DOI: https://doi.org/10.5114/ait/208286

Ultrasound-assisted peripheral venous cannulation in patients undergoing elective surgery under general anaesthesia: prospective randomized trial

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Abstract

Background: Peripheral venous catheter (PVC) insertion is a common intervention, conventionally performed using visualization and palpation techniques. It has been reported that the first attempt success rate can be as low as 51%. Ultrasound guidance improves the overall success rate and the success rate of the first attempt. Therefore, we performed a randomized, prospective, clinical trial to compare two different techniques of PVC insertion in the setting of an operating theatre with a focus on the first attempt success rate.

Methods: This clinical trial allocated patients scheduled for elective surgery in general anaesthesia to undergo PVC cannulation with ultrasound guidance (Group A) or to undergo PVC cannulation without the use of ultrasound (Group B).

Results: A total of 613 adult patients were enrolled. The success of the first cannulation attempt was significantly higher in Group A compared to Group B (Group A: 90.6%, Group B: 84.5%, $P = 0.039$). The overall success rate in both groups was 100%. The time needed to perform PVC cannulation was significantly lower in Group B than Group A (Group A: 406 ± 200 s, Group B: 301 ± 215 s, $P < 0.001$).

Conclusions: We found that ultrasound-guided PVC cannulation was associated with a higher first-attempt success rate than the conventional technique.

Key words: anaesthesia, peripheral venous catheter, ultrasound-assisted cannulation.

Anaesthesiol Intensive Ther 2025; 57: e219–e225

Received: 15.09.2024, **accepted:** 15.07.2025

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Peripheral venous catheter (PVC) insertion is one of the most common interventions in medicine. It is also an essential part of the patient's preparation for elective surgery unless the insertion of a central venous catheter is required. Conventionally, the visualization and palpation technique of insertion is used. However, it has been reported that the success rate of the first puncture using this method can be as low as 51% in various settings and that 3 or more punctures may be required in up to 7% of patients [1]. Unsuccessful attempts to insert a PVC in patients undergoing surgery prolong patient preparation and increase patient stress and discomfort before surgery. A way to increase the success rate of the first cannulation attempt is ultrasound (US) guidance or assistance in patients with or without predicted difficult PVC insertion [2]. A recent significant improvement in ultrasound technology made it possible to use this method nearly everywhere. It has been shown that, in the setting of the emergency department, the ward, and pre-hospital emergency medicine, ultrasound guidance or assistance improves the overall success rate and success rate of the first attempt, and may reduce the total number of necessary attempts in different patient populations [1–5].

However, the method of ultrasound-assisted PVC insertion has not been evaluated in the environment

of an operating theatre yet in a non-selected patient population. Therefore, we decided to perform a prospective randomized clinical trial to compare the conventional method and ultrasound-assisted method for peripheral venous cannulation in patients undergoing surgery in general anaesthesia. The aim of the trial was to assess the superiority of US assisted PVC insertion over conventional technique. We hypothesized that there is a statistically significantly higher success rate on the first attempt when the ultrasound assistance method is used in comparison with the conventional method.

METHODS

We conducted a prospective randomized controlled unblinded clinical trial on adult patients scheduled for elective surgery in general anaesthesia indicated for PVC placement in the operational theatre. The trial was approved by the local ethical committee (Ethics Committee, Masaryk Hospital Usti and Labem, Czech Republic, reference code 290/13). The study was conducted following the Declaration of Helsinki and good clinical practice. All patients or their legal surrogates agreed to be included in the clinical trial and signed a written informed consent form. The trial has been registered with the number NCT05119985 at https://clinicaltrials.gov/study/NCT05119985.

Trial design

After obtaining informed consent, patients were randomized to one of the two predefined groups in a 1 : 1 ratio. The randomization was done as part of the pre-anaesthetic examination. This examination was minimally three weeks before the surgery. In Group A, the further intervention was the insertion of a PVC using ultrasonographic assistance, whereas, in Group B, cannulation was performed using the conventional visualization and palpation technique. The procedure of cannulation was carried out in the operating theatre, immediately before the surgery. The indication, the procedure of cannulation and the maintenance of PVC were conducted according to the international ERPIUP consensus [6].

Standard PVCs, with a gauge size from 16 G up to 22 G and a length of 32 mm, were used in both groups. The Sonosite SII-VA (Bothell, Washington, USA) probe was used with a Fujifilm Sonosite PX ultrasound machine (Bothell, Washington, USA) for ultrasound-assisted cannulation in Group A.

The target vein was selected according to the protocol: the upper arm basilic vein, upper arm cephalic vein, or median cubital vein as the first choice; the lower arm basilic vein or the lower arm cephalic vein as the second choice; the rete venosum dorsale manus was selected as the third choice. However, the final decision was made by the investigator based on individual assessment of the possibility of cannulation in a given cannulation site, including the selection of the right or left upper limb. After selecting the target vein, the cannulation was performed as described below. If the first cannulation attempt was unsuccessful, at least two more attempts were performed in both groups. If even those were unsuccessful, further attempts were allowed according to the investigator's decision, or an alternative procedure (including ultrasound guidance in Group B) could be used. If all cannulation attempts failed, alternative approaches were used for securing vascular access.

The duration of the trial intervention was measured using a Decathlon Kalenji ONstart 110 stopwatch (Villeneuve d'Ascq, France). The measurement began with the start of the cannulation attempt and stopped when the sterile covering of the inserted cannula was finished, or when cannulation attempts were terminated due to failure. In all enrolled patients, the modified A-DIVA score was used for evaluating the difficulty of peripheral venous access [7].

Patients' enrolment

All patients included in the trial were admitted to the Masaryk Hospital in Usti nad Labem, Czech Republic for elective surgery. This is a tertiary hospital in the North Bohemian region. Eligible participants were enrolled from the 1st of December 2021 to the 15th of December 2022. The inclusion criteria were an adult patient scheduled for elective surgery under general anaesthesia, an indication for PVC insertion, and a signed informed consent form. The exclusion criteria were as follows: unconsciousness, age < 18 years, primary indication for central venous catheter placement, contraindication of an ultrasound examination, contraindication of peripheral venous cannulation on both upper arms (acute skin lesion, phlebitis, phlegmon, burns, frostbite, eczema, trauma, arteriovenous malformations, arteriovenous fistulas) and the patient's refusal.

Study interventions

In Group B, conventional PVC insertion was performed in accordance with the recent common practice without ultrasound or other guidance or assistance guidance except for visual and tactile identification of the target vein after proximal limb compression [8].

In Group A, the basic technique was the same as in Group B with added ultrasound assistance. After tourniquet placement in the middle of the upper arm, a display depth of 3.0 cm was set on an ultrasound device. Ultrasound scanning with the linear probe in the transverse orientation was used for target vein

identification. To differentiate the target vein from an artery, a compression test was used for each patient and assessed the pulsatility of an artery. The target vein was chosen taking into account the diameter and depth of the vein. Preference was given to the vein with the largest diameter of all those found and located preferably no deeper than 1 cm below the skin surface [9]. The optimal puncture site was chosen. Then, the cannulation was performed conventionally, without further help of ultrasound.

Competence of investigators

Twenty anaesthetist nurses participated in the trial as investigators and measured the data. All investigators met the local competence for obtaining peripheral venous access with or without ultrasound guidance.

Anaesthetist nurses were naive to ultrasound guidance methods prior to the trial but were highly experienced in the conventional method. Each had performed more than 2000 peripheral venous cannulations in the setting of an operating theatre – an assumption based on the years of experience. One month before patient recruitment started, all investigators took part in a course that aimed to provide the necessary theoretical and practical background for ultrasound-assisted peripheral venous cannulation. All investigators attended 2 hours of theoretical and 2 hours of practical hands-on courses, 2 hours of a course about anatomical areas on upper limb, a 4-hour long theoretical session with a discussion regarding the use of ultrasound for venous identification (Doppler imaging, pulsatility, compression test, most common mistakes in vein identification), and a 4-hour long practical course on ultrasound guidance for peripheral venous cannulation. The hands-on course focused on ultrasound-assisted peripheral venous access cannulation using the CAE Blue Phantom Branched 4 Vessel Ultrasound Training Block Model (CAE, Sarasota, Florida, USA). The four-hour practical session provided participants with the opportunity to perform ultrasound-assisted peripheral venous cannulation on patients undergoing general anaesthesia, all under the direct supervision of a course instructor. The course had an instructor–attendant ratio of 1 : 5.

The primary objective of the trial was to compare the success rate of the first attempt of PVC insertion into the superficial venous system of the upper extremities in an operating theatre in patients undergoing surgery in general anaesthesia between the groups.

The secondary objective was to compare the overall peripheral venous cannulation success rate, the number of attempts required for securing peripheral vein access, the time needed for PVC placement, and the functionality of the catheter the day after insertion.

Statistical analysis

A sample size of 498 subjects was calculated to identify a 20% difference in the primary outcome between the two groups with 90% power with a cut-off for statistical significance of $P = 0.05$. The mean values ± standard deviation (SD) or percentages were calculated as necessary. Patients were randomized by Study Randomizer Software Application 2017, Available at: https://www.study-randomizer.com. Differences between groups were compared using the χ^2 test, and statistical significance was calculated by the Fisher exact test for alternative variables. For ordinary variables, the Mann-Whitney *U* test was used to calculate statistical significance. Statistical significance for continuous variables was determined by the paired Student *t*-test. The data were analysed using Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) and JMP 3.2 statistical software (SAS Institute, Cary, NC, USA). A *P*-value less than 0.05 was considered statistically significant. Subgroups, predicted difficult PVC insertion, non-predicted difficult PVC insertion, one attempt for successful PVC insertion and multiple attempts for successful PVC insertion, were identified and statistically compared during post hoc analysis.

RESULTS

A total of 837 patients were assessed for eligibility. A total of 613 subjects were randomized to two groups equally. There were 61 patients in Group A and 49 patients in Group B who did not receive the allocated intervention because of surgery cancelation due to the COVID-19 pandemic outbreak. See Figure 1 for a diagram of the enrolment process.

The baseline demographic data and clinical characteristics of the patients in the groups are presented in detail in Table 1. There were no statistically significant differences in demographic and clinical characteristics between the patients in the groups and patients excluded due to the COVID-19 pandemic outbreak.

The success rate of the first cannulation attempt was significantly higher in Group A compared to Group B (Group A: 90.6%, Group B: 84.5%, $P = 0.039$). Both groups achieved a 100% overall success rate, with no cases requiring a change of the cannulation method beyond the randomized intervention. We did not observe a statistically significant difference in the total number of cannulation attempts performed per patient in Group A compared to Group B (Group A: median 1, Q1 = 1, Q3 = 1, Group B: median 1, Q1 = 1, Q3 = 1, interquartile range in both groups 0,

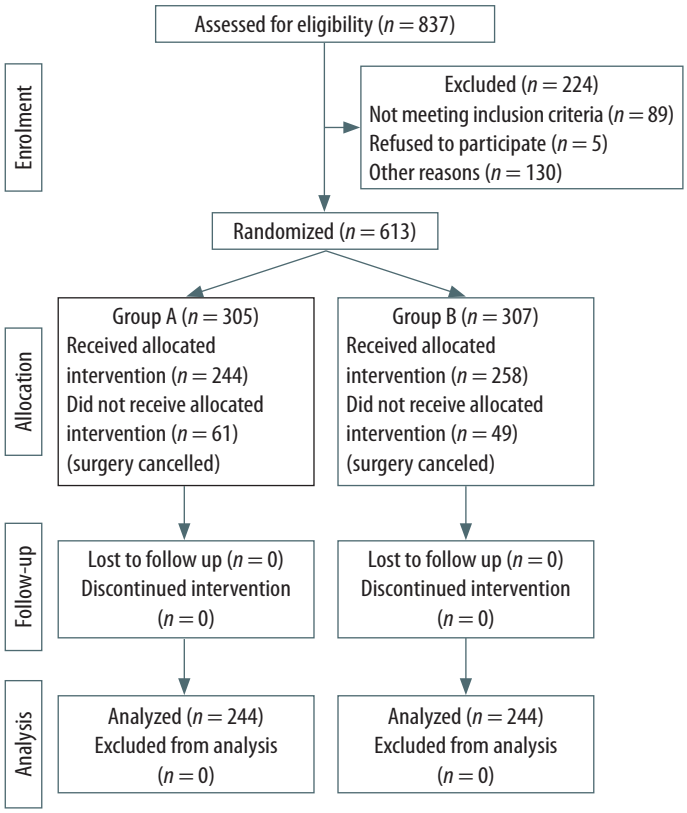

FIGURE 1. Diagram of enrolment process

$P = 0.117$). The time required for the procedure regardless of the number of attempts was significantly longer in Group A than in Group B (Group A: 406 ± 200 s, Group B: 301 ± 215 s, $P < 0.001$). We did not observe a statistically significant difference in functionality of the catheter on the day after insertion, as the functionality was in both groups 100% at that time. For details see Table 2.

The mean score of predicted cannulation difficulty was comparable in both groups (Group A: 0.6, Group B: 0.7, $P = 0.267$).

There were no statistically significant differences between the groups in the selection of the cubital and distal part of the forearm as the target cannulation site. In Group A, the median cubital vein was cannulated in 32.8% of cases, compared to 31.4% in Group B ($P = 0.737$). The basilic vein was cannulated in 52.5% of cases in Group A and 46.1% in Group B ($P = 0.152$). The cephalic vein was cannulated in 14.7% of cases in Group A and 22.5% in Group B, with a statistically significant difference ($P = 0.025$).

There were no cannulation attempts on the rete venosum dorsale manus in either group.

In post hoc analysis of the subgroup of patients in whom only one attempt was sufficient for PVC insertion, we found that the time required for the procedure was longer in Group A ($n = 221$) than in Group B ($n = 217$) (Group A: 377 ± 152 s, Group B: 246 ± 138 s, $P < 0.001$).

In the post hoc analysis of the subgroup of patients who required more than one attempt to successfully insert the PVC, we identified a comparable number of attempts in both groups (Group A: median 2, Group B: median 2, interquartile range 0, $P = 0.409$), as well as the time required to successfully insert the PVC (Group A: 691 ± 342 s, Group B: 601 ± 301 s, $P = 0.283$). We found no significant difference in the proportion of different cannula sizes used between the groups.

Upon analysing the subgroup of patients predicted to have difficult cannulation and those predicted to have non-difficult cannulation, we found that the difference in the success rate of the first cannulation attempt was in favour of Group A in both subgroups, but it did not reach statistical significance. The findings are presented in detail in Table 3.

The estimated effect sizes for the trial outcomes were small, as indicated by Cohen's *d* values below 0.2.

DISCUSSION

Peripheral vein cannulation is an intervention that is performed in the case of nearly every patient undergoing any type of anaesthesia. The reported first-attempt success rate in different in-hospital clinical settings may be as low as 51%, and in up to 7% of cases, three or more attempts are needed to successfully perform peripheral vein cannulation [1, 4, 5]. Paradoxically, to our best knowledge, there are insufficient data for cannulation in the operating theatre setting.

However, great emphasis should be placed on the success of first-attempt cannulation in this setting to optimize workflow, reduce patient discomfort, and limit the number of punctures as potential sources of bleeding. There are several methods to increase the first attempt success rate of the procedure [10, 11]. The generally accepted one is ultrasound navigation [12]. Published clinical trials in an adult and paediatric population are characterized by a similar design and definition of the specific clinical setting in which the studies were conducted (emergency department, pre-hospital setting, in-hospital ward) [2, 4, 5, 8, 13, 14].

Most of the trials were conducted on patient populations with anticipated difficult or moderate peripheral venous access. Van Loon *et al*. [3] published a meta-analysis of eight clinical randomized trials, with a total of 1660 patients, showing the overall success rate in the ultrasound group to be 81% and 70% in the control group, with an odds ratio for success associated with ultrasound guidance of 2.49 (95% confidence interval [CI]: 1.37–4.52, $P = 0.003$). Moreover, reduction of the number of puncture attempts and the time needed

TABLE 1. Demographic data and clinical characteristics of patients in the groups

	Group A	Group B	*P*
Demographics			
Age (years), mean ± SD	54.2 ± 16.0	56.6 ± 18.0	0.116
Men/women (*n*/*n*)	138/106	156/102	0.374
Body mass (kg), mean ± SD	83.6 ± 16.0	85.2 ± 18.2	0.280
Body height (cm), mean ± SD	173.5 ± 8.2	173.9 ± 11.2	0.643
Medical history			
Diabetes mellitus (%)	12.7	14.3	0.592
Arterial hypertension (%)	38.1	45.7	0.084
Coronary artery disease (%)	8.6	8.1	0.850
Congestive heart failure and/or valvular disease (%)	6.1	2.3	0.032
Cerebrovascular disease (%)	2.9	5.8	0.107
Renal disease (%)	4.5	5.4	0.636
Chronic pulmonary disease (%)	13.9	16.3	0.464
Chronic liver disease (%)	1.2	1.5	0.759
Endocrine disease (%)	5.3	2.7	0.134
Oncological disease (%)	19.7	29.5	0.011
Clinical characteristics			
ASA physical status score (%)			
1	32.0	26.0	0.077
2	49.6	47.3	
3	18.0	24.8	
4	0.4	1.9	
> 4	0	0	
A-DIVA score (mean)	0.6	0.7	0.267
Type of surgery (%)			
Abdominal	10.2	10.1	0.950
Vascular	4.5	3.9	0.724
Neurosurgery	17.2	11.2	0.055
Traumatology	19.7	19.0	0.847
Gynaecological	12.7	8.1	0.093
Stoma surgery	7.0	4.6	0.266
Orthopaedic	1.2	2.3	0.355
Urologic	7.4	15.2	0.007
Other surgery	19.7	25.6	0.114

to achieve overall success and a trend of increasing success rates with the first puncture attempt were documented [2, 3]. The largest randomized clinical trial was completed by McCarthy *et al*. [11] on 1189 emergency department patients. In the patients with anticipated difficult or moderately difficult access, ultrasound guidance was associated with an increased success rate, while in the easy access group, it was not. In a recent randomized clinical trial completed by Skulec *et al*. [2] in 2020, ultrasound guidance in the non-selected patient population was associated with an increased success rate. This clinical trial is the only one previously conducted on a non-selected patient population, like ours. In our study, we used the A-DIVA score to predict difficult peripheral vein cannulation; however, patients were not selected based on this evaluation [7]. Other studies provide only limited information, individually, for small numbers of participants.

TABLE 2. Results for primary and secondary outcomes

	Group A	Group B	*P*
First attempt success rate (%)	90.6	84.5	0.039
Overall cannulation attempt success rate (%)	100	100	
Number of cannulation attempts (median)	1	1	0.117
Time for PVC insertion (s, ± SD)	406 ± 200	301 ± 215	< 0.001
Functionality of the catheter 24 hours after insertion (%)	100	100	

In the clinical setting of the operating theatre, as in our trial, two studies have been published: one by Aponte [15] and the second by Pappas [16], both on a patient population with predicted different PVC insertion, which is a different population compared to that in our trial. An important aspect of our trial is that participants were not classified according to the anticipated difficulty of cannulation, and therefore data could be extrapolated to the general patient population. Both studies mentioned differ in the number of participants compared to our trial; thus, although their findings align with ours, they cannot be generalized.

Moreover, in the clinical trials conducted on patients with anticipated difficult or moderate venous access, different methods of anticipation were used.

In conclusion, published data have shown that ultrasound guidance or assistance may increase the success rate of PVC placement in the hospital ward, emergency department and operating theatres.

These findings are in concordance with our findings. The main finding of our trial was that the ultrasound-assisted insertion of a PVC in the general patient population scheduled for elective surgery in general anaesthesia was associated with a higher first-attempt success rate than the conventional method. This may be attributed to the enhanced visualization of vessel position and trajectory provided by ultrasound assistance. Moreover, with this information, the operator can select a more suitable vessel for cannulation. Benkhadra *et al*. [17] also reported a higher success rate at first puncture attempt (85% vs. 35%, $P = 0.001$) and a shorter procedure time (63.5 vs. 420.5 s, $P < 0.001$) when using ultrasound guidance in a general paediatric population.

The most common method of ultrasound guidance is based on vein visualization on its short axis and needle tip control until it reaches the centre of the vein [18]. Skulec *et al*. [2] compared two different ultrasound guidance methods – full ultrasound guidance and ultrasound alone – for finding the target vein with subsequent conventional PVC placement, and they found that the latter was non-inferior to the former. Based on this finding, we chose visualization of the vein on its short axis.

In the control group, the overall success rate did not differ from the interventional group and was consistent with predictions based on several clinical studies [1, 3–5]. The overall success rate was 100%. We attribute this high rate to two factors. First, all the patients enrolled in this clinical trial were elective patients, and second, all the operators participating in this clinical trial were skilful and routinely performed PVC insertions on a daily basis. Therefore, we cannot extrapolate our findings to professionals who are not trained in PVC insertion.

We found that the time needed to insert the PVC was statistically significantly longer when ultrasound assistance was used in the cohort in which only one attempt was needed. In the cohort where more than one attempt was needed to successfully insert the PVC, the time did not differ. We attribute this prolongation to the extra time needed to turn on the ultrasound machine. However, the prolongation seems not to be clinically important.

All procedures in our trial were performed in a single-operator manner. Therefore, the results support the option to delegate ultrasound-guided cannulation of a peripheral vein to nurses. This is particularly relevant to the European medical setting, in which ultrasound usage falls mainly within the physician's scope of practice. However, a sufficient level of training must be provided before the widespread implementation of this technique among nurses, who are typically inexperienced in ultrasound application.

We recognize several limitations of the trial. First, it is a single-centre trial, and therefore its generalizability is limited. Another limitation is the number of ultrasound machines available. During the trial there were seven ultrasound machines in the complex of nine operating theatres. Therefore, there was

TABLE 3. Comparison of outcomes between groups in patients with predicted difficult cannulation and non-difficult cannulation

	Predicted difficult cannulation			Predicted non-difficult cannulation		
	Group A ($n = 61$)	Group B ($n = 82$)	*P*	Group A ($n = 183$)	Group B ($n = 176$)	*P*
Success of the first cannulation attempt (%)	86.9	79.2	0.232	91.8	86.9	0.132
Time required for the procedure (s, mean ± SD)	432.8 ± 279	303 ± 251	0.008	398 ± 165	300 ± 197	< 0.001
Total number of cannulation attempts (number, median)	1	1	0.69	1	1	0.119

no issue in accessing the ultrasound equipment when needed. The results for centres with limited access to ultrasound may differ regarding the time needed for cannulation. Also, the trial did not include acute surgical patients. We did not include this group of patients for safety reasons to avoid any potential delay due to trial intervention. The trial did not include the paediatric patient population. The findings of our trial could therefore be extrapolated only to the adult population. We observed a significantly higher first attempt success rate than was anticipated. The higher first pass success rate in our trial compared to other trials was likely due to different settings. To our best knowledge, there have been no reported data of first pass attempt success rates in operating theatres in the general patient population. The final limitation we should note is the number of patients who were lost after randomization that was done three weeks prior to surgery. These patients were lost due to cancelation of their surgery because of the COVID-19 pandemic outbreak. During this outbreak, according to Czech law, all scheduled elective surgical procedures had to be cancelled to preserve the hospital capacity for emergency cases and to enhance the hospital's ability to care for patients with respiratory failure.

CONCLUSIONS

The results of our trial show that ultrasound guidance of peripheral vein cannulation in elective surgical patients in general anaesthesia increases the first attempt success rate in comparison with the conventional landmark method. Moreover, our trial shows that ultrasound guidance and selecting the left upper limb for peripheral cannulation improve the chance of successful peripheral vein cannulation on the first attempt. We consider the ultrasound guidance method for introducing PVC to be an effective and clinically relevant method for implementation in an operating theatre setting. We recommend structured training on this method before implementation in daily practice.

ACKNOWLEDGEMENTS

1. Assistance with the article: None.
2. Financial support and sponsorship: None.
3. Conflicts of interest: None.
4. Presentations of preliminary data: None.

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