



Ultrasound-Guided Peripheral Venipuncture Decreases the Procedure's Pain and Positively Impacts Patient's Experience: The PRECISE Randomized Clinical Trial

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ABSTRACT

This study aimed to compare patients' experience of pain during ultrasound (US)-guided peripheral venipuncture versus conventional peripheral venipuncture. This randomized clinical trial was conducted at a public university hospital in 2021. Adult patients with indication for intravenous therapy compatible with peripheral intravenous catheters (PIVCs) were included: intervention group (IG), US peripheral venipuncture executed by specialist nurses; control group (CG), conventional peripheral venipuncture executed by clinical practice nurses. The primary outcome was patient experience of pain during the procedure and patient experience related to the PIVC placement method. Sixty-four patients were included, 32 for each group. The pain experienced was none-to-mild in the IG for 25 patients (78.1%) and moderate-to-severe in the CG for 21 patients (65.7%; $P < .001$). The overall pain rating was 2 (1-3) in the IG and 4 (3-6) in the CG ($P < .001$). The recommendation of the procedure in IG (net promoter score [NPS] + 90.6%) versus

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CG (NPS + 18.8%) was considered excellent and good, respectively ($P < .001$). Patients had less pain and significantly recommended the US-guided procedure. Patient experience with US-guided PIVC, performed by a specialist nurse, was superior to that of conventional peripheral venipuncture.

Key words: catheterization, intravenous, pain, patient experience, ultrasonography, vascular access team, venipuncture

BACKGROUND

To provide a better experience to patients in need of vascular access, technologies can be added to the adoption of good practices. Specialist nurses in vascular access teams (VATs) enable the addition of technologies, such as ultrasound (US), to improve success in the first venipuncture attempt and to promote positive experiences for patients.¹

The assessment of patient experience, especially under frequent invasive procedures, such as peripheral venipuncture, which might cause pain, can improve technical aspects of procedures and reduce unpleasant experiences.² This action is also related to the quality and improvement of hospital service.³⁻⁵

Studies showed that the pain felt by patients, classified through pain scales, was significantly lower in those in whom US was used for venipuncture compared with those subjected to the conventional method.⁶⁻⁸ This fact is sometimes associated with a higher success rate in the first venipuncture attempt of the device. Moreover, other studies showed that the rates of patient satisfaction with the procedure, scored according to the Likert scale, were higher for those subjected to US-guided venipuncture.⁹⁻¹⁴

A systematic review with meta-analysis aimed to compare the success rate of US-guided peripheral venipuncture with the traditional venipuncture.⁶ Publications from 2000 to 2017 (5 randomized clinical trials and 3 cohort studies) were included, totaling 1660 patients. The success rate in venipuncture was 81% ($n = 855$) in the group using US and 70% ($n = 805$) in the control group (traditional venipuncture). Only 1 study mentioned pain assessment.⁷ In this study, the group subjected to US-guided venipuncture scored lower (4.77 ± 1.74) than the control group (6.00 ± 1.98), which is a statistically significant difference ($t = 0.013$; $P = .013$). Of the 8 studies analyzed, 6 were performed in emergency departments, 1 in the operating room, and 1 in an intensive care unit. Both physicians and nurses performed the US technique.⁶

Results suggest that pain experience during the procedure may decrease with the US technique. However, its

evaluation must be considered according to what is important for patients. Using US to aid the peripheral venipuncture procedure may produce less pain and a better experience.^{8,11} The few available clinical trials were performed with patients in emergency or intensive care units^{11,12,15,16} under clinical conditions that hindered the effective assessment of patient experience regarding the chosen venipuncture technique. Moreover, these studies assessed patient experience as a secondary outcome.

Thus, to value the patient experience in relation to pain during the procedure and the peripheral intravenous catheter (PIVC) placement method used during hospitalization, this study aimed to compare the US-guided peripheral venipuncture performed by specialist nurses of a VAT with the conventional peripheral venipuncture (palpation/visualization) performed by clinical practice nurses.

METHODS

Study Design and Setting

This is a parallel, single-center, randomized controlled trial (RCT), blind for the outcome and data assessment. It was registered on ClinicalTrials.gov platform under NCT04853290. The methodological procedures followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.¹⁷

The study was conducted in 5 clinical inpatient units at a public hospital in southern Brazil from September to November 2021. The studied population was composed of clinical patients who required hospitalization for treatment with intravenous (IV) therapy and were referred for peripheral access venipuncture.

Participants

The participants recruited for the study were randomized into blocks of different sizes, stratified by age (a stratum comprising ages 18-59 years and 60 years or above) into 2 groups: the intervention group (IG) — receiving US-guided peripheral venipuncture by specialist nurses of the

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institutional VAT and the control group (CG) — receiving conventional peripheral venipuncture by the clinical practice nurses at these units.

Eligibility Criteria

Adult patients hospitalized due to clinical health conditions, aged 18 years or above, undergoing PIVC insertion for treatment other than emergency care were included. Patients who already received US-guided peripheral venipuncture during the current hospitalization; those who showed a critical or unstable clinical condition preventing them to consent to the study (eg, patients cared for by rapid response teams and/or clinical duty due to some hemodynamic/respiratory instability); those who had cognitive impairment hindering the understanding of the study; and clinical patients in COVID-19 care units were excluded.

Study Protocol and Procedures

Whenever hospitalized patients required a PIVC for proposed IV therapy, researchers were contacted by the assistance care team via a cell phone application informing them of potentially eligible participants' names, medical records, and beds. Patients who met the inclusion criteria were evaluated by the research team, informed of the goal of the study, and invited to participate. If accepted, the patients signed the informed consent form (ICF), and they were randomly allocated to one of the groups:

(a) IG: participants received PIVC guided by US, with the procedure performed by specialist nurses from the VAT. Either Site-Rite 8 or Site-Rite 5 US (Bard Access Systems Inc., Salt Lake City, UT) was used.

(b) CG: participants received conventional PIVCs, performed by the clinical practice nurses in their inpatient units.

In both groups of patients, venipuncture was performed according to institutional protocols of good safety practices. The PIVC, provided by the hospital, was selected according to vessel thickness and the purpose of therapy. Participants were submitted to up to 4 venipuncture attempts by 2 professionals (2 attempts per experienced nurse).¹⁸

Regardless of their groups, all participants were monitored from the moment the catheter was inserted until access was lost or the device was removed due to the end of therapy, discharge, death, or after 8 days of monitoring. This last criterion stems from the 2019 average 8.09-day clinical hospitalization rate at the institution studied.¹⁹ The PIVC dwell time longer than 8 days was computed as an event-free survival. In cases in which the venous access was lost for any reason before day 8 of follow-up, patients were monitored for another 48 hours to assess complications. In cases where there was procedure failure, participant treatments were not hampered, as the routine of the institution was followed with another appropriate vascular access device, and follow-ups up to 48 hours were performed to evaluate possible complications in venipuncture sites.

Participant data were collected via the following forms developed in the Research Electronic Data Capture (REDCap)²⁰ software: baseline data, insertion data, medication, patient experience (including net promoter score [NPS] and verbal numerical rating scale [NRS]) and daily monitoring for 8 days. In cases where there was procedure failure, the insertion failure form was applied; in case of participant exclusion, the excluded patient form was completed.

VAT and Clinical Practice Nurses

The nurses of the VAT are interventionists in this study. They joined the program 4 years ago and performed theoretical-practical training in the techniques (with a minimum of 50 successful guided venipunctures) and an 18-hour theoretical-practical training on ultrasonography.

Clinical practice nurses have distinct levels of professional experience in performing the conventional peripheral venipuncture technique. In this study, the nurses responsible for performing peripheral venipuncture procedures, with and without US guidance, did not receive extra training to standardize the techniques used; the research was conducted in accordance with the care processes in force at the institution, respecting good practice protocols.

Data Collection Team

The outcome evaluation was conducted by a team of collaborators composed of 3 undergraduate nursing students who had applied the forms and instruments for data collection blinded to the procedure performed (ie, the group to which the patient was allocated). The collection team had expertise in evaluating PIVC venipunctures and technical competence in care and its maintenance. The team was trained to ensure uniformity and agreement in outcome evaluation and instrument application.

ICF application, screening, and selection of eligible participants were performed by all members of this study. The researchers responsible for collecting follow-up and complementary data daily in medical records were blinded to patient allocation. The available data in electronic medical records were collected by researchers and collaborators to complement the pertinent information in the forms. Subsequently, data were fed into a database prepared in the REDCap software.²⁰

Outcome Measurements

The patient experience was evaluated considering 2 aspects: first, the pain felt during the peripheral venipuncture; and second, patient perception of the PIVC placement method used (with US by a specialist nurse or with conventional technique by a clinical practice nurse).

Primary Outcomes: Pain response during the procedure was evaluated via an 11-cm NRS ranging from 0 to 10, in which 0 refers to no pain and 10, the most intense pain ever experienced. Patient perception of the PIVC

placement method used was evaluated by NPS. The NPS metric is calculated based on responses to a single question: “How likely are you to recommend this procedure (to another person who may need it)?” There are 3 response categories: “promoters” (who would definitely recommend the procedure), “passives” (widely satisfied individuals who would refuse to recommend it), and “detractors” (actively discouraging others from trying the procedure).²¹

The NPS metric was applied to the patients in this study so they could recommend or not the usage of a technology associated with a frequent procedure. It is a simple and easy-to-understand tool for the consumer (patient) to express in a numerical way their experience about the received service. These quantifiable data can be used as indicators to allow better management of services with a view to quality, safety, and care results.

Secondary Outcomes: The first includes peripheral venous catheter dwell days. Intact, fixated, and functioning accesses without phlogistic signs in the venipuncture point were considered durable. The device was replaced following insertion site replacement guidelines only when complications were identified.¹⁸ The second includes complications that occurred during venous device dwell days (phlebitis, obstruction, extravasation, and infiltration), assessed via daily observational monitoring, according to the conceptual definitions of complications, and the phlebitis scale, according to models of the Infusion Nurses Society.¹⁸

Noncompliance With Protocol

The following were considered as noncompliance with the protocol: (1) randomly assigned patients who left the study at any time; (2) patients randomly assigned to the CG who received IG treatment; or (3) patients randomly assigned to the IG who received CG treatment. For the last 2 cases, participants were considered part of their originally randomized group until the end. This protocol followed the intent-to-treat principle. In case of insertion failure, venous access was approached with another method, in line with institutional guidelines for venous access as the feasibility of intravenous therapy.

Sample Size

Sample size was estimated to assess the 3.5-point difference in the verbal NRS between conventional and US-guided techniques, following the data in Sou et al,⁸ which showed an estimated standard deviation of 3 points, 90% power, and a .05 significance level. With a 20% increase in losses, 54 patients divided equally between 2 groups were required. The estimate was performed via the Winpepi software version 11.65. At the end of the study, 64 subjects were included: 32 in the IG and 32 in the CG.

Randomization, Allocation Concealment, and Blinding

A tool in the REDCap²⁰ software was used to generate age-stratified blocks of random sizes: a block of

hospitalized clinical patients aged 18 to 59 years and a block of hospitalized clinical patients aged 60 years and over. The strategy of random variation of block sizes was used to ensure allocation secrecy.²² Results researchers and statisticians were blinded to results and data analysis.

Statistical Analysis

Data were entered in the REDCap²⁰ database and analyzed via the SPSS version 21 (IBM Corp, Armonk, NY). The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess normality among the quantitative variables.

Symmetric continuous variables were described as mean and standard deviation and compared using the Student's *t*-test; asymmetries were described as median and interquartile range and were compared using the Mann-Whitney test. Categorical variables were shown as percentages and relative frequencies. The Fisher's exact test or Pearson χ^2 test were used to associate clinical characteristics of patients and devices with follow-up events. Groups were compared for device event-free dwell days by Cox analysis and log-rank test. A 2-tailed $P < .05$ was considered statistically significant.

Ethical Considerations

This study was approved by the institutional research ethics committee and registered on the Clinical Trials platform under the identification number NCT04853290. All participants signed an informed consent form.

RESULTS

Figure 1 shows the number of participants screened and considered eligible for the study, the number of those who were excluded, and the reasons. In total, 64 patients were randomly assigned: 32 in the IG and 32 in the CG. Three patients randomly assigned to the CG presented insertion failure and were referred to obtain venous access according to institutional flow.

Clinical, Demographic, and Procedural Characteristics

Table 1 shows the baseline characteristics of both groups. Most participants were women (51.5%) and white (87.5%), and the mean age was 56 ± 16 years. The clinical variables related to the Charlson Comorbidity Index and A-DIVA score were similar in both groups ($P = .258$ and $P = .579$, respectively). Among the variables related to the procedures, catheter dwell days was not different between groups, but the number of venipunctures (attempts performed beyond the single puncture) and duration of the procedure (in minutes) were shorter in the IG ($P < .001$).

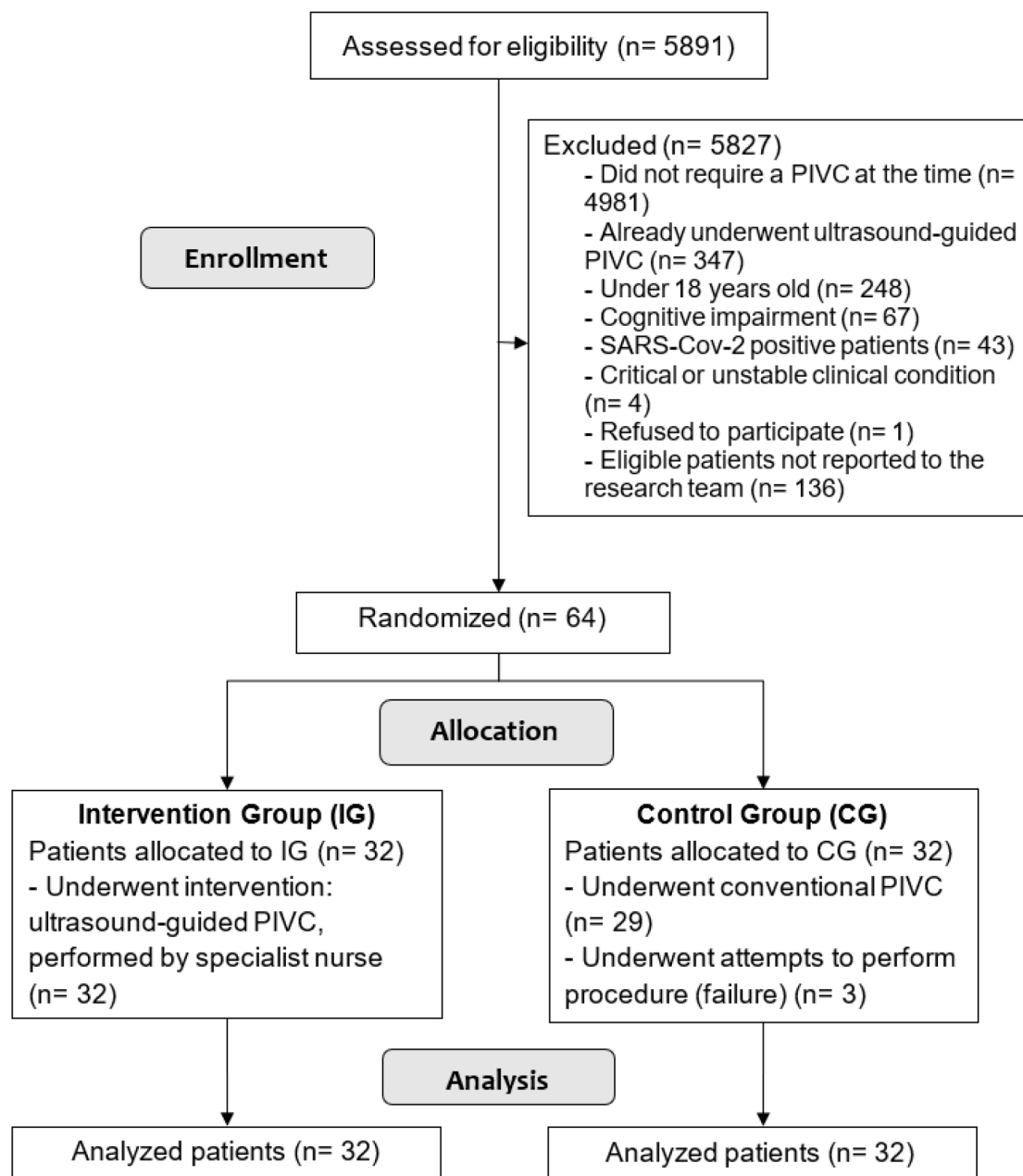


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram.

Patient Experience: Pain During the Procedure

The pain experienced by patients was assessed immediately after performing peripheral venipuncture. In Figure 2, the variable pain is categorized as none (score 0), mild (score 1–3), moderate (score 4–6), and intense (score 7–10). Most patients in the IG classified pain as “none” or “mild” (25 patients; 78.1%), but in the CG, the predominance was moderate-to-severe pain (21 patients; 65.7%; $P < .001$). The overall pain rating was 2 (1–3) in the IG and 4 (3–6) in the CG ($P < 0.001$). Patients in the IG (subjected to the US-guided peripheral venipuncture performed by specialist nurses) presented 67% less relative risk of perceiving moderate-to-severe pain (95% CI, 0.17–0.67).

Patient Experience: PIVC Placement Method Used

Patient experience in relation to the PIVC placement method was assessed by the NPS. Figure 3 shows the results of both groups (IG and CG). In the IG, 90.6% (n = 29) of participants were promoters, 9.4% (n = 3) were passive, and none were detractors. In the CG, 34.4% (n = 11) of participants were promoters, 50% (n = 16) were passive, and 15.6% (n = 5) were detractors.

The assessment of patient experience was considered positive in both groups. The recommendation in the IG (NPS + 90.6) versus the CG (NPS + 18.8) with $P < .001$ was considered excellent and good, respectively (Figure 4). Total NPS was calculated by subtracting the percentage of detractor

TABLE 1.

Clinical, Demographic, and Procedural Characteristics of Patients Subjected to Peripheral Venipuncture—Porto Alegre, 2021

Variables	Total n = 64 n (%)	IG (n = 32) n (%)	CG (n = 32) n (%)	P value
Age range ^a	56.2±15.7	56.5±16.7	55.8±13.8	.802 ^d
Sex ^b				.802 ^d
Women	33 (51.5)	16 (50)	17 (53.1)	
Men	31 (48.5)	16 (50)	15 (46.9)	
Ethnicity ^b				.229 ^d
White	56 (87.5)	26 (81.3)	30 (93.8)	
Other	8 (12.5)	6 (18.7)	2 (6.2)	
Charlson Comorbidity Index ^c		3 (1 – 4.75)	3.5 (2 – 5.75)	.258 ^e
A-DIVA score^b				
Low risk	24 (37.5)	10 (31.3)	14 (43.8)	
Moderate risk	15 (23.4)	8 (25.0)	7 (21.9)	.579 ^d
High risk	25 (39.1)	14 (43.8)	11 (34.4)	
Number of venipunctures^b				
Single	40 (62.5)	29 (90.6)	11 (34.4)	< .001 ^d
2 attempts	12 (18.8)	2 (6.3)	10 (31.3)	
3 attempts	5 (7.8)	1 (3.1)	4 (12.5)	
4 attempts	7 (10.9)	0 (0)	7 (21.9)	
Procedure time (min) ^a	9.5±6.7	6.3±3.4	12.8±7.7	< .001 ^e
Catheter dwell days ^c		3 (1.25 – 6.75)	3 (2 – 5)	.704 ^e

^aVariables expressed by mean ± standard deviation

^bVariables expressed by absolute number and percentage (%)

^cVariables expressed by median and percentiles 25 and 75

^dPearson χ^2 test

^eMann-Whitney test.

Abbreviations: A-DIVA, Adult Difficult Intravenous Access Scale; CG, control group; IG, intervention group; n, number of patients. Source: Research Data.

patients from the percentage of promoter patients (IG: NPS + 90.6 and CG: NPS + 18.8).

Complications During the Dwell Days of the Vascular Access Device

Groups presented no significant difference regarding complications (phlebitis, lesion, and infiltration) during the catheter dwell days. In the IG, 6 patients (18.8%) presented complications. In the CG, 2 patients (6.3%) presented complications ($P = .257$).

Relationship Between Pain and Number of Venipuncture Attempts

The most intense pain was related to more venipuncture attempts ($P = .012$), regardless of the group. Of the 64 patients, 40 (62.5%) required only 1 venipuncture attempt, and 24 (37.5%) received 2 or more venipuncture attempts. Among patients who received only 1 venipuncture,

70% reported no pain or mild pain. Among those who received more venipuncture attempts, 66.7% reported moderate or severe pain.

Relationship Between Procedure Recommendation and Number of Venipuncture Attempts

Of the 40 patients who received a single venipuncture, 34 (85%) were promoters (they would recommend the procedure; $P < .001$). Of the 24 patients who received 2 or more venipuncture attempts, 13 (54.2%) were passive and would not actively recommend the procedure.

DISCUSSION

This is the first randomized clinical trial performed with patients hospitalized for clinical conditions that assessed

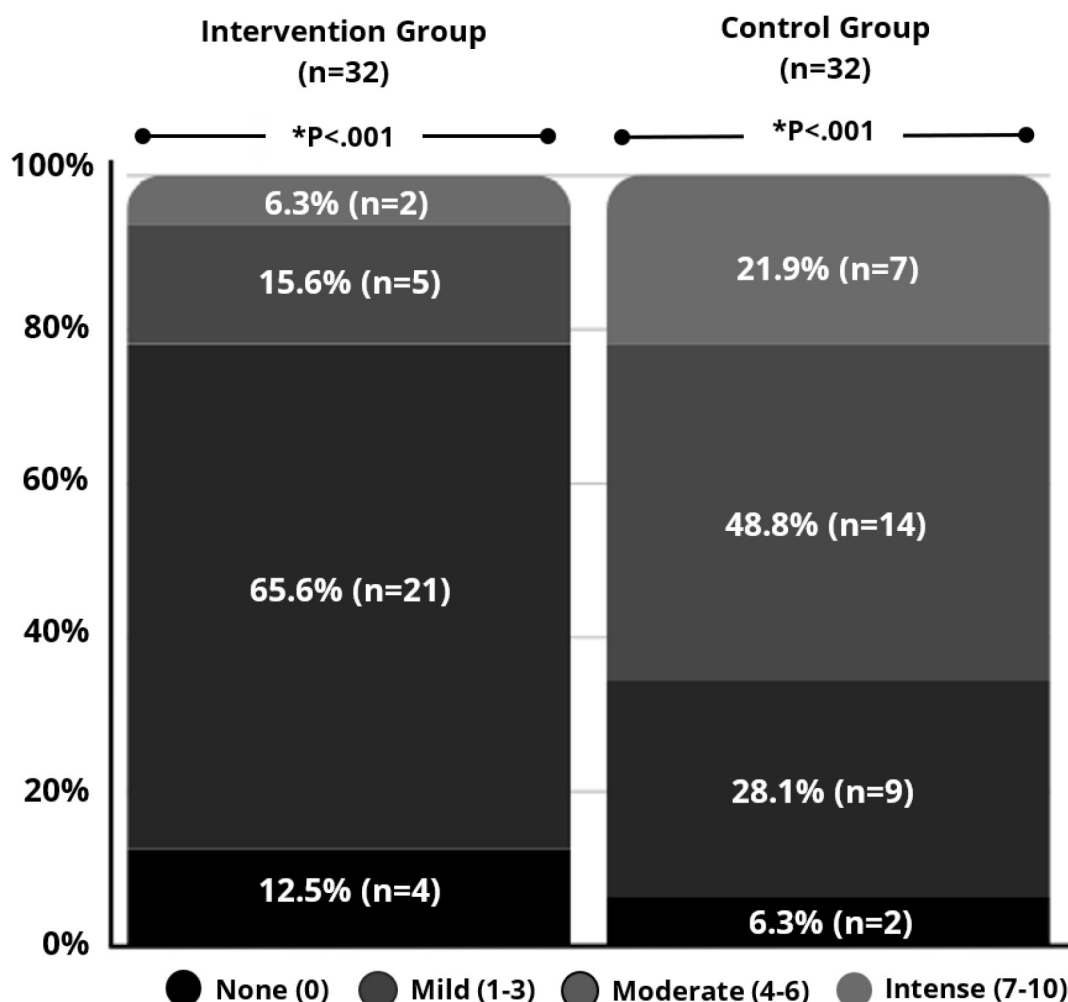


Figure 2. Pain experienced by patients during the procedure.

the hypothesis that US-guided peripheral venipuncture improves the patient experience (by reducing pain and optimizing the obtainment of venous access) when compared with traditional peripheral venipuncture. The main results showed that the intensity of pain experienced in the group subjected to the US-guided venipuncture performed by specialist nurses was significantly lower in comparison with the pain experienced by those who underwent conventional venipuncture. The 2 venipuncture methods used to obtain venous access were considered positive in patients' experience; however, the use of US stood out for obtaining excellent recommendations, while the conventional procedure obtained good recommendations.

The researchers assessed the patient experience as the main result of this study, with a comprehensive focus, trying to include aspects beyond patient satisfaction with the procedure. Moreover, to reach most hospitalized patients and cause a positive effect noticeable to them, this study was developed outside emergency or intensive care units, with patients able to be heard in relation to their perception of the study topic. The results agree with the prioritization

given to the topic of patient experience and may contribute to its development.

The NPS, a tool used to evaluate products and services based on the user experience, has gradually been introduced as a method to comprehensively measure the patient experience in health services.^{21,23} The use of this tool is still incipient, as it has been used to assess the patient experience in studies that address the follow-up after Achilles tendon rupture²⁴ and arthroscopic rotator cuff repair.²⁵ It has also been used to measure patient experience in community mental health services for older adults²⁶ and in patients with amyotrophic lateral sclerosis undergoing treatment for spasticity.²⁷

The authors used the NPS in this study so patients could analyze their peripheral venipuncture procedure. This is an appropriate tool to assess patient experience, but its exclusive application limits other inferences, such as why the patient did or did not recommend the procedure.

A better catheter insertion (as 90.6% of patients who underwent the US-guided and received a single venipuncture experienced) and shorter mean time to perform the procedure (due to the use of the device), associated with the positive results reported by patients, highlighted the

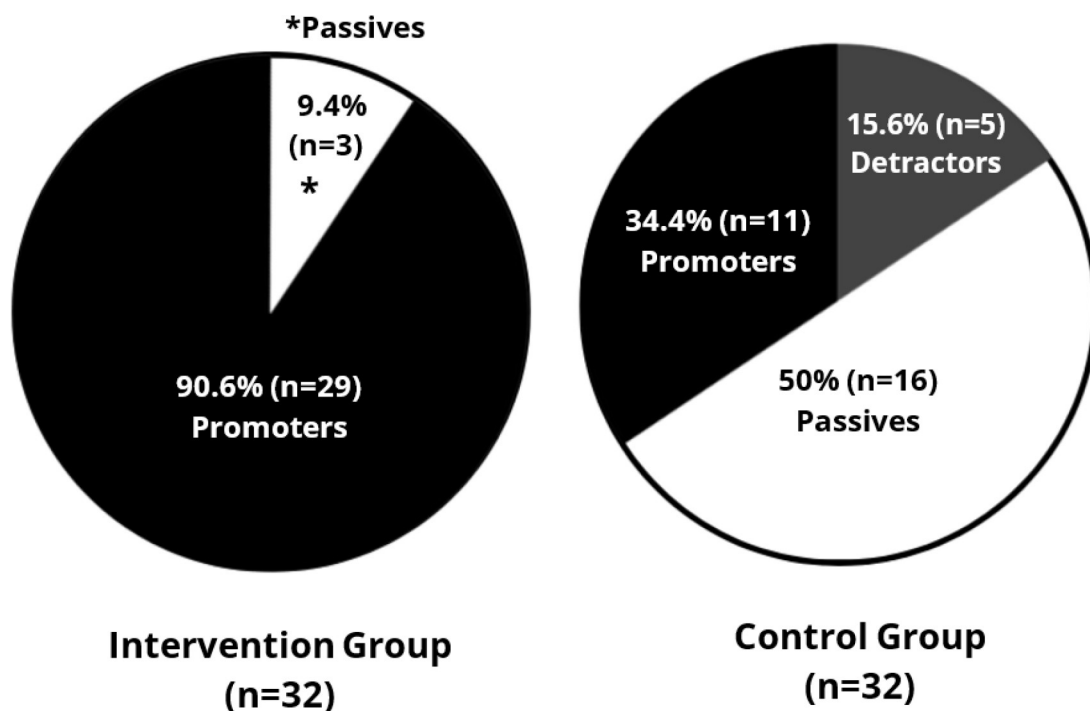


Figure 3. Patient recommendation of the peripheral intravenous catheter (PIVC) placement method.

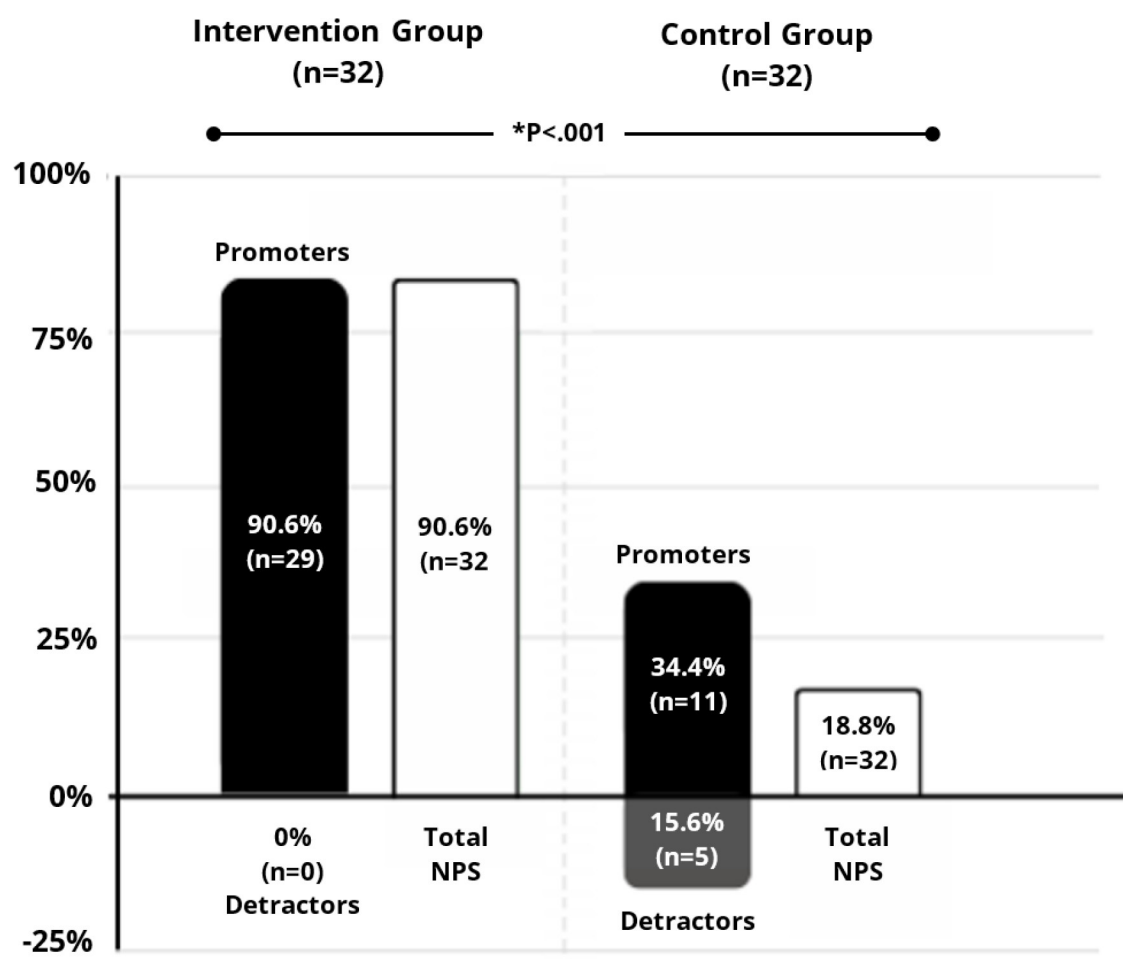


Figure 4. Net promoter score (NPS) calculated for each group.

importance of using the available technologies operated by specialist nurses. Adequate training, along with the experience of the US-guided procedure, proved to be an influence factor for success in the first insertion.^{11,12}

Studies have already shown that the use of US to guide peripheral venipuncture decreases the number of attempts by the professional.^{11,12} Multiple venipuncture attempts cause significant pain to patients and require more time and resources.¹¹ Moreover, the effect of several failures reduces the number of vessels available, causing exhaustion of peripheral venous access sites.¹⁶

Most studies comparing the traditional peripheral venipuncture and US-guided technique were performed with patients with difficult venous access.^{7,8,10-13} To maintain uniformity in terms of the characteristics of the venous network of patients, the researchers separated groups by age, considering that older adults are more susceptible to adverse events associated with intravenous therapy.

Performing this type of research in the clinical area is important, as it creates a scenario of patients with varied characteristics and comorbidities and a difficult venous network (often in the process of exhaustion), which require special care. The process of viability of the venous access and the administration of medications entails much more than nurses fulfilling a routine and expected venipuncture and considering that the work is completed. Since it is a frequent and common process, it deserves more attention and questions about how it is performed and how it affects the patient. Currently, professional practices are not always in accordance with the standards of care recommended in this area.

Incorporating technology, expert professionals, and processes to evaluate health resources and services may favor decision-making and improve patient outcomes regarding procedure performance, quality of care, risk reduction, resource efficiency, and improvement of the patient experience. Peripheral venipuncture is improved by using US, an available technology legally supported to be used by specialist nurses, improving the patient experience by increasing the insertion success rates, reducing pain, satisfying the emotional state of patients, and allowing them to recommend what they experienced. These aspects contribute to increasing patient satisfaction with the procedure.

STRENGTHS

This study has several strengths. First, it is an unprecedented RCT performed in the clinical area, which was developed to assess the patient experience as a primary outcome by comparing 2 methods of peripheral venipuncture. Second, it is a study performed in a real environment that underwent situations and provisions of everyday practice of the researched institution.

Moreover, the researchers obtained robust results in the assessment of the primary outcome using NPS, a tool

considered incipient in health care. This study also obtained positive results regarding the number of venipunctures and ease of insertion with the use of US. Even though these aspects were not considered main outcomes, data of both were in accordance with previous studies. These results can be linked to the quality of services and understood as institutional indicators.

Finally, the patient experience was positive regarding pain reduction and optimization of the PIVC placement method with the use of the US performed by specialist nurses. Giving voice and expression to patients, considering them the focus of care, is important, regardless of the scenario. The authors recommend returning patients to the decision-making and care improvement processes.

Using measurement tools alone can produce positive but limited results and causes little progress in advancing understanding. The association of more than one tool and open questions can improve results. Thus, the peripheral US-guided venipuncture performed by specialist nurses can be formalized as a gold-standard procedure regarding quality, safety, and positive patient experience.

LIMITATIONS

This study had some limitations. First is the lack of technical leveling among nurses in the CG. However, this is the real scenario of the institution and was recorded. All nurses must follow the protocols of the institution, especially after 2 unsuccessful venipuncture attempts. The second limitation is the lack of a validated tool to assess the patient experience regarding peripheral vascular access.

CONCLUSION

The results of this RCT show that the patient experience with US-guided peripheral venipuncture performed by specialist nurses was higher than that of patients subjected to the conventional technique.

Patients subjected to the US-guided procedure performed by specialist nurses presented less pain and significantly recommended its use. Participants from both groups positively recommended the 2 procedures, supporting their performance. The number of venipuncture attempts and time spent to enable venous access were lower in the group subjected to the US-guided procedure. The catheter dwell days and complications that occurred during the use of this device were similar in both groups.

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