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Clinical use of electrical stimulation with the Veinplicity® device and its effect on the first attempt success rate of peripheral intravenous cannulation: A non-randomized clinical trial

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Fredericus HJ van Loon[1,2], Freek JP Willekens[2], Marc P Buise[2], Hendrikus HM Korsten[2,3], Arthur RA Bouwman[2,3] and Angelique TM Dierick-van Daele[4]

Abstract

Background: Peripheral intravenous cannulation is one of the most frequently performed medical procedures. Venodilation, which can be achieved with different techniques, is an important factor for first attempt success. The objective of this study was to compare the first attempt success rates upon peripheral intravenous cannulation after applying a tourniquet, with venous dilation by electrical stimulation using the Veinplicity® device, or a combination of both techniques, in participants at moderate risk of a difficult peripheral intravenous access.

Methods: This non-randomized clinical trial was carried out in adult patients divided into three parallel study groups, consisting of cannulation with a tourniquet (control group), cannulation after electrical stimulation without using a tourniquet (intervention group 1), and cannulation after applying electrical stimulation followed by the application of a tourniquet on the selected upper extremity (intervention group 2). The primary outcome was the first attempt success rate of peripheral intravenous catheter placement.

Results: In all, 141 participants were included in this study, with an overall success rate of 86%. Success rates of 78%, 88%, and 92% were observed in the control group, intervention group 1, and intervention group 2, respectively ($p = 0.25$, $\chi^2 = 2.771$, $df = 2$). A higher first attempt success rate was detected in participants in intervention group 2, when compared to the control group ($p = 0.04$, $\chi^2 = 4.63$, $df = 1$).

Conclusion: Increase in first attempt success was clinically relevant when electrical stimulation with the Veinplicity® device was combined with the application of a tourniquet in participants at moderate risk of a difficult peripheral intravenous access.

Keywords

Catheterization, peripheral (D002406), vascular access devices (D062666)

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[1]Department of Technical and Anesthesia Nursing Sciences, Fontys University of Applied Sciences, Eindhoven, The Netherlands
[2]Department of Anesthesiology, Pain Medicine and Intensive Care, Catharina Hospital, Eindhoven, The Netherlands
[3]Department of Signal Processing Systems and Electrical Engineering, TU/e Eindhoven University of Technology, Eindhoven, The Netherlands
[4]Department of Research and Education, Catharina Hospital, Eindhoven, The Netherlands

Corresponding author:
Fredericus HJ van Loon, Department of Anesthesiology, Pain Medicine and Intensive Care, Catharina Hospital, Michelangelolaan 2, 5623 EJ Eindhoven, The Netherlands.
Email: rick.v.loon@catharinaziekenhuis.nl

Question	Additive score
Is the participant at an emergency or unplanned indication for surgery?	1
Was it difficult to insert a peripheral intravenous catheter in the past?	1
Is there an inability to identify the target vein by palpating the extremity?	1
Is there an inability to identify the target vein by visualizing the extremity?	1
Does the target vein have a diameter of at most 2 millimeters?	1

Figure 1. The A-DIVA scale is represented as an additive scoring system to calculate the predicted risk for an individual participant; the scores for existing risk factors are added to give an approximate estimation of a difficult intravenous access. Scores are added after answering a question with "yes." Based on a participants individual score, they were classified to either a low risk group (A-DIVA score 0 or 1), moderate risk group (A-DIVA score 2 or 3), or high risk group (A-DIVA score 4 or 5).[11]

Introduction

Peripheral intravenous cannulation is clinically indispensable, with an estimated prevalence of 85% in modern health care.[1,2] The first attempt success rate of peripheral intravenous cannulation, however, is approximately 83% according to the results of a recently published meta-analyses.[3] Failed attempts of intravenous cannulation do not only put patients in distress and pain but also results in delayed treatment, increased nursing and medical workload, raised overall hospital costs due to multiple attempts, and an increased risk of complications such as infection, vein injury, and infiltration.[2,4–7]

Peripheral intravenous cannulation requires technical skills from the practitioner, and traditionally involves vein and equipment selection before cannulation.[8] With the traditional approach to peripheral intravenous cannulation, suitable veins are selected based on their visibility and palpability.[9,10] Venodilation is recommended to facilitate successful cannulation and is associated with an increased success rate, because dilated veins are generally larger and have an increased level of visibility and palpability.[1,8,11–13] Common techniques to create dilated veins include local warming and tourniquet application.[14] Another quite novel and modern technique is the use of electrical stimulation of the extremity to achieve venodilation.

The Veinplicity® device (Physeon GmbH, Schaffhausen, Switzerland) is an electrical stimulation device that can be used as an adjunct for peripheral intravenous cannulation. Electrical stimulation of the nerves and muscles of the selected extremity is said to increase local blood volume, and therefore improve the practitioners' ability to gain intravenous access. Besides increasing blood flow, stimulation with the Veinplicity® device is expected to induce other temporary physiological changes, namely, thickening of the vein wall, increased stability of the vein, and an expanded vessel diameter, as mentioned by the manufacturer.

This study focused on the effectiveness of electrical stimulation on peripheral intravenous cannulation in those patients with an expected difficult intravenous access. The existence of a difficult intravenous access can be estimated with the A-DIVA scale (Figure 1).[11] This additive five-variable scale is a reliable predictive model that serves to identify patients with a difficult intravenous access prospectively, and subsequently allows clinicians to classify them according to their individual risk score into either a low, moderate, or high risk profile.[11] Briefly, a score on the A-DIVA scale will predict the likelihood of failed peripheral intravenous catheter placement in a group of patients with a similar risk profile, whereby a higher score indicates a higher risk for difficult intravenous catheter placement and an increased risk for failure on the first attempt of peripheral intravenous cannulation. Using the A-DIVA scale, clinicians are alerted to potential issues and the possibility of using techniques such as electrical stimulation on a low threshold and in an earlier time frame, to avoid these issues.

In this study, the effect of electrical stimulation was compared to both the traditional technique of peripheral intravenous cannulation and the combination of the device with a tourniquet, on the first attempt success rate in participants at moderate risk of a failed first attempt according to the A-DIVA scale. This study hypothesizes that the first attempt success rate will increase up to 90% in patients at moderate risk according to the A-DIVA scale when the Veinplicity® device is used to achieve venodilation for peripheral intravenous cannulation, whether or not combined with application of a tourniquet.

Methods

Ethical considerations

The Medical research Ethics Committees United (MEC-U, Nieuwegein, The Netherlands) reviewed the study protocol (ref: R17.053), and it was registered in the Dutch Trial Register (ref: 7150). Written informed consent was obtained from all participants before inclusion. The study was carried out in accordance with the Medical Research Involving Human Subjects Act and guidelines of Good Clinical Practice (GCP), and according to current hospital guidelines for peripheral intravenous cannulation, as well as the international standard for peripheral intravenous catheter placement.[12,15–18]

Design

This non-randomized clinical trial was carried out in three study groups using stratified permuted blocks. Treatment in the study groups consisted of either cannulation with the traditional approach using palpation and visualization after application of a tourniquet to the selected extremity (control group), cannulation after electrical stimulation without using a tourniquet (intervention group 1), or cannulation after first applying electrical stimulation and then applying a tourniquet to the selected upper extremity (intervention group 2). Participants were consecutively divided into one of three study groups based on coincidence, because each treatment strategy was applied for a period of 4 weeks. During this period of 4 weeks, no other technique of peripheral intravenous cannulation was applied, so it was not possible for participants to change between study groups or intervention, nor did they or the practitioners have any influence on the applied treatment. Blinding of both participant and the practitioner was not possible due the simple fact that the applied technique was obvious to both. The study was performed in the preoperative holding area of the operating theater complex of the Catharina Hospital (Eindhoven, The Netherlands), which is a tertiary teaching hospital.

Study groups

Before cannulation, a tourniquet was secured around the chosen arm of the participants in the control group to ensure dilation of the veins, at least 10 cm proximal to the elbow crease.[19,20] The tourniquet was tightened while maintaining pulsations of the radial artery, as tested manually by palpating the artery.[21] The tourniquet was removed after cannulation.

For participants in intervention group 1, the target vein was not dilated by using a tourniquet, but with electrical stimulation with the Veinplicity® device. The device was connected to the participant via two electrodes placed on the selected arm for peripheral intravenous access (white electrode patch on the palmar surface of the hand and the blue electrode patch on the bicep of the arm), which were then attached to the stimulator using the main cable, as shown in Figure 2. In turning on the device, a physical response could be observed. If muscle fasciculation was not present, the intensity of stimulation was slowly increased until a response was observed. The participant experienced tingling, but no painful sensation. If the stimulation was not tolerable, the intensity was lowered to a tolerable level that still produced muscle fasciculation. The stimulation was continued for at least 2 min, but no more than 10 min. Stimulation was discontinued and the device removed when the target vein had become visible and/or palpable. Peripheral intravenous cannulation was then performed. The procedure of electrical stimulation was done according to the guidelines and policy of the manufacturer.

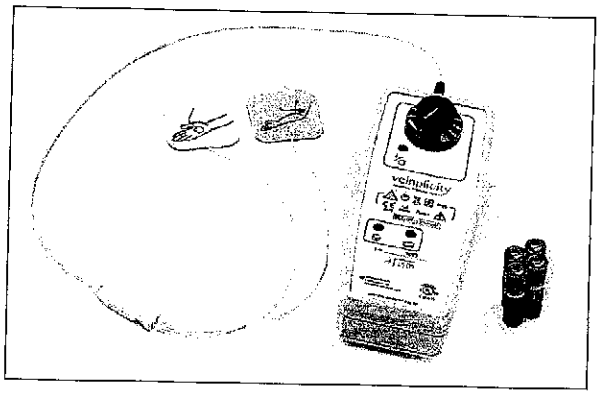

Figure 2. Display of the Veinplicity® electrical stimulation device, with the connected patches. Picture is taken with permission from the manufacturer of the device (Physeon GmbH).

For participants in intervention group 2, electrical stimulation was performed in the same way as described for intervention group 1. Directly after disconnection of the stimulation device, a tourniquet was applied to keep the target vein dilated. The tourniquet was applied at least 10 cm proximal to the elbow crease while maintaining pulsations of the radial artery, similar to the procedure as described in the control group. The tourniquet was removed after cannulation.

Peripheral intravenous cannulation

A peripheral intravenous catheter is a small hollow catheter that is advanced over a needle into a peripheral vein through the skin. The puncture site was prepped with chlorhexidine 0.5% in ethanol 70%. Nurse anesthetists and PACU (post anesthesia care unit) nurses (those specialized in post anesthesia care), who were familiar with the study protocol, obtained the peripheral intravenous access. A peripheral intravenous catheter was inserted in the upper extremity, and veins on the dorsal and ventral surfaces of the upper extremity, including the metacarpal, cephalic, basilic, and median veins on the dorsal side of the hand, fore arm, and elbow crease, were considered for cannulation. Short intravenous catheters sized 14–22 gauge (Venflon Pro Safety; BD Infusion Therapy AB, Helsingborg, Sweden) were inserted; the size of the inserted catheter depended on the clinical situation and was chosen by the practitioner. Intravenous cannulation was performed according to practice guidelines and hospital policy.[12,17,22] In all study groups, peripheral intravenous cannulation was performed when the practitioner was able to detect a suitable, dilated vein by palpating and/or visualizing the extremity. Throughout the study, peripheral intravenous cannulation was performed by experienced nurse anesthetists and PACU nurses, who gained at least 1 year of experience in intravenous catheter placement. Practitioners were trained in Veinplicity® device

usage by the manufacturer with an oral presentation, followed by a hands-on training in at least 10 patients.

Participants

Participants at moderate risk for a failed first attempt of peripheral intravenous cannulation according to the A-DIVA scale were eligible to participate in this study, regardless the medical specialism or type of surgery they were admitted for, if they were aged 18 years or older, conscious, and able to adequately answer questions. Risk classification of participants on the A-DIVA scale was performed by the practitioner prior to cannulation. A potential participant who met any of the following criteria was excluded from participation in this study: participants in whom an intravenous catheter was already inserted, participants who were unwilling or unable to provide consent, participants with medical devices implanted in the body (pacemaker or implantable cardioverter defibrillator (ICD), for example), and participants who did not understand questions or generate adequate data due to physical or communicational disorders.

Sample size calculation

The current study focused on participants with a moderate risk profile according to the A-DIVA scale (A-DIVA score of 2 and 3), who had a relative risk (RR) for an unsuccessful first attempt of 1.3 (95% confidence interval (CI) = 1.24–1.55) according to a previous study by Van Loon et al.[11] This means that 63% of participants with a moderate risk profile had an unsuccessful first attempt of inserting a peripheral intravenous catheter.[11] Actually, we hypothesized that the success rate would increase to as high as 90% in this category of participants when electrical stimulation was used. Power analysis indicated that at least a sample size of 39 participants with a moderate risk profile according to the A-DIVA scale was required in each study group, assuming a mean difference of 27% with respect to the incidence of a successful first attempt as a result from a previous study, with $\alpha = 0.05$ and $\beta = 0.80$.[11] Finding of at least that 27% difference in successful peripheral intravenous cannulation on the first attempt between the study group in which the traditional technique was applied (control group) and the groups in which electrical stimulation was used (intervention groups) will result in a first attempt success rate of 90% in the intervention groups, which was denoted as both a clinically relevant and statistically significant difference. Finally, 45 participants were asked to participate in each study group, with a total of 135 participants with a moderate risk profile throughout this study, allowing for 10% attrition due to data collection incompleteness.

Outcome measures

The primary outcome was the first attempt success rate of peripheral intravenous catheter placement. An attempt was defined as one percutaneous needle puncture, regardless the amount of subcutaneous exploration from the single puncture site.[9] After a failed attempt, a new attempt was considered as any change in localizing a vein, followed by a new percutaneous puncture. After each puncture, the practitioner checked and registered whether the attempt was successful or not. Peripheral intravenous cannulation was defined as successful if blood returned in the catheter and/or a saline flush could be injected without compromising the vein or without signs of subcutaneous infiltration.[17,18] After two failed attempts with electrical stimulation, peripheral intravenous cannulation was executed using the traditional technique, as described in the control group. The time needed for intravenous cannulation, pain score upon intravenous cannulation, the relation between the success rate and participant demographics (age, sex, length, weight, American Society of Anesthesiologists (ASA) physical status, medical history, and comorbidities), and the relationship between the success rate and procedure-related data (size of the vein in millimeters measured by placing a ruler on the selected vein, size of the inserted catheter, side of cannulation, site of cannulation, duration of electrical stimulation, and the intensity of stimulation) were assessed as secondary outcome parameters. Time needed for intravenous cannulation was registered in minutes, from applying the tourniquet in the control group or from applying electrical stimulation in the intervention groups, until an intravenous catheter was inserted successfully. Participant satisfaction, the pain score upon intravenous cannulation, and the practitioner satisfaction were measured on an 11-point verbal numeric rating scale (VNRS), with "0" representing no pain or totally not satisfied and "10" representing the worst pain imaginable or totally satisfied. The VNRS is a valid and reliable scale to measure pain intensity and satisfaction, although the VNRS evaluates only one component of the pain experience and pain intensity, or satisfaction.[23–25]

Statistical analyses

The Kolmogorov–Smirnov test assessed the normality assumption for continuous variables, which were expressed as mean and standard deviation. Those without normal distribution, on the contrary, were represented as median with the minimum and maximum value. Discrete variables were expressed as frequencies with percentages. The success rate was calculated as the number of successful first attempts divided by the total number of first attempts, and multiplied by 100%. The success rates of the intervention and control groups were compared visually first, and statistical analysis was performed afterward. Comparison of variables was performed using the chi-square test for testing categorical (discrete) unpaired measurements in more than two study groups; the one-way analysis of variance (ANOVA) test for unpaired, normally distributed, continuous variables in more than two study groups; or the

Table 1. Demographic data and baseline characteristics of the participants included in this study, divided into either one of three study groups.

	Control group Tourniquet ($N=45$)	Intervention group 1 Veinplicity® ($N=48$)	Intervention group 2 Veinplicity® + tourniquet ($N=48$)
Sex (male: female)	10: 35	27: 21	22: 26
Age (years)	52 ± 18	54 ± 16	55 ± 14
Length (centimeters)	168 ± 7	174 ± 10	174 ± 9
Weight (kilograms)	86 ± 25	88 ± 19	89 ± 24
ASA classification (ASA1: ASA 2: ASA 3: ASA 4)	10: 27: 8: 0	11: 19: 18: 1	10: 27: 10: 1
Smoking (yes: no)	10: 35	14: 34	12: 36
Alcohol abuse (yes: no)	5: 40	3: 45	2: 46
Drugs abuse (yes: no)	1: 45	2: 46	1: 47
Cardiovascular diseases (yes: no)	9: 36	12: 36	15: 33
Pulmonary diseases (yes: no)	4: 41	6: 42	3: 45
Renal failure (yes: no)	0: 45	3: 45	1: 47
Chemotherapy (yes: no)	7: 38	12: 36	8: 40
Diabetes mellitus (yes: no)	6: 39	7: 41	9: 39

Kruskal–Wallis test for unpaired continuous variables without normal distribution in more than two study groups. The Mann–Whitney U test was used to determine differences between two study groups, in addition to the Kruskal–Wallis or one-way ANOVA test. The relation between the success rate and participant demographics and the relation between the success rate and procedure-related data were detected with the use of Spearman's rho or Pearson's rho correlation analysis, based on the normality assumption for continuous variables. The RR for unsuccessful first attempts was calculated afterward and represented with 95% CI. Throughout the study, a p value less than 0.05 was denoted as statistically significant. SPSS, version 25.0 (SPSS Inc., Chicago, Illinois, USA), was used for all statistical analysis. The results of this non-randomized controlled trial are reported according to the TREND statement.[26]

Results

A total of 141 participants were included for final analysis in this study, divided over three study groups. The control group consisted of 45 participants, while 48 participants were included in both intervention groups 1 and 2. All three study groups were comparable with respect to the demographics and baseline characteristics of the included participants, as shown in Table 1.

The overall success rate of first attempt peripheral intravenous cannulation throughout this study was 86%, whereby success rates of, respectively, 78%, 88%, and 92% were observed in the control group (traditional approach), intervention group 1 (electrical stimulation), and intervention group 2 (electrical stimulation combined with a tourniquet) ($p=0.25$, $\chi^2=2.771$, $df=2$). A clinically relevant and statistically significant higher first attempt success rate was detected in participants in intervention group 2, when compared to the control group ($p=0.04$, $\chi^2=4.63$, $df=1$). On the contrary, no relevant and significant difference was observed in intervention group 1 in comparison to the control group ($p=0.23$, $\chi^2=1.97$, $df=1$) with respect to the first attempt success rate, and between both intervention groups ($p=0.50$, $\chi^2=0.45$, $df=1$). A median number of 1 attempt was needed to achieve successful intravenous access in all three study groups ($p=0.24$, $H=2.89$, $df=2$). The RR for a failed first attempt of peripheral intravenous cannulation was 2.1 (1.0–4.8) in the control group, with a first attempt failure rate of 22% (12.3–36.5). The RR in intervention group 1 was 0.8 (0.3–2.0) with a risk of an unsuccessful first attempt of 12% (5.5–25.1), while the RR and failure rate on the first attempt in intervention group 2 were 0.5% (0.2–1.4) and 8% (2.8–20.1).

Differences in stimulation time ($p=0.09$, $U=925$, $Z=-1.69$) and intensity of stimulation ($p=0.66$, $U=1095$, $Z=-0.44$) could not be detected between both intervention groups in which electrical stimulation was used. The diameter of the dilated target vein was, on the contrary, increased significantly in participants from intervention group 1 ($p=0.03$, $U=731$, $Z=-2.78$) and intervention group 2 ($p=0.01$, $U=635$, $Z=-3.43$) when compared to the control group, although there was no significant difference between these two intervention groups ($p=0.35$, $U=1027$, $Z=-0.94$). Despite, no clinically relevant difference could be objected in dilated vein diameter between the control group, intervention group 1, and intervention group 2, with diameters of, respectively, 3 (1–5), 3 (1–8), and 3 (1–7) mm. Other data related to either the procedure of peripheral intravenous cannulation or regarding the applied intervention throughout the study were comparable between the three study groups, as represented in Table 2.

A known history of a difficult intravenous access correlated positively with the outcome of interest ($p=0.01$,

Table 2. Data related to the procedure of intravenous cannulation, divided into either one of three study groups.

	Control group tourniquet (N=45)	Intervention group 1 Veinplicity® (N=48)	Intervention group 2 Veinplicity® + tourniquet (N=48)
Successful first attempt (yes: no)	35: 10	42: 6	44: 4
Success rate on the first attempt	78%	88%	92%
Total number of attempts	1 (1–4)	1 (1–6)	1 (1–3)
Duration of stimulation (minutes)	N/A	5 (3–11)	5 (2–12)
Intensity of stimulation	N/A	6 (4–9)	6 (3–8)
Expectation of difficult intravenous access (yes: no)	8: 37	11: 37	8: 40
Difficult intravenous cannulation in the past (yes: no)	10: 35	11: 37	10: 38
Palpable vein (yes: no)	37: 8	41: 7	43: 5
Visible vein (yes: no)	44: 1	41: 7	44: 4
Diameter of the vein (millimeters)	3 (1–5)	3 (1–8)	3 (1–7)
Side of cannulation (left: right)	12: 33	13: 35	14: 34
Place of cannulation on the extremity (dorsum of the hand: lower arm: elbow crease)	38: 7: 0	34: 9: 5	42: 4: 2
Size of the inserted catheter (22: 20: 18: 16 gauge)	5: 27: 11: 2	0: 29: 19: 0	1: 25: 21: 1
Time to successful intravenous cannulation (minutes)	3 (1–8)	4 (3–13)	4 (3–15)
Pain score (11-points VNRS)	3 (0–8)	2 (0–8)	3 (0–9)
Patients satisfaction (11-points VNRS)	7 (2–9)	8 (1–9)	7 (2–10)
Practitioners satisfaction (11-points VNRS)	8 (6–9)	7 (4–9)	7 (4–8)

VNRS: verbal numeric rating scale.
Diameter of the vein is represented as mean ± standard deviation. Number of attempts, duration of stimulation, intensity of stimulation, a participants pain score, a participants score for satisfaction, and the practitioners score for satisfaction are represented as median (minimum–maximum).

$\rho=0.23$). An inability to detect the target vein by palpating ($p<0.001$, $\rho=0.23$) or visualizing ($p<0.001$, $\rho=0.23$) the selected extremity, and the diameter of the dilated target vein ($p=0.04$, $\rho=0.18$), correlated positively with the outcome of interest as well. Any correlation between the other measured and recorded variables could not be obtained, assuming that the outcome measure was not biased by any of these factors. Adverse events (such as skin irritation, inflammation, and skin burns or local erythema of the skin), related to the intervention, were not registered during the study period.

Discussion

This study proved the effect of electrical stimulation on the first attempt success rate of peripheral intravenous cannulation in patients at moderate risk of a difficult intravenous access. When compared to the traditional technique of palpating and visualizing the extremity after applying a tourniquet, the first attempt success rate increased by 10% up to 88% when electrical stimulation was used. Moreover, the success rate was even higher when the device was combined with a tourniquet, resulting in a first attempt success rate for peripheral intravenous cannulation of 92%.

The baseline first attempt success rate for peripheral intravenous cannulation using the traditional approach, regardless of a participants risk profile on the A-DIVA scale, was 83% in a previous study.[11] Of the participants with a moderate risk profile according to the A-DIVA scale from that study, 63% of patients suffered a failed first attempt.[11] Participants in that study with a low or high risk profile according to the A-DIVA scale had a first attempt success rate, on the contrary, of, respectively, 95% and 7%.[11] In this study, focusing only on participants with a moderate risk profile on the A-DIVA scale, participants had a baseline success rate of 78% when using the traditional technique, which was slightly higher when compared to the previous study by Van Loon et al.[11] As the circumstances regarding peripheral intravenous cannulation with the traditional approach were not changed or improved in the period between the previous and current studies, this increase in baseline success is considered by the researchers to be coincidental. In addition, the sample size of participants included in the control group was considerably smaller when compared to the total cohort of participants in the moderate risk group in that previous study.[11]

The first attempt success rate rose above the level of 90% in the group of participants in whom electrical stimulation was combined with tourniquet use. Although this level of 90% was chosen arbitrarily, it seems to be a well-accepted level, especially for those suffering a moderate risk of a failed first attempt. This study was deliberately performed in participants at moderate risk only for several reasons. The success rate in participants at low risk according to the A-DIVA scale was already 95%, which was thought to be acceptable.[11] Compared to these low risk participants, additional techniques are strongly recommended

for those at moderate and high risk of a difficult intravenous access. In those participants with a high likelihood of a failed first attempt, identification of the target vein by palpating and visualizing the extremity remains hardly possible, even after applying venodilation techniques.[3,20] New techniques to make the target vein visible, like infra-red and ultrasound for instance, are supposed to be more appropriate techniques in this category of participants.[3,8,9,27] Nevertheless the deployment of medical devices, including the Veinplicity® device, should be decided on evidence-based guidelines and prediction scales.[21,28–30] Risk identification with the A-DIVA scale prior to peripheral intravenous cannulation can guide effective and efficient use of additional techniques for this medical procedure.[3,8,21] The application of electrical stimulation, when combined with tourniquet use, is an appropriate additional technique for peripheral intravenous cannulation and can be applied early and easily by different health care practitioners. Its usability in daily clinical practice and quick learning curve makes it particularly suitable in participants at moderate risk of a failed first attempt. Ultrasound, on the contrary, may be considerably more expensive for this group of participants due to higher device-related costs and the need for specialized trained staff.[3,31,32]

Venodilation is an important part of peripheral intravenous cannulation.[1,14,19,20] The odds ratio for an unsuccessful first attempt increased to 42.7 (22.9–79.7) when the target vein could not be detected by both palpating and visualizing the extremity, as a result of a previous published study.[11] Several techniques have been developed and were part of research projects in the past decades, including local warming and tourniquet application.[1,19,20,33] Yamagami et al. concluded in a previous study that local warming may be an effective and practical technique for venodilation for peripheral intravenous cannulation.[1] To add on this, tourniquet application after local warming of the forearm resulted in a significant increased cross-sectional area of the vein, when compared to tourniquet application alone.[33] Furthermore, the combination of local warming and tourniquet use appears to be safe, and without adverse effects for the participant.[33] Topical application of nitroglycerine 4% ointment in combination with local warming also decreased the number of cannulation attempts and facilitated the insertion of an intravenous catheter.[34] However, topical nitroglycerine acts systematically and therefore requires considerably longer to produce venodilation than local heating, as stated by Lenhardt et al.[34] Other techniques, like vein tapping or keeping the extremity down, seem to be effective as well, but were not applied throughout this study. The study was performed in participants receiving a short peripheral intravenous catheter solely, which was inserted according to routine treatment, in which only the technique to create venous dilation was changed.

The Veinplicity® device, on the contrary, is a neuromuscular electrical stimulator that causes muscle contraction either by activating the muscle itself (direct) or the nerve supplying a muscle group (indirect).[35] A physiological response to muscle contraction is an increase in blood flow with an increased diameter of the veins on the stimulated extremity.[35] Although no clinically relevant difference was observed in the diameter of the vein between the three study groups, it is significant that the combination of electrical stimulation with tourniquet usage resulted in the best results. As expected by the researchers, applying a tourniquet after a decent period of electrical stimulation maintains the effect, as the increased blood volume is held in the veins of the extremity.

Despite the predominantly positive result of this study, the increased blood volume and its effect should be quantified in further studies, for example, with venous occlusion plethysmography.[36] This also applies to the stabilizing and vein wall thickening effect of Veinplicity® use, which could not be demonstrated in this study. Further research should subsequently focus on identification of risk factors and prevention of failed intravenous cannulation.[8,11,37,38] The impact of the combination of electrical stimulation with other venodilation techniques, such as local warming or nitroglycerine use, on the success rate of peripheral intravenous cannulation and target vein characteristics should be the subject of further research projects as well.[1,19,20,33,34] Furthermore, unidimensional and validated prediction scales should be created in order to classify those participants at risk of failed attempts of intravenous cannulation prospectively. Guidance on the application of additional technical devices, such as the Veinplicity® device or ultrasound, can be based on these prediction scales. This will guide the practitioner on the appropriateness and timing of the deployment of different devices, for different degrees of risk of failed intravenous cannulation, ultimately resulting in more effective and efficient use of these techniques.

Limitations

A limitation to the study concept and design was the lack of randomization. An optimal allocation procedure attempts to minimize the variance of the estimated treatment effect in the presence of covariates.[39,40] Allocation bias can be induced by a lack of randomness in the treatment allocation.[39] In an attempt to deal with this risk of bias, stratified permuted blocks were created, in which participants were treated in consecutive groups. An advantage of the use of permuted blocks is the consistent control of treatment imbalance within each stratum, although permuted block stratification and treatment in consecutive groups lacks treatment allocation randomness and is therefore vulnerable to selection bias.[39] Another issue that can have possibly influenced the study results is the presence of the Hawthorne effect. The Hawthorne effect is a prevalent observer effect that causes behavioral changes among

practitioners because they feel they are being observed or merely participating in an experiment.[41–43] This phenomenon can both provide insight into individuals' behavior and confound the interpretation of experimental manipulations.[41–44] In this study, participants were only included if they had moderate risk according to the A-DIVA scale, creating a possible awareness of difficulty upon peripheral intravenous cannulation by the practitioner. This could have resulted in more attention to the procedure, which can explain the higher success rates upon the first attempt when compared to a previous study.[11] Blinding of the treatment applied to the participant could have dealt with the problem of the Hawthorne effect.[41,42] Nonetheless blinding of treatment for both the participant and the practitioner was not possible, unfortunately.

Conclusion

In conclusion, as a result of this study, we found that the first attempt success rate increased with the use of the Veinplicity® device in participants at moderate risk of a difficult access of peripheral intravenous cannulation, as calculated with the A-DIVA scale. However, the increase of the first attempt success rate was only clinically relevant when electrical stimulation was followed by the application of a tourniquet.

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Author Contributions

Fredericus HJ van Loon is the main investigator and involved in study conception and design, generated the protocol, and administrated it at the institutional review board, drafting of the manuscript, analysis, and interpretation of data. Freek JP Willekens helped collecting data and critical revision of the article. Marc P. Buise helped in critical revision of the article. Hendrikus HM Korsten helped in critical revision of the article. Arthur RA Bouwman generated the protocol and administrated it at the institutional review board, and helped in collecting data and critical revision of the article. Angelique TM Dierick-van Daele helped in critical revision of the article.

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Trial registration

Dutch Trial register (NTR) registration number: NTR7150, http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=7150

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