the providers. Further study of transillumination and other noninvasive modalities, such as ultrasound, to facilitate IV insertion should be encouraged.

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