

The VeinViewer Vascular Imaging System Worsens First-Attempt Cannulation Rate for Experienced Nurses in Infants and Children with Anticipated Difficult Intravenous Access

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BACKGROUND: The VeinViewer (Luminetx, Memphis, TN) helps identify veins by projecting an image of subcutaneous vasculature on the skin surface. We tested the primary hypothesis that VeinViewer use improves cannulation success by skilled nurses in pediatric patients with anticipated difficult IV access. A secondary goal was to evaluate the relationship between obesity and cannulation success.

METHODS: Patients aged 0 to 18 years were included. Anticipated cannulation difficulty was evaluated with the difficult IV access score. All cannulations were performed by members of the Intravenous Access Team. Patients were randomized to: (1) routine IV catheter insertion; or (2) insertion facilitated by the VeinViewer. The primary outcome was first-attempt insertion success. The proportion of successful insertions was evaluated using Cochran-Mantel-Haenszel χ^2 analysis to adjust for any imbalanced baseline variables. The effect of obesity on cannulation success was evaluated with multivariable logistic regression.

RESULTS: Two hundred ninety-nine patients (49%) were randomly assigned to VeinViewer and 301 (51%) to routine cannulation. First-attempt cannulation success was 47% in patients assigned to VeinViewer vs 62% in patients assigned to routine cannulation, with an adjusted relative "risk" (95% confidence interval), of 0.76 (0.63–0.91). The Z-statistic of -3.6 crossed the "harm" boundary ($Z < -2.41$), with corresponding P value of 0.0003. The trial was stopped on statistical grounds since the harm boundary for the primary outcome was crossed. There was no association between first-attempt success and the 4-level categorization of obesity after adjusted for baseline variables ($P = 0.94$).

CONCLUSIONS: The VeinViewer worsened first-attempt IV insertion success by skilled nurses. Surprisingly, first-attempt success for IV cannulation was not worsened by obesity. (Anesth Analg 2013;116:1087–92)

Establishing IV access is a common procedure, but can be among the most frustrating tasks encountered by medical professionals.^{1,2} Moreover, the veins of pediatric patients are frequently small, embedded in subcutaneous fat tissue, or simply exhausted from previous venipuncture attempts. Multiple attempts are thus often required in children before successful vein cannulation which increases the pain and anxiety they experience and reduces parental satisfaction. For example, first-attempt failures range from 56% for pediatric nurses to 20% for IV access specialists.³ Others report a failure rate of 24%⁴ and 25%.⁵

Methods that improve the success rate of IV placement would provide obvious clinical benefits.⁶ The VeinViewer (Luminetx, Memphis, TN) uses near-infrared light to project an image of subcutaneous vasculature on the skin surface. The VeinViewer consists of: (1) a 760-nm near-infrared light source; (2) a digital video camera that captures the near-infrared light reflected back from the patient; (3) an image processing unit; and (4) a digital image projector that displays real-time images of subcutaneous vasculature onto the surface of the skin in a 7.0 × 5.5 cm rectangle. The illumination is green, with veins appearing darker than surrounding tissue (Fig. 1). Although attractive on theoretical grounds, the extent to which the VeinViewer might improve cannulation success remains to be adequately evaluated.

The overall prevalence of obesity among US children and adolescents in 2010 was 16.9%.⁷ Nafiu et al.⁸ assessed the relationship between body mass index (BMI) and ease of venous access in 103 children aged 2 to 18 years. They found that obese children were more likely to have failed first-attempt cannulations than lean controls, and that obese patients were more likely to require ≥ 2 attempts at cannulation. However, the extent to which pediatric obesity worsens cannulation success by skilled nurses remains unclear.

The primary goal of our study was to measure cannulation success by skilled nurses in pediatric patients with

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Figure 1. Image of veins captured and projected on the skin by VeinViewer.

anticipated difficult IV access. The secondary goal was to determine the relationship between obesity and first-attempt cannulation success.

METHODS

This study was conducted at Children's Medical Center, Dallas, TX with approval of the IRB of University of Texas Southwestern, Dallas, TX. The IRB waived written informed consent, but we obtained verbal informed consent from parents and assent from patients aged ≥ 10 years.

We considered patients aged 0 to 18 years who required nonemergent peripheral IV access. The patients were either hospitalized or having procedures (hemodialysis, hematologic and/or oncologic therapy, imaging procedures, etc.) on an outpatient basis. Our goal was to test the device in pediatric patients with presumed difficult access.

The potential for cannulation difficulty was evaluated with the difficult IV access (DIVA) score which is well validated (Table 1).⁵ First-attempt success in pediatric patients with a DIVA score ≥ 4 is reduced by approximately a factor of 2.⁵ Because the VeinViewer is expected to be especially helpful in patients without visible veins, we excluded all patients in whom veins were visible under bright ambient light (< 4 points).

All cannulations were performed by members of the Intravenous Access Team, a group of 7 nurses specialized in cannulation who together insert about 1000 peripheral IV cannulae per month. The patients included in the study were referred to the Intravenous Access Team either after

unsuccessful attempts by primary care medical personnel (physicians, nurses, phlebotomists) or when a history of difficult IV access was present or at the request of the parents.

No general anesthesia or additional sedative medication was given before IV cannulation. According to the manufacturer, "the VeinViewer is easy to use and does not require any special training or skills." Nonetheless, participating nurses each used the VeinViewer at least 20 times before starting the study to familiarize themselves with the system. An independent investigator who was not part of the insertion team assessed inclusion and exclusion criteria and recorded study data.

The potential study patients were examined by members of the Access Team and if no veins were visible on any of the upper and lower extremities in ambient light, they were included in the study. Patients with need for scalp cannulation were excluded. Only the upper extremities were used for cannulation in the outpatient population. Additional potential difficulty factors (including hematoma or evidence of previous attempts at the site) that are not part of the DIVA score were recorded. At the nurse's discretion, analgesia at the planned puncture site was performed with lidocaine 1% (0.25 mL) delivered with a needle-free injector (J-Tip, NMP Inc., Irvine, CA).

Eligible patients were randomized to 1 of 2 cannulation approaches: (1) routine procedure under bright ambient light or (2) insertion facilitated by the VeinViewer system. Allocations were based on computer-generated codes that were maintained in sequentially numbered opaque envelopes. The envelopes were opened after the Access Team nurse has selected the access site, assessed status of the vein, and positioned a venous tourniquet. None of the insertions was facilitated by ultrasound imaging.

In patients assigned to VeinViewer assistance, the system was calibrated and positioned over the planned insertion site at a 90° angle. The resulting image was then used for real-time cannulation. In case no vein would have been identified with the help of the VeinViewer, the plan was to abandon the study in that specific patient. In the routine group, vein cannulation was performed using palpation and anatomical landmarks.

Successful cannulation was defined as IV cannula insertion followed by flushing saline through the cannula without signs of infiltration. The study concluded after the initial cannulation attempt. Subsequent attempt(s) were managed at the discretion of the Access Team nurse.

Data Analysis

The VeinViewer and routine cannulation randomized groups were descriptively compared for balance on all baseline variables. Variables for which the absolute value of the standardized difference (difference in means or proportions divided by the standard deviation) was larger than ± 0.16 were considered imbalanced and were adjusted for in the primary analysis, $1.96 \times \text{sqrt}(2/n) = 0.16$ as in Austin (2009).⁹ All analyses were intent-to-treat, and all tests were 2-sided.

Primary Outcome

We assessed the effect of cannulation assisted by VeinViewer versus routine cannulation on the proportion with success on the first attempt using Cochran-Mantel-Haenszel

Table 1. Difficult IV Access (DIVA) Score

Factors	DIVA score points
Prematurity	3
Age: younger than 1 year/1-2 years	3/1
Vein not palpable	2
Vein not visible	2 ^a
Maximum of 10 points	

Subjects with a DIVA score ≥ 4 are about 50% more likely to have failed IV placement on first attempt.⁵ We thus considered subjects with a DIVA score ≥ 4 to be potentially difficult and excluded those with < 4 points.

^aOnly patients with vein not visible were admitted to the study.

χ^2 analysis to adjust for any imbalanced baseline variables DIVA score, age, and nurse; the treatment effect was summarized as relative risk and 95% confidence interval (CI).¹⁰

Secondary Outcomes

We assessed the a priori hypothesis that obesity is associated (presumably, inversely) with success on the first attempt using a multivariable logistic regression model adjusting for all baseline variables in Table 2, including treatment assignment. Children aged ≥ 2 years were classified as underweight (BMI < 5th percentile), normal (5th \leq BMI < 85th percentile), overweight (85th \leq BMI < 95th percentile), and obese (BMI \geq 95th percentile) using BMI-for-age growth charts for girls and boys from the National Center for Health Statistics/Centers for Disease Control and Prevention. Instead of BMI, children aged <2 years were classified into the same percentile categories as above

Table 2. Baseline Characteristics

Factor	VeinViewer (N = 299)	Routine (N = 301)	Standardized difference ^a
Age (d) median (Q1, Q3)	394 (138, 1323)	323 (96, 897)	0.18 ^a
Male (%)	60	57	0.042
Race (%)			0.14
Caucasian	24	25	
African American	25	26	
Hispanic	50	45	
Other	2	4	
Inpatient (%)	86	90	-0.11
Body mass index group (%)			0.056
Underweight	12	12	
Normal	52	50	
Overweight	10	11	
Obesity	26	28	
Previous IV count >1 (%)	25	27	-0.042
Hematoma count >1 (%)	79	78	0.024
Analgesia J-tip (%)	59	56	0.055
Sedation status (%)			0.16
Sedated	8	10	
Calm	27	21	
Agitated	51	52	
Uncontrolled	14	16	
DIVA score, mean \pm SD (%)	6.5 \pm 1.9	6.9 \pm 1.9	-0.19 ^a
4	23	17	
5	15	13	
6	1	1	
7	37	40	
8	10	11	
9	1	0	
10	13	18	
Nurse (%)			0.22 ^a
a	13	16	
b	18	14	
c	17	15	
d	16	11	
e	14	17	
f	11	12	
g	10	14	

^a Standardized difference (STD) = difference in means or proportions divided by pooled standard deviation; imbalance (age, difficult IV access [DIVA] score, nurse) defined as absolute value of STD > 0.16, i.e., $1.96 \sqrt{2/n}$. Imbalanced variables were adjusted for in all analyses.

but using weight-for-height percentiles from charts on the Center for Disease Control website.^a

Interim analysis to assess efficacy and futility on the primary outcome was conducted at each 25% of the planned enrollment. We used the α (type 1 error) and β (type 2 error) spending approach of Hwang et al.¹¹ with parameters $\gamma = -4$ for efficacy and -2 for futility, thus spending β somewhat faster than α . Interim results were evaluated by an Executive Committee (DIS, EJM) not involved in the performance of the study; the committee did not include the principal investigator or anyone else from the Children's Medical Center.

Sample size was based on being able to detect a relative improvement of $\geq 15\%$ in the primary outcome of initial success. Based on Access Team logs, we expected about 70% initial success for the standard group. We thus planned to enroll a maximum of 790 patients to have 90% power at the 0.05 significance level to detect a relative increase of $\geq 15\%$ in the proportion with initial success using cannulation assisted by VeinViewer versus routine cannulation. This included provisions for interim analyses after each 25% of the maximum sample size for both efficacy and futility.

Assuming that the alternative hypothesis was true (15% higher initial success), there was an 8%, 29%, and 38% chance of crossing either an efficacy or futility boundary at the first, second, and third interim analyses, respectively. There was thus a cumulative 75% chance of crossing a boundary through the third interim analysis. For the secondary analysis assessing the relationship between BMI and success at first attempt, we had $>90\%$ power to detect an odds ratio of ≥ 1.3 for an increase in 1 BMI group (underweight, normal, overweight, obese).

To limit bias, investigators were not informed of the results and were only instructed by the Executive Committee to continue or stop at each predefined interim analysis point.

RESULTS

Six hundred patients were enrolled from January 2009 to July 2010. Among these, 299 (49%) were randomly assigned to VeinViewer and 301 (51%) to routine cannulation. The randomized groups were generally well balanced on baseline variables; however, patients assigned to VeinViewer were slightly older, had somewhat lower DIVA scores, and were slightly imbalanced on assigned nurse (absolute standardized differences >0.16), Table 2. For the primary analysis below we therefore adjusted for these variables.

In all VeinViewer patients, veins were visualized with the help of the device. First-attempt cannulation success proportions were estimated at 0.47 in patients assigned to VeinViewer and 0.62 in those assigned to routine cannulation, with an adjusted relative "risk" (95% CI), of 0.76 (0.63–0.91), Table 3. For comparison, the unadjusted or "crude" relative risk was very similar to the adjusted, estimated as relative risk (95% CI) of 0.75 (0.62–0.90). The observed effect was in the unexpected direction, and the Z-statistic of -3.6 crossed the "harm" boundary ($Z < -2.41$, Fig. 2), with a corresponding *P* value of 0.0003. The trial was stopped on statistical grounds since the harm boundary for the primary

^a Centers for Disease Control and Prevention. Growth charts. Available at: http://www.cdc.gov/growthcharts/percentile_data_files.htm. Accessed June 15, 2009.

Table 3. Primary Outcome Results—Success on First Attempt

Method	Total	Success (N)	Success Proportion (95% CI)	Adjusted ^a relative risk (95% CI)	Z-statistic	P value ^a
VeinViewer	299	140	0.47 (0.41–0.53)	0.76 (0.63–0.91) _a	–3.58 ^b	0.0003 ^b
Standard	301	187	0.62 (0.56–0.68)			

^a From log-link binomial regression model adjusting for age, difficult IV access (DIVA) score, and nurse; confidence interval (CI) also adjusted for interim monitoring using Z-statistic of 2.40.

^b Crossed “harm” boundary (success proportion higher in Standard group). With the first 600 patients (75% of planned enrollment), the prespecified P value boundaries for efficacy/harm (futility) were $P \leq 0.016$ ($P > 0.22$).

outcome was crossed. The needle-free injector was used for analgesia in 29% of VeinViewer patients and in 32% of standard group patients.

Thirty-six and thirty-nine percent of patients were either overweight or obese in the VeinViewer and routine groups, respectively. Patients aged ≥ 2 years had an estimated incidence of overweight or obesity of 46% compared with 32% for those < 2 years. Among the 510 patients (85%) in whom BMI measurements were available, there was no association between first-attempt success and the 4-level categorization of obesity after adjusting for baseline variables ($P = 0.94$), Table 4. In the same multivariable model, higher raw DIVA score was independently associated with outcome (odds ratio [95% CI] = 0.84 [0.75–0.94], $P = 0.0031$); a 1-point increase in DIVA score was associated with an estimated 16% lower odds of success on first attempt.

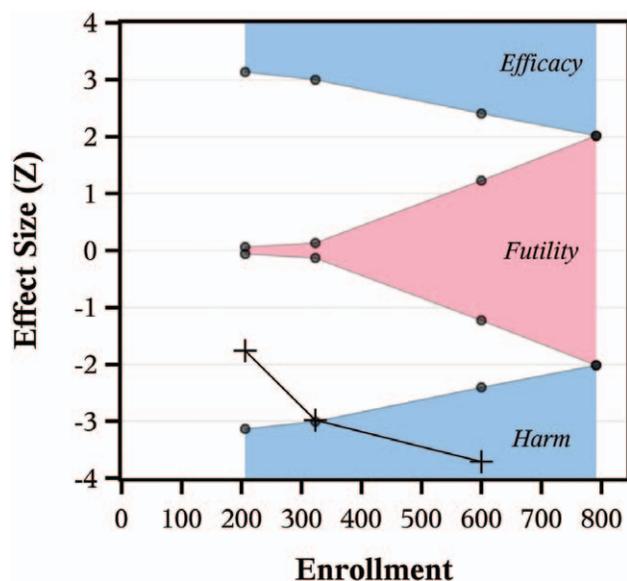


Figure 2. Group sequential monitoring for efficacy and futility: stopping boundaries and interim analyses results (boundary crossed favoring standard care). Monitoring of our group sequential design with the predetermined boundaries for efficacy, harm, and futility. The vertical axis is the standardized effect size Z (i.e., difference in proportions divided by the standard error of difference); Z of 0 means no effect, $Z > 0$ indicates that VeinViewer has higher success on first attempt than routine insertion, $Z < 0$ means that the VeinViewer has lower success. The horizontal axis is the cumulative number of planned ($N = 790$) and observed ($N = 600$) patients. Our 3 interim analyses are shown by the solid line (+), with Z-statistics of -1.78 , -2.92 , and -3.58 . The third analysis crossed into the “harm” region and led to a recommendation to stop the study on statistical grounds. By nature of the group sequential design, the maximum allowable type 1 and type 2 errors were 0.05 and 0.10 across the interim analyses.

DISCUSSION

Health care professionals rely heavily on the senses of sight and touch to locate veins. Nonetheless, veins are often invisible in pediatric patients, especially those who have received considerable previous medical care because the most obvious veins have already been used. We restricted our population to pediatric patients without visible veins, all of whom had high DIVA scores. Our patients were thus those most likely to benefit from the assistance of infrared-based visualization assistance.

VeinViewer visualization nonetheless failed to improve first-attempt cannulation success, and in fact significantly worsened success from 62% to 47%, a reduction of $>20\%$. These percentages easily crossed the harm boundary for the primary outcome; the Executive Committee thus stopped the study on statistical grounds at the third preplanned interim analysis point.

There is limited information on efficacy of the VeinViewer for IV cannulation in pediatric patients. For example, in 50 patients aged ≤ 16 years, Strehle¹² reported that 1.7 puncture attempts per child were necessary for successful venipuncture or cannulation and that visibility of peripheral veins was improved in 76% of children. Hess¹³ evaluated first-attempt cannulation success and the number of attempts per patient in 91 patients aged from 3 days to 17 years. The first-attempt success rate was 80%, and an average of 1.3 attempts was required per patient.¹³ However, the results of these studies are essentially uninterrupted without randomized control groups.

In a randomized trial, Phipps et al.¹⁴ compared VeinViewer visualization to routine practice in 120 neonates for peripheral insertion of central catheters. Success was greater with visualization assistance (86% vs 75%) but the difference was not statistically significant in this underpowered trial.¹⁴ Perry et al.¹⁵ similarly randomized 123 patients aged ≤ 20 years to have either routine IV cannulation or cannulation assisted by the VeinViewer. They were unable to find a significant difference in first-attempt success rate between the standard (79% [95% CI, 67%–88%]) and the VeinViewer (72% [59%–83%]) groups. Ninety percent of the participating nurses reported that the device facilitated otherwise difficult cannulations.¹⁵ A more recent randomized trial found no differences in time to IV catheter placement, number of attempts, or pain scores in patients randomized to have their peripheral IV catheter placed with standard technique or with the aid of VeinViewer.¹⁶

Our randomized trial differs from previous reports in being adequately powered and including only patients with anticipated difficult access based on an objective scoring system.⁵ Furthermore, the nurses who participated in our study were highly experienced with IV catheter insertion in pediatric patients, often in patients with anticipated

Table 4. Multivariable Association Between Body Mass Index (BMI) and Success of IV Cannulation Placement on First Attempt

Factor	Success (N = 272)	Failure (N = 234)	Odds ratio (95% CI) ^a	P value ^a
BMI groups (4 levels) ^b (%)				
Obese	26	28	0.94 (0.60–1.46)	0.94 ^c
Overweight	12	9	1.14 (0.62–2.12)	0.77 ^d
Normal	50	52	1.0 (reference)	0.67 ^d
Underweight	12	11	1.06 (0.58–1.92)	0.86 ^d

N = 506 patients had complete data for BMI and all logistic regression model covariables (N = 90 of 600 had unavailable BMI).

^a Children were classified as underweight (BMI < 5th percentile), normal (BMI < 85th percentile), overweight (BMI < 95th percentile), and obesity (BMI ≥ 95th percentile) using BMI-for-age growth charts for girls and boys from the National Center for Health Statistics/Centers for Disease Control and Prevention.

^b From logistic regression adjusting for race, gender, age, difficult IV access (DIVA) score, Analgesia, Sedation Status, previous IV, hematoma, and treatment assignment (VeinViewer or standard).

^c Overall association.

^d Compared with normal weight.

difficult access or in whom cannulation by floor nurses failed previously.

Our patients had a much higher incidence of age-adjusted obesity than the general population, possibly because obesity-related comorbidities increase the need for hospitalization. We thus included a wide range of patients ranging from lean to morbidly obese. Interestingly, there was no association between degree of obesity and cannulation success. This result differs from that reported by Nafiu et al.,⁸ possibly because of the skill level of our nurses. We note that our sample size was nearly 6 times that of Nafiu et al.⁸ and that we thus had considerable power to identify obesity-related cannulation difficulty had it existed.

One limitation to our study is the lack of blinding, which was not possible in this study. Thus bias against the VeinViewer on the part of the study team could have contributed to our conclusion that the system worsens first-attempt insertion. However, everyone's belief going into the study was that the VeinViewer would improve the first-attempt cannulation rate. Furthermore, interim results were not shared with members of the Access Team to limit bias.

At the time we started the study, the system we chose was the only available infrared vein visualization enhancement system. There is now at least one other system available. Furthermore, after data acquisition for our study was complete, Perry et al.¹⁵ reported that the VeinViewer magnifies the projected vein image, making veins appear 50% to 100% larger than actual size. It is possible that vein magnification could have worsened cannulation success rate by encouraging inaccurate needles positioning. The magnification effect was reportedly corrected in a newer version of the VeinViewer system (Christie Medical Holdings, Inc. Memphis, TN). It is thus possible that results would be better with the newer VeinViewer system or systems other than the one we tested. And finally, the Access Team nurses who participated in this study were extremely skilled; it remains possible that others with less experience might benefit more from visual assistance.

We compared VeinViewer visual assistance with routine cannulation technique. However, other systems have been developed to facilitate insertion of IV cannulae. Transillumination, which shows the veins as dark superficial linear shadows, has been successfully used by some for IV access. For example, Atalay et al.¹⁷ found that transillumination improved the total success rate of venous cannulation from 70% to 94% in children with anticipated

difficult access. However, the technique has not become popular in anesthesiology practice.¹⁸ Ultrasound,¹⁹ smart catheters that contain a Doppler probe, and Vein Entry Indicator Devices²⁰ have also been used to improve the success rate of venous access but are not readily available.

In conclusion, the VeinViewer worsened first-attempt IV insertion success by skilled nurses. It remains possible that the VeinViewer will facilitate access by less skilled clinicians, or that newer versions are more helpful. Surprisingly, first-attempt success for IV cannulation was not worsened by obesity. ■■

DISCLOSURES

Name: Peter Szmuk, MD.

Contribution: This author helped design and conduct the study, analyze the data, and write the manuscript.

Attestation: Peter Szmuk has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

Name: Jeffrey Steiner, DO.

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