



Effect of two tourniquet techniques on peripheral intravenous cannulation success: A randomized controlled trial [☆]



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ABSTRACT

Objectives: Peripheral intravenous (IV) cannulation is the most common procedure performed in the emergency department (ED). Elastic tourniquets (ETs) and blood pressure cuffs (BPCs) are frequently used for venodilation. Although BPCs lead to increased venodilation and decreased compressibility, it is unclear whether this translates into a meaningful patient-centered outcome. This study aimed to determine whether one method is superior for success on the first attempt.

Methods: This was a prospective, single-blinded, randomized controlled trial in the ED of a tertiary care center. A convenience sample of adult patients was randomly assigned to an ET or BPC with a cover concealing the type of tourniquet. The primary outcome was success rate on the first attempt. Secondary outcomes were number of attempts, number of providers, and rate of rescue techniques.

Results: Of the 121 patients enrolled, 119 qualified for analysis. In the ET group, 42 of 59 patients (71%) had successful IV cannulation on first attempt compared with 43 of 60 (72%) in the BPC group ($P = .95$). The number of attempts ($P = .87$), number of nurses ($P = .67$), and use of rescue techniques ($P = .32$) did not differ significantly. A history of difficult IV access and site other than the antecubital vein were associated with decreased success.

Conclusions: ETs and BPCs performed similarly in providing venodilation for successful peripheral IV cannulation. History of difficult IV access and IV site are important factors in determining the likelihood of success.

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1. Introduction

Successful peripheral intravenous (PIV) cannulation depends on several factors, including patient anatomy, catheter size, and clinical expertise. On average, the first-time failure rate for gaining PIV access (PIVA) has been reported to be 12% to 26% [1–3]. Dilated veins are easier to cannulate than collapsing veins, and various ways to improve venodilation include tourniquet application, fluid administration, and administration of medications with peripheral

vasodilatory effect. The tourniquet technique to constrict blood flow proximal to the PIVA site is the oldest method and has been a generally accepted standard practice for centuries [4,5]. The most commonly used tourniquets are disposable elastic tourniquets (ETs) and blood pressure cuffs (BPCs). Use of a BPC inflated to 150 mm Hg, compared with an ET, decreased basilic vein compressibility, although the importance of this finding for patient care is unknown [6].

PIV cannulation is the most common invasive procedure performed in the emergency department (ED) [3]. In addition to being time-consuming, failure to cannulate a peripheral vein on the first attempt may negatively affect patients by causing anxiety, unnecessary pain, a delay in therapy, and loss of potential venous access sites. Therefore, any increase in the success rate for PIV cannulation could potentially improve patient satisfaction, ED throughput, and patient outcomes related to various time-sensitive diseases.

The aim of this study was to compare the standard ET with a BPC to promote venodilation for PIV cannulation. The primary outcome was success rate on the first attempt. Secondary outcomes

Abbreviations: BPC, blood pressure cuff; ED, emergency department; ET, elastic tourniquet; IV, intravenous; PIV, peripheral intravenous; PIVA, peripheral intravenous access; REDCap, Research Electronic Data Capture.

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were number of attempts, number of nurses who attempted PIVA, and rate of use of rescue techniques.

On the basis of previous noninvasive research on venodilation and compressibility, we hypothesized that the BPC would be superior to the ET. To the best of our knowledge, no studies have compared the effect of different tourniquet techniques on the first-time success rate of PIV cannulation.

2. Methods

2.1. Study design

We conducted a single-center, prospective, single-blinded randomized controlled trial of emergency department patients in need of PIV access. The study protocol was approved by the Mayo Clinic Institutional Review Board, and the trial was registered with clinicaltrials.gov. Study reporting adheres to the CONSORT guidelines for reporting parallel group randomized trials [7]. Direct observations of PIV cannulation by nursing staff occurred from October 1 through December 31, 2014 to determine the department's baseline PIVA success rate. Patients were recruited from April 11, 2015, through June 8, 2016. Allocation to the treatment groups was risk-stratified by patient-reported history of difficult intravenous (IV) access.

2.2. Study setting and population

Participants were chosen from a convenience sample of adult patients who underwent PIV cannulation as part of their treatment in the ED at Mayo Clinic Hospital—Rochester, Saint Marys Campus, a tertiary referral center and teaching hospital in Rochester, Minnesota. Patients were excluded if they were younger than 18 years, prison inmates, pregnant, unable to give informed consent, or critically ill and needed emergent IV access as determined by the ED clinician. Study participants were identified by screening the ED census for potentially eligible patients and by referral from nursing staff or ED clinicians who were aware of the study. Written informed consent was obtained by a member of the study team. No compensation was offered to participants.

2.3. Study protocol

After obtaining consent, the Research Electronic Data Capture (REDCap) application's randomization tool was used to randomly assign patients to either an ET or a reusable BPC (Adcuff, American Diagnostic Corp) inflated to 150 mm Hg for venodilation before the first attempt at PIVA. Allocation to the treatment groups was risk-stratified with the REDCap stratification function according to patient-reported history of difficult IV access. A special cover concealed the type of tourniquet used, and the nurses then attempted PIVA under direct observation (Fig. 1).



Fig. 1. Cover for concealing the tourniquet.

The study investigators then recorded participants' characteristics at the bedside. A standard Fitzpatrick scale was used to classify the patient's skin type from I through VI [8]. In the absence of the nurse performing the PIV cannulation, the study investigator applied an ET or a BPC to the patient's upper arm and covered the tourniquet so the nurse would not see whether it was an ET or a BPC. The patient's nurse inserted the IV catheter distal to the covered tourniquet under the direct observation of an investigator. The insertion site on the arm and the gauge of the IV catheter were left to the nurse's discretion. If the patient's other arm was needed for the first attempt, the nurse left the room while the investigator applied the tourniquet and the cover on that arm. Study investigators used REDCap to record their direct observations, including arm site, catheter gauge, number of PIVA attempts, number of nurses attempting access, and any rescue techniques used. An *attempt* was defined as a needle penetrating the surface of the patient's skin. *Successful access* was defined as good flow through an IV catheter with a saline flush and without subcutaneous fluid collection.

2.4. Data analysis

Continuous data were summarized as medians, interquartile ranges, and ranges; categorical data were summarized as number of participants and percentage of the sample. The Wilcoxon rank sum test, the χ^2 test, and the Fisher exact test were used for comparisons between the ET and BPC groups, between patients with and without successful IV access on the first attempt, and between patients who did and did not receive rescue techniques. Statistical analyses were performed with SAS software version 9.4 (SAS Institute Inc.). All tests were 2-sided, and *P* values < 0.05 were considered statistically significant.

2.5. Sample size calculation

By directly observing 52 IV attempts in our ED from October 1 through December 31, 2014, we found that the success rate for the first attempt with standard ETs was 56%. We determined that a sample size of 108 patients would provide a power of at least 80% to detect a 25% difference in the first-attempt success rates between the ET and BPC groups.

2.6. Outcome measures

The primary end point was the first-attempt PIVA success rate with use of an ET compared with a BPC. Secondary outcomes included the total number of nurses required to attempt PIVA for

each type of tourniquet and the rate of rescue techniques used for each type of tourniquet.

3. Results

3.1. Characteristics of study participants

Of the 121 patients enrolled and randomly assigned to receive an ET or BPC from April 11, 2015, through June 8, 2016, 2 did not receive an IV catheter and were therefore not eligible for the study, leaving 119 patients for analysis (Fig. 2).

3.2. Main results

Baseline features and outcomes are summarized in Table 1 for the 59 patients in the ET group and the 60 in the BPC group. None of the baseline features were significantly different between the 2 groups; randomization successfully balanced these features by intervention. Among all 119 participants, 57% were female; median age was 65 years; median body mass index was 28.1 (calculated as weight in kilograms divided by height in meters squared); and median mean arterial pressure was 91 mm Hg. The most common Fitzpatrick skin type was type III, which indicates cream to medium skin that develops a slightly tender burn at 24 h and a moderate tan at 7 days [8].

Of the patients in the ET group, 42 (71%) had successful IV access on the first attempt compared with 43 of the patients (72%) in the BPC group (*P* = .95). The number of attempts (*P* = .87), the number of nurses who attempted IV access (*P* = .67), and the use of rescue techniques (*P* = .32) did not differ significantly between the 2 groups.

4. Discussion

The goal of any invasive procedure should be a successful outcome on the first attempt. However, despite being the most common invasive procedure in the ED, PIVA misses that patient-centered goal about 25% of the time. Although successful IV cannulation is hindered by several patient characteristics, such as patient body habitus, age, sex, race, vein depth, vein size, and coexisting medical conditions [2,3,9], several techniques have been studied to improve the outcome. Among those are near-infrared light devices [10–13], ultrasonographic guidance [14,15], and nitroglycerin ointment [16]. In a systematic review and meta-analysis of novel interventions to improve PIVA in children, use of a near-infrared light device and transilluminator possibly provided some benefit over traditional methods, but nitroglycerin ointment was associated with increased failure rates and adverse effects [17]. Although near-infrared light devices are not readily available in many EDs, ultrasonographic guidance is becoming widely accepted for difficult PIVA and has a success rate of up to 97% [18] and an increased likelihood of successful cannulation (pooled odds ratio, 2.42) [19].

Regardless, the simplest and most widely used technique for venodilation is still the traditional method of using a tourniquet. Previous studies of ETs and BPCs have had conflicting results. On ultrasonography, a BPC apparently leads to increased vein size and decreased compressibility [6], possibly from higher sustained pressure and increased vessel wall tension, but Nelson et al. [20] reported that for ultrasonographically guided PIVA, an ET leads to a higher success rate. Several factors have been hypothesized to explain this discrepancy: The BPC is cumbersome and interferes with site access; prolonged BPC inflation causes patient discomfort; and increased venous pressure causes difficulty differentiating veins from arteries with ultrasonography. However, the effect on standard PIVA without ultrasonographic guidance was unclear.

In our single-center, single-blinded, randomized controlled trial, we found that success rates for first-time PIVA were similar

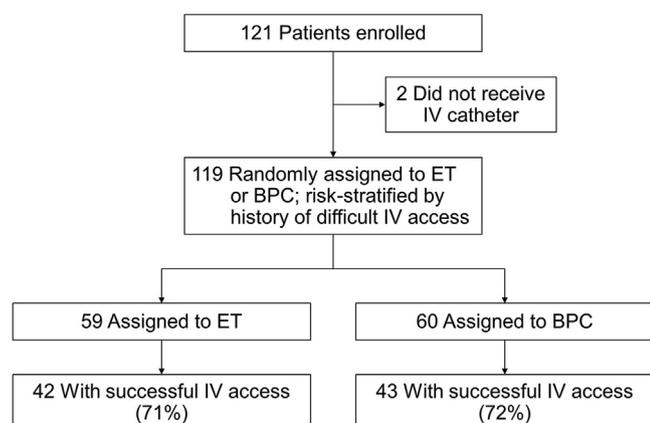


Fig. 2. Patient flowchart. BPC indicates blood pressure cuff; ET, elastic tourniquet; IV, intravenous.

Table 1
Baseline features and outcomes for participants receiving an elastic tourniquet (ET) or a blood pressure cuff (BPC).

Feature	All (N = 119) ^a	ET (n = 59) ^a	BPC (n = 60) ^a	P value
Age, y	65 (46–77; 20–92)	67 (54–78; 23–92)	62 (41–75; 20–92)	0.26
BMI ^b	28.1 (24.0–32.6; 16.1–51.6)	28.3 (25.1–32.6; 18.9–51.6)	28.0 (23.4–32.7; 16.1–51.2)	0.21
SBP, mm Hg	136 (121–155; 82–199)	142 (125–154; 89–183)	133 (119–156; 82–199)	0.27
DBP, mm Hg	76 (65–90; 40–145)	78 (63–91; 43–145)	74 (65–89; 40–100)	0.33
MAP, mm Hg (n = 117)	91 (81–103; 50–156)	93 (82–106; 57–156)	90 (80–103; 50–126)	0.30
Genetic disposition score	9 (7–10; 1–16)	9 (7–10; 2–14)	8 (8–10; 1–16)	0.78
Sun exposure score	8 (5–12; 0–16)	8 (5–12; 0–15)	9 (5–12; 0–16)	0.30
Tanning habits score	3 (1–7; 0–8)	2 (0–7; 0–8)	4 (1–7; 0–8)	0.25
Total skin type score	20 (15–27; 4–37)	20 (14–26; 4–33)	22 (17–28; 5–37)	0.19
Sex				0.79
Female	68 (57)	33 (56)	35 (58)	
Male	51 (43)	26 (44)	25 (42)	
Eye color				0.11
0	9 (8)	6 (10)	3 (5)	
1	37 (31)	19 (32)	18 (30)	
2	43 (36)	23 (39)	20 (33)	
3	26 (22)	11 (19)	15 (25)	
4	4 (3)	0 (0)	4 (7)	
Natural hair color				0.34
0	10 (8)	3 (5)	7 (12)	
1	27 (23)	12 (20)	15 (25)	
2	30 (25)	17 (29)	13 (22)	
3	38 (32)	20 (34)	18 (30)	
4	14 (12)	7 (12)	7 (12)	
Color of nonexposed skin				0.82
0	6 (5)	3 (5)	3 (5)	
1	44 (37)	21 (36)	23 (38)	
2	44 (37)	22 (37)	22 (37)	
3	23 (19)	13 (22)	10 (17)	
4	2 (2)	0 (0)	2 (3)	
Freckles on nonexposed areas				0.17
0	11 (9)	6 (10)	5 (8)	
1	6 (5)	3 (5)	3 (5)	
2	20 (17)	11 (19)	9 (15)	
3	18 (15)	12 (20)	6 (10)	
4	64 (54)	27 (46)	37 (62)	
Reaction to sun exposure				0.35
0	13 (11)	7 (12)	6 (10)	
1	18 (15)	8 (14)	10 (17)	
2	29 (24)	16 (27)	13 (22)	
3	38 (32)	22 (37)	16 (27)	
4	21 (18)	6 (10)	15 (25)	
Degree of turning brown				0.31
0	26 (22)	15 (25)	11 (18)	
1	26 (22)	13 (22)	13 (22)	
2	15 (13)	9 (15)	6 (10)	
3	32 (27)	12 (20)	20 (33)	
4	20 (17)	10 (17)	10 (17)	
Turn brown in several hours				0.13
0	27 (23)	17 (29)	10 (17)	
1	15 (13)	7 (12)	8 (13)	
2	28 (24)	12 (20)	16 (27)	
3	29 (24)	17 (29)	12 (20)	
4	20 (17)	6 (10)	14 (23)	
Reaction of face to sun				0.96
0	20 (17)	8 (14)	12 (20)	

Table 1 (continued)

Feature	All (N = 119) ^a	ET (n = 59) ^a	BPC (n = 60) ^a	P value
1	31 (26)	17 (29)	14 (23)	
2	26 (22)	14 (24)	12 (20)	
3	19 (16)	10 (17)	9 (15)	
4	23 (19)	10 (17)	13 (22)	
Last exposure to sun				0.18
0	60 (50)	34 (58)	26 (43)	
1	11 (9)	5 (8)	6 (10)	
2	4 (3)	1 (2)	3 (5)	
3	4 (3)	1 (2)	3 (5)	
4	40 (34)	18 (31)	22 (37)	
IV site exposed to sun				0.33
0	28 (24)	16 (27)	12 (20)	
1	18 (15)	11 (19)	7 (12)	
2	19 (16)	9 (15)	10 (17)	
3	38 (32)	13 (22)	25 (42)	
4	16 (13)	10 (17)	6 (10)	
Fitzpatrick skin type				0.15
I	4 (3)	2 (3)	2 (3)	
II	16 (13)	11 (19)	5 (8)	
III	40 (34)	19 (32)	21 (35)	
IV	33 (28)	17 (29)	16 (27)	
V	24 (20)	10 (17)	14 (23)	
VI	2 (2)	0 (0)	2 (3)	
History of difficult IV access	39 (33)	18 (31)	21 (35)	0.60
Needle gauge				0.93
18	66 (55)	34 (58)	32 (53)	
20	43 (36)	18 (31)	25 (42)	
22	10 (8)	7 (12)	3 (5)	
First-attempt IV site				0.46
Antecubital	93 (78)	49 (83)	44 (73)	
Forearm	13 (11)	5 (8)	8 (13)	
Wrist	5 (4)	1 (2)	4 (7)	
Hand	8 (7)	4 (7)	4 (7)	
First-attempt success	85 (71)	42 (71)	43 (72)	0.95
No. of attempts				0.87
1	85 (71)	42 (71)	43 (72)	
2	22 (18)	13 (22)	9 (15)	
3	9 (8)	3 (5)	6 (10)	
4	3 (3)	1 (2)	2 (3)	
No. of nurses				0.67
1	101 (85)	51 (86)	50 (83)	
2	17 (14)	7 (12)	10 (17)	
3	1 (1)	1 (2)	0 (0)	
Rescue technique used	9 (8)	6 (10)	3 (5)	0.32
Type of rescue technique (n = 9)				>0.99
IV team	8 (89)	5 (83)	3 (100)	
Ultrasonographic guidance	1 (11)	1 (17)	0 (0)	

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; IV, intra-venous; MAP, mean arterial pressure; SBP, systolic blood pressure.

^a Data are presented as median (interquartile range; range) or as number of participants (percentage of sample).

^b Calculated as weight in kilograms divided by height in meters squared.

for ET and BPC, which are both commonly used for venodilation. The similar success rates suggest that a patient-centered advantage does not exist for using 1 method over the other, in contrast to previous suggestions. In a prospective single-center trial, BPC was superior in increasing vein size and decreasing vein compressibility when compared to 1 or 2 ETs, although the IV access success rate was not addressed [6]. In another randomized trial (where success was defined as <3 attempts, <30 min of procedure time, and patient tolerance of the procedure) ultrasonographically guided PIVA by physicians using an ET was superior to BPC for

Table 2

Baseline features for patients with and without successful IV access on the first attempt.

Feature	Not successful (n = 34) ^a	Successful (n = 85) ^a	P value
Age, y	66 (44–76; 20–92)	62 (47–77; 23–92)	0.81
BMI ^b	27.5 (22.0–33.5; 16.1–51.6)	28.3 (24.2–32.2; 18.5–51.2)	0.29
SBP, mm Hg	133 (121–146; 82–183)	139 (122–156; 89–199)	0.24
DBP, mm Hg	76 (65–85; 43–121)	76 (65–91; 40–145)	0.40
MAP, mm Hg (n = 117)	92 (80–102; 57–129)	91 (81–104; 50–156)	0.51
Genetic disposition score	8 (7–9; 2–14)	9 (7–11; 1–16)	0.22
Sun exposure score	9 (7–12; 0–15)	8 (5–11; 0–16)	0.35
Tanning habits score	3 (1–7; 0–8)	3 (1–7; 0–8)	0.65
Total skin type score	22 (16–28; 5–32)	20 (15–26; 4–37)	0.79
Sex			0.29
Female	22 (65)	46 (54)	
Male	12 (35)	39 (46)	
Fitzpatrick skin type			0.54
I	1 (3)	3 (4)	
II	4 (12)	12 (14)	
III	11 (32)	29 (34)	
IV	9 (26)	24 (28)	
V	9 (26)	15 (18)	
VI	0 (0)	2 (2)	
History of difficult IV access	17 (50)	22 (26)	0.01
Needle gauge			0.050
18	14 (41)	52 (61)	
20	16 (47)	27 (32)	
22	4 (12)	6 (7)	
First-attempt IV site			0.03
Antecubital	22 (65)	71 (84)	
Forearm	8 (24)	5 (6)	
Wrist	1 (3)	4 (5)	
Hand	3 (9)	5 (6)	

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; IV, intravenous; MAP, mean arterial pressure; SBP, systolic blood pressure.

^a Data are presented as median (interquartile range; range) or as number of participants (percentage of sample).

^b Calculated as weight in kilograms divided by height in meters squared.

patients with a history of difficult IV access (82.4% vs 47.6% in 38 patients) [20]. In our assessment, where the primary patient-centered end point was the success rate of initial attempts, ET and BPC performed similarly in patients with similar baseline characteristics. First-attempt success rates during our intervention period (with ET, 71%; with BPC, 72%) were higher than during our observation period (56%), although our intervention success rates were similar to results reported in a literature review (74%–88%) [2]. While the cause of the increased success rates during our intervention period is unclear, they may reflect different skill levels of nursing staff. We did not identify any safety concerns or differences in patient satisfaction between the 2 methods. However, one could argue that reusable BPCs require more maintenance and are potential infection hazards when used on multiple patients, so that the ET would have an overall advantage.

A secondary analysis of baseline features between patients with and without successful IV access on the first attempt is shown in Table 2. Sebbane et al. [3] and Fields et al. [21] previously identified a history of difficult IV access as being significantly associated with first-attempt success. In our study, of the 85 patients whose first attempt was successful, only 22 (26%) had a history of difficult IV access compared with 17 of the 34 patients (50%) who required 2 or more attempts ($P = .01$). Success on the first attempt appeared to vary by needle gauge, but in our study this difference was not statistically significant ($P = .050$). Most patients with first-attempt success (52; 61%) had an 18-gauge needle compared with 14 of the patients (41%) who required 2 or more attempts. The difference may partly reflect that nurses preferentially insert large IV cath-

Table 3

Baseline features for patients on whom rescue techniques were used and not used.

Feature	Not used (n = 110) ^a	Used (n = 9) ^a	P value
Age, y	62 (43–76; 20–92)	74 (66–80; 52–82)	0.09
BMI ^b	28.0 (24.0–32.6; 16.1–51.6)	28.9 (26.1–31.0; 17.1–42.0)	0.61
SBP, mm Hg	136 (122–156; 82–199)	131 (106–140; 97–161)	0.13
DBP, mm Hg	76 (65–90; 40–145)	67 (62–82; 43–110)	0.37
MAP, mm Hg (n = 117)	92 (82–104; 50–156)	81 (71–94; 63–127)	0.17
Genetic disposition score	9 (7–10; 1–16)	8 (6–8; 6–12)	0.09
Sun exposure score	8 (5–12; 0–16)	9 (7–10; 4–15)	0.58
Tanning habits score	3 (1–7; 0–8)	1 (0–3; 0–4)	0.04
Total skin type score	22 (15–27; 4–37)	18 (15–21; 11–27)	0.26
Sex			0.08
Female	60 (55)	8 (89)	
Male	50 (45)	1 (11)	
Fitzpatrick skin type			0.33
I	4 (4)	0 (0)	
II	15 (14)	1 (11)	
III	35 (32)	5 (56)	
IV	30 (27)	3 (33)	
V	24 (22)	0 (0)	
VI	2 (2)	0 (0)	
History of difficult IV access	32 (29)	7 (78)	0.006
Needle gauge			0.03
18	63 (57)	3 (33)	
20	41 (37)	2 (22)	
22	6 (5)	4 (44)	
First-attempt IV site			0.20
Antecubital	86 (78)	7 (78)	
Forearm	13 (12)	0 (0)	
Wrist	5 (5)	0 (0)	
Hand	6 (5)	2 (22)	

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; IV, intravenous; MAP, mean arterial pressure; SBP, systolic blood pressure.

^a Data are presented as median (interquartile range; range) or as number of participants (percentage of sample).

^b Calculated as weight in kilograms divided by height in meters squared.

eters in patients with easily palpable veins. In addition, specific IV sites were associated with first-attempt success ($P = .03$). For example, for most of the patients with first-attempt success (71; 84%), the antecubital site was used, in contrast to the 22 patients (65%) who required 2 or more attempts. Among our patients, 7.6% required a rescue technique that included a specialized IV access team that used ultrasonography if needed. Results of a secondary analysis comparing the characteristics of patients with and without the need for a rescue technique are summarized in Table 3. In our study, a history of difficult IV access was the strongest predictor for the need of some kind of rescue technique. This finding is consistent with those of previous reports of predictors of difficult IV access [21].

4.1. Limitations

Our study has several limitations. Our patients were chosen from a convenience sample that may not truly represent our general ED patient population. We excluded critically ill patients and pediatric patients, in whom IV cannulation may have been more difficult. Data were collected only during daytime hours when research staff members were available, so it is possible that the intervention was performed by a subpopulation of nurses not reflective of the entire ED. Additionally, we did not record the skill level of the nurse, which may be a predictor of PIVA success [3,9,22,23]. However, randomization ensured that the participants in the 2 treatment groups were similar in regard to all recorded

baseline characteristics, and we assume that it also helped to lessen the effects of the different skill levels of the nurses.

For technical reasons, this study was only single-blinded; the patient knew the group assignment (ET or BPC). In addition, we are aware that patient discomfort from the BPC method of venodilation has been previously documented [20]. We did not observe this directly, and we did not collect data on patient discomfort. Greater patient discomfort may have indicated allocation to the BPC group to the nurse.

Finally, this study was performed at a single academic institution, and our findings may not be generalizable to other institutions or clinical settings.

4.2. Conclusions

Although previous research has shown conflicting evidence of superiority between BPCs and ETs, our study showed no clinically meaningful difference between the 2 devices for success in first-attempt PIVA. We suggest that ED providers use whichever method of venodilation they are more comfortable with. A patient-provided history of difficult IV access and available IV sites can be used to predict the likelihood of successful peripheral IV cannulation.

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Conflict of interest

None.

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Author contributions

Dr. Tran: Study concept and design, acquisition of the data, analysis and interpretation of the data, drafting of the manuscript, and critical revision of the manuscript for important intellectual content. Ms. Lund: Acquisition of the data and drafting of the manuscript. Mr. Nichols: Acquisition of the data and analysis and interpretation of the data. Dr. Kummer: Study concept and design, analysis and interpretation of the data, drafting of the manuscript, critical revision of the manuscript for important intellectual content, administrative, technical, or material support, and study supervision.

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