RANDOMIZED CROSS OVER STUDY COMPARING THE FIRST ATTEMPT SUCCESS RATE OF INTRAVENOUS CANNULATION IN CHILDREN USING THE ACCUVEIN AV 300 APPARATUS VERSUS THE STANDARD TECHNIQUE

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Background: The AccuVein AV300 device helps in venipuncture and intravenous (IV) cannulation. It uses infrared light that can be absorbed by the blood hemoglobin so that veins location is clearly viewed on the skin's surface.

Objectives: To assess the effectiveness of the AV300 device over the standard technique in increasing the first-time success rate (SR) for pediatric patients who needed IV cannulation.

Methods: This was a prospective crossover study of patients aged 0-18 years scheduled for surgery or examination under anesthesia but without having an existing IV access and after providing consent form. Patients were randomized into two groups; cannulation with AV300 or standard insertion performed by experienced pediatric anesthesiologists and residents under training.

Results: A total of 184 pediatric patients were included in this study. The difficult veins children were younger than those with easy veins (5.4±3.2 vs 4.3±3.7 P = 0.04). The first-attempt SR was similar for all participants, 67% (95% CI, 57-77%) when using AV300 and 70% (95% CI, 61-79%) when using the standard method (P = 0.9). The same applies when comparing the first-attempt SR between easy and difficult veins groups. The successful cannulation time of difficult veins by residents was longer in the standard vs. AccuVein group respectively 65s (27-168) vs 50s (15-222).

Conclusion: Intravenous cannulation using AcccuVein 300 Was not superior to the standard method in children except for a shorter time to cannulation in patients with difficult veins.

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Introduction

Intravenous cannulation is usually performed by inserting an intravenous catheter blindly through the skin, into the lumen of a peripheral vein. Finding a suitable vein for intravenous cannulation may pose a challenge, especially in young children, in children with a history of prematurity or dark skin[1], in obese patients[2], and in patients with a history of repeated diagnostic or therapeutic procedures requiring multiple venous cannulations. Difficult cannulation with multiple attempts is a frequent problem, and various techniques have been tried to improve the chance of successful first time cannulation. The use of several light emitting techniques has been reported, and their limitations have been noted. Existing machines can be large and difficult to transport, requiring a power cord to function[3]. Some must touch the patient's skin, which is associated with a risk of burns. The AccuVein AV300 (AccuVein LLC, Cold Spring Harbor, NY, USA) uses infrared reflection and does not touch the patient's skin and therefore avoids the risk of infection at the IV insertion site and the risk of patient burn and was used for IV insertion[3-7]. In a previous study, the use of AV300 was not found superior to the standard technique of inserting an intravenous cannula in unselected pediatric patients[7]. Many variables may affect the success rate of intravenous cannula insertion in pediatric patients including prematurity, younger age, and dark skin. Yen et al. found an overall first attempt success rate of 75% in 615 pediatric patients, while patients with difficult intravenous access (DIVA) score of 4 or more had less than 50% first attempt success rate of intravenous insertion[1]. The aim of our randomized crossover study is to evaluate the cannulation success rate using the AV300 either as the first attempt, or as a second attempt if the standard technique has failed, having each patient as his own control and therefore minimizing the many variables that might affect the success rate.

Methods

After approval of this study by our Institutional Review Board, written informed consent was obtained from the parent or guardian of each participant. The child's assent was obtained for children older than 7 years of age. Research candidates were recruited by screening the patients scheduled for surgery on the day prior to surgery, based upon the inclusion/exclusion criteria. Inclusion criteria included patients younger than 18 years of age, American Society of Anesthesiologist Physical Status (ASA) status I, II or III, undergoing elective surgery or examination under anesthesia, which did not have existing intravenous access. Exclusion Criteria included existing intravenous access, malformations or infections at the potential site of insertion, need for emergency surgery, and inability or unwillingness of parent or legal guardian to give written informed consent.

Patients who fulfilled the inclusion criteria and provided informed consent were assigned to one of two groups using a randomization program that assigned research participants into group A (AccuVein AV300 assisted intravenous catheter insertion) or group B (standard technique of insertion of the intravenous cannula). After pre-anesthetic evaluation, the research participant was brought to the operating room and standard monitors were applied (EKG, SpO_2, Blood Pressure (BP)) if tolerated. Anesthesia was induced via face mask with sevoflurane in 100% O_2. The anesthesiologist and resident decided on a site believed to be the best for cannulation and on the size of the venous cannula as 22 gauge or 24 gauge. When the supervising anesthesiologist deemed it appropriate, the venous cannulation was attempted by the resdient, according to the randomization groups, either with the AccuVein device (group A) or blindly (group B). A rating of the vein attempted as either difficult or easy to cannulate was established by the attending anesthesiologist before randomization.

An observer member of the research team recorded the time between the placement of the tourniquet and the successful cannulation. If the first cannulation attempt was not successful with the assigned technique, the second attempt was made using the alternative technique. Patients who were randomized to the standard group (group B) and had an unsuccessful first attempt underwent the second attempt using the AV300. Patients who were randomized to AV300 (group A) and had an unsuccessful first attempt by the resident underwent

the second attempt using the standard technique. After the first two attempts, the supervising anesthesiologist took over for two additional attempts using the same sequence as the resident. A maximum of 4 attempts for each patient were allowed and the number of attempts were recorded by the observer. After 4 attempts, the patient was dropped from the study and further attempts at cannulation used the standard technique. A successful first attempt success was defined as successful cannulation on the first attempt and a failed first attempt was defined as more than 1 attempt to attain cannulation.

Statistical Analysis

A block-randomization using stratification as per vein assessment (easy vs difficult veins) was implemented to assign patients to the AccuVein 300 (group A) and standard method (group B) groups. Based on the literature, an increase of 28% in the first attempt success rate of cannulation for patients with easy veins (from 70% to 90%) was considered clinically significant[7]. With $\alpha = 0.05$ and $\beta = 0.2$, 62 patients were recruited for each group. As for patients with difficult veins, an increase of 87% in the first attempt success rate of cannulation (from 40% to 75%) was considered clinically significant; therefore 30 patients were recruited in each group. Thus, the total number was 184; 92 patients randomized to Group A (AV300 assisted cannulation) and 92 patients randomized to Group B (standard cannulation technique). These 92 patients in each group are divided into two subgroups: 62 patients with easy veins and 30 patients with difficult veins. The first attempt success rate was estimated with a 95% confidence interval (CI). Normally distributed continuous data were reported as mean±SD and analyzed using Student *t* test with equal variances. Categorical data were reported as numbers and percentages and were analyzed using Fisher exact test. Medians and ranges were analyzed using Mann-Whitney *U* test. A *P* value <0.05 was considered significant.

Results

Between February 2013 and February 2014, 184 patients were enrolled and randomly assigned to the AccuVein 300 vs the standard method groups. Each group included 62 patients with easy veins and 30 patients with difficult veins whereby none of the

Table 1
Demographic Characteristics of Patients with Easy Veins versus Difficult Veins

	Easy veins N = 124	**Difficult veins N = 60**	***P***
Age (years)	5.4±3.2	4.3±3.7	0.04
Weight (kg)	21.3±11.6	19.6±12.5	0.4
Height (cm)	110.9±21.5	104.8±25.9	0.1
Gender (M/F)	77/47	38/22	0.9
Level of resident			0.8
PGY1	4	3	
PGY2	34	15	
PGY3	37	21	
PGY4	49	21	
ASA class			0.5
ASA 1	91	39	
ASA 2	30	19	
ASA 3	3	2	
Gauge of IV cannula			0.001
22G	79	23	
24G	45	37	

Values are means±SD and numbers

Table 2
Cannulation Characteristics of Patients with Easy Veins versus Difficult Veins

	Easy veins N = 124	**Difficult veins N = 60**	***P***
Success rate at first attempt	90 (73)	36 (60)	0.09
Success rate distribution Resident success at first attempt Resident success after switching to the other technique Attending success at first attempt* Attending success after switching to other technique*	 90 (73) 24 (19) 8 (80) 2 (20)	 36 (60) 10 (17) 10 (71) 4 (29)	 0.09 0.8 1 1
Resident performed successful cannulation	114 (92)	46 (77)	0.004
Resident cannulation time (sec)**	44 (6-350)	60 (15-222)	0.03
Attending cannulation time (sec)*	47 (15-90)	55 (15-106)	0.7
Number of pricks to successful cannulation	1 (1-4)	1 (1-4)	0.03

Values are numbers (%) and medians (range)
*n = 10 in easy veins group and n = 14 in difficult veins group
**n = 114 in easy veins group and n = 46 in difficult veins group

Table 3
Comparison of First Attempt Success Rates with the AccuVein 300 Device versus Standard Method

Group	**First attempt success rate**	**First attempt failure rate**	**95% CI of first attempt success rate (%)**	***P***
Overall AccuVein 300 Standard method	 64 (70) 62 (67)	 28 (30) 30 (33)	 61-79 57-77	 0.9
Easy veins AccuVein 300 Standard method	 46 (74) 44 (71)	 16 (26) 18 (29)	 63-85 60-82	 0.8
Difficult veins AccuVein 300 Standard method	 18 (60) 18 (60)	 12 (40) 12 (40)	 42-78 42-78	 1

Values are numbers (%) and medians (range)

Table 4
Demographic Characteristics of Patients with Easy Veins in the Standard Technique versus AccuVein 300

	Standard technique N = 62	**AccuVein N = 62**	***P***
Age (years)	5.3±3.6	5.5±2.9	0.8
Weight (kg)	21.8±13.7	20.8±8	0.6
Height (cm)	110.7±24.8	111.1±18.4	0.9
Gender (M/F)	38/24	39/23	0.9
Level of resident PGY1 PGY2 PGY3 PGY4	 3 17 21 21	 1 17 16 28	0.4
ASA class ASA 1 ASA 2 ASA 3	 45 15 2	 46 15 1	0.8
Gauge of IV cannula 22G 24G	 38 24	 42 20	0.5

Values are means±SD and numbers

Table 5
Cannulation Characteristics of Patients with Easy Veins in the Standard Technique versus AccuVein 300

	Standard technique N = 62	**AccuVein N = 62**	***P***
Success rate at first attempt	44 (71)	46 (74)	0.8
Success rate distribution Resident success at first attempt Resident success after switching to the other technique Attending success at first attempt* Attending success after switching to other technique*	 44 (71) 13 (21) 4 (80) 1 (20)	 46 (74) 11 (18) 4 (80) 1 (20)	 0.8 0.8 1 1
Resident performed successful cannulation	57 (92)	57 (92)	1
Resident cannulation time (sec)**	40 (15-152)	52 (6-350)	0.1
Attending cannulation time (sec)*	60 (15-90)	47 (30-69)	0.7
Number of pricks to successful cannulation	1 (1-4)	1 (1-4)	0.7

Values are numbers (%) and medians (range)
*n = 5 in standard technique group and n = 5 in AccuVein group
**n = 57 in standard technique group and n = 57 in AccuVein group

cases were excluded. The demographic characteristics of patients, described in the easy versus difficult veins categories are presented in Table 1. Patients with difficult veins were younger than patients with easy veins (4.3±3.7 vs 5.4±3.2 $P = 0.04$,) and a 24 gauge cannula was used more often in patients with difficult veins. The cannulation success rate in patients with difficult veins versus patients with easy veins was lower when residents attempted the cannulation (77% vs 92% $P = 0.004$), and it took a longer time (60s (15-222) vs 44s (6-350) $P = 0.03$) and a higher number of attempts (1 (1-4) vs 1 (1-4) $P = 0.03$) irrespective of the technique used (Table 2).

The overall first attempt success rates were similar between the standard and AccuVein groups respectively (67% (95% CI 57%-77%) vs 70% (95% CI 61%-79%), $P = 0.9$), in easy (71% (95% CI 60-82) vs 74% (95% CI 63-85), $P = 0.8$), as well as in difficult veins (60% (95% CI 42-78) vs 60% (95% CI 42-78), $P = 1$) subgroups (Table 3).

As for the subgroup analysis, in the group with easy veins, the demographic characteristics were similar between the standard and the AccuVein groups (Table 4). The cannulation characteristics were similar between the 2 groups (Table 5). In the group with difficult veins, demographic characteristics were comparable between the standard and the AccuVein groups (Table 6). The cannulation characteristics were also similar between the standard and the AccuVein groups, except for a longer residents' cannulation time to successful cannulation in the standard vs AccuVein group respectively 65s (27-168) vs 50s (15-222) $P = 0.01$) (Table 7).

Discussion

In our randomized crossover trial comparing the AV300 to the standard technique of intravenous line insertion in anesthetized pediatric patients we found

Table 6
Demographic Characteristics of Patients with Difficult Veins in the Standard Technique versus AccuVein 300

	Standard technique N = 30	**AccuVein N = 30**	***P***
Age (years)	4.8±4.2	3.7±3.2	0.3
Weight (kg)	21.7±14.7	17.5±9.6	0.2
Height (cm)	109.8±28.5	99.2±22	0.2
Gender (M/F)	19/11	19/11	1
Level of resident PGY1 PGY2 PGY3 PGY4	 2 8 9 11	 1 7 12 10	0.8
ASA class ASA 1 ASA 2 ASA 3	 20 9 1	 19 10 1	1
Gauge of IV cannula 22G 24G	 11 19	 11 19	1

Values are means±SD and numbers

Table 7
Cannulation Characteristics of Patients with Difficult Veins in the Standard Technique versus AccuVein 300

	Standard technique N = 30	**AccuVein N = 30**	***P***
Success rate at first attempt	18 (60)	18 (60)	1
Success rate distribution Resident success at first attempt Resident success after switching to the other technique Attending success at first attempt* Attending success after switching to other technique*	 18 (60) 4 (13) 6 (75) 2 (25)	 18 (60) 6 (20) 4 (67) 2 (33)	 1 0.7 1 1
Resident performed successful cannulation	22 (73)	24 (80)	0.5
Resident cannulation time (sec)**	65 (27-168)	50 (15-222)	0.01
Attending cannulation time (sec)*	55 (15-106)	54 (29-73)	0.7
Number of pricks to successful cannulation	1 (1-4)	1 (1-4)	0.9

Values are numbers (%) and medians (range)
*n = 8 in standard technique group and n = 6 in AccuVein group
**n = 22 in standard technique group and n = 24 in AccuVein group

no difference between the two groups in the first attempt success rate. This was already demonstrated by Kaddoum et al in a previous study[7]. The first attempt success rate was also the same when analyzed by subgroups (easy and difficult veins). However, in the difficult veins subgroup we found a difference in the time to successful cannulation. This partially met our hypothesis that such device would be beneficial for difficult veins patients more than easy ones. The AccuVein AV300 is the first hand-held tool established to facilitate the visibility of superficial veins using infrared light. For better visualization, the device should be held approximately at right angle and at 15-18 cm from the skin. It has recognized advantages; it is a portable device with lightweight that requires no power cord[8]. The finding of this study may be considered a clinically valuable outcome for AV300 since it matched what we were originally assuming, that using this device will reduce the difficulty of insertion mainly for children with difficult veins. This was evidenced by a shorter time to cannulation when the device was used.

Though several studies have investigated the efficacy of the near-infrared (NIR) devices or techniques during intravenous access, none have showed that they have major impact on the success rates at first attempt or the time it requires to complete a successful cannulation. Besides, using real-time visualization techniques became a standard of care during intravenous access in nursing practice[10]. In a randomized controlled study performed in a tertiary referral center in Netherlands, the VascuLuminator, a near-infrared vascular imaging device, showed no significant difference in first attempt success rate (59% with the device vs. 54% without, P = 0.41). The VascuLuminator has certain limitations in its visualization depth where it uses transillumination of near-infrared light while having the image on a monitor located above the limb. Another concern with the VascuLuminator is its requirements for eye-hand precise coordination during the puncture[11]. Another randomized study used the VeinViewer, a different NIR intravenous assistive device, in a pediatric oncology clinic that showed similar results. Nevertheless, VeinViewer had significant reduction in procedural time and patient experience with the nurses who used the device was higher than those who did not ($P \leq 0.05$)[12]. Additional studies using VeinViewer, by Sun et al and Szmuk et al, reported conflicting outcomes; using VeinViewer worsened the first attempt success rate and it improved finding the first available vessel respectively[13,14]. A more recent randomized study in our institution utilized the ultrasound as a real-time viewing technique in femoral artery cannulation in children where the reduction in the number of attempts and time to cannulate were significant. Also, there was a major increase in first attempt success rate (45% with ultrasound vs. 25% without, 95% CI P = 0.025)[9,15]. All these studies and other systematic reviews reaffirm again the challenge behind the success of intravenous cannulation in pediatric patients in different clinical situations and settings[15].

Regarding AccuVein 300, a non-randomized

study in pediatric operating room in Berlin showed that it has no impact on the improvement of the cannulation time or the number of attempts. It reported that success at first attempt was 0.45 using AccuVein 300 (51 of 114, 95% CI 0.35-0.54) vs. 0.73 without (90 of 124, 95% CI 0.35-0.54) and the median time until successful venous cannulation was 2 min using AccuVein 300 vs. 1 min without ($P< 0.01$)[16]. Though the Berlin study used the same device we are evaluating, it displayed bias in the sample size and in the selection of research participant without being originally ASA classified[16]. Same result has been also presented by Aulagnier et al when he used AccuVein 300 in adults in an emergency department and found that failure and pain did not differ from standard method[17]. All these common findings including ours reiterate that this apparatus might be needed only for pediatric patients who have difficult veins, when clinical practitioners do not have enough experience with cannulation such as residents, and feel less anxious with its availability.

In 2013, AccuVein LLC announced a new version of vein illumination devices, AccuVein 400, which can be held in any direction and has broader viewing range than AccuVein 300. It allows better visibility with 10 mm depth that makes it easier to identify large as well as small veins. A recent study in a rehabilitation center in New York highlighted a new benefit from the AccuVein 400 device in the reduction of hospital readmissions in addition to the elimination of the need to call for support to cannulate[18]. Yet, there are no further studies pertaining to AV400 use to increase the first attempt success rate. This study has some limitations; the sample of children with difficult veins was rather small. Also, there might be observer bias in recording the time and number of attempts. Another limitation is the fact that the classification of veins as easy or difficult was subjective. However, our overall analysis of cannulation characteristics of easy versus difficult vein clearly showed the accuracy of the classification since residents had a higher failure rate, took a longer time and a higher number of skin punctures to cannulate in the difficult veins group. In conclusion, the AccuVein AV300 apparatus does not increase the first-attempt success rate in anesthetized pediatric patients. It might be useful to decrease the cannulation time for difficult veins when practitioners are not experienced. Performing similar studies using AccuVein 400 might be recommended with anticipation of better outcomes than AccuVein 300 in addition to stratification of patients by age and obesity.

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