Eficacia da venopunción ecoguiada en Atención Primaria. Ensaio aleatorizado en pacientes que requiran un segundo intento

Eficacia de la venopunción guiada por ultrasonido en Atención Primaria. Ensayo aleatorizado en pacientes en los que se necesita un segundo intento

Efficacy of ultrasound-guided venipuncture in Primary Care. Randomized trial in patients in whom a second attempt is needed

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SUMMARY

Objective: To compare the use of ultrasound-guided venipuncture with blood draw by an expert nurse in patients who need a second try.

Design: randomized clinical trial

Setting: Primary care center San Martí in Barcelona that serves 45,000 people.

Participants: of the 3791 patients with extraction on Monday from April to October 2017, we selected the 94 failures on the first attempt.

Methods: The second venipuncture was done either by an expert nurse, or guided by ultrasound. We collected barely palpable veins, self-perception of "bad veins", fear of extraction, and ultrasound characteristics of the vessels. Pain and patient satisfaction were assessed using a Likert scale, side effects the next day.

Results: Obese patients were overrepresented in the intervention group (61.9% vs 36.2% p = 0.015). No differences were found in the median(IQR) of attempts 2 (2-3) vs 2 (2-2) p = 0.127), pain or satisfaction with both procedures (p = 0.122). There were fewer bruises in the intervention group (16.67% versus 25.53%, p = 0.531).

Conclusion: In primary care, the use of ultrasound did not affect the number of venipuncture attempts compared to the usual technique performed by an expert nurse. There were no differences in patient satisfaction or complications.

Keywords: Peripheral, Injections, Intravenous, Nursing practice, Ultrasonography, Venipuncture, Randomized control trials

RESUMO

Obxectivo: comparar o uso da venopunción guiada por ultrasóns coa recollida de sangue por parte dunha enfermeira experta en pacientes que precisan un segundo intento.

Deseño: ensaio clínico aleatorizado

Entorno: Centro de atención primaria San Martí de Barcelona que atende a 45.000 persoas.

Participantes: dos 3791 pacientes con extracción do luns de abril a outubro de 2017, seleccionamos os 94 fallos no primeiro intento.

Métodos: a segunda venopunción foi realizada por unha enfermeira experta ou ben guiada por ecografía. Recollemos veas apenas palpables, autopercepción de "malas veas", medo á extracción e características de ultrasóns dos vasos. A dor, a satisfacción do paciente avaliáronse mediante a escala Likert e os efectos secundarios ao día seguinte.

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Resultados: os pacientes obesos estaban sobrerrepresentados no grupo de intervención (61,9% vs 36,2% p = 0,015). Non se atoparon diferenzas na mediana (IQR) dos intentos 2 (2-3) vs 2 (2-2) p = 0,127), dor ou satisfacción con ambos os procedementos (p = 0,122).

Houbo menos hematomas no grupo de intervención (16,67% fronte a 25,53%, p = 0,531).

Conclusión: na atención primaria, o uso da ecografía non afectou o número de intentos de venopunción en comparación coa técnica habitual realizada por unha enfermeira experta. Non houbo diferenzas na satisfacción do paciente nin nas complicacións.

Palabras chave: Periférico, Inxeccións, Intravenosa, Práctica de enfermaría, Ultrasonografía, Venopunción, Ensaios controlados aleatorios

RESUMEN

Objetivo: Comparar el uso de la venopunción guiada por ecografía con la extracción de sangre por una enfermera experta en pacientes que necesitan un segundo intento.

Diseño: ensayo clínico aleatorizado

Entorno: Centro de atención primaria San Martí en Barcelona que atiende a 45.000 personas.

Participantes: de los 3791 pacientes con extracción en lunes de abril a octubre de 2017, seleccionamos los 94 fallos al primer intento.

Métodos: La segunda venopunción se hizo o bien por una enfermera experta, o bien guiada por ecografía. Recogimos venas apenas palpables, autopercepción de "venas malas", miedo a la extracción, y características ecográficas de los vasos. Se evaluó el dolor, la satisfacción del paciente mediante escala Likert y al día siguiente los efectos secundarios.

Resultados: los pacientes obesos estaban sobrerrepresentados en el grupo intervención (61, 9% frente a 36, 2% p = 0,015). No se encontraron diferencias en la mediana (RIQ) de los intentos 2 (2-3) vs 2 (2-2) p = 0,127), dolor o satisfacción con ambos procedimientos (p = 0,122).

Hubo menos hematomas en el grupo intervención (16, 67% versus 25, 53%, p = 0,531).

Conclusión: en atención primaria, el uso de la ecografía no afectó el número de intentos de venopunción en comparación con la técnica habitual realizada por una enfermera experta. No hubo diferencias en la satisfacción o las complicaciones del paciente.

Palabras clave: periférico, inyecciones, intravenoso, práctica de enfermería, ecografía, punción venosa, ensayos controlados aleatorizados.

INTRODUCTION

Peripheral venipuncture is performed routinely at Primary Care Settings to sample blood. Although the procedure is mostly successful, several attempts have been reported, especially in obese, chronically ill and hypovolemic patients. Difficulties have also been reported in healthy individuals[1].

Ultrasound-guided cannulation has been successfully used in hospitalized patients with difficult central and peripheral vascular access. Although Peters (2015)[2] found no difference between an expert nurse following anatomical landmarks and ultrasound-guided radial artery cannulation, the vast majority of studies have found that ultrasound-guided cannulation improves success rate, requires fewer attempts, reduces over all time and increases patient satisfaction[1,3]. However, there are not studies to evaluate ultrasound in Primary Care, where hundreds of blood draw tests are routinely performed every day. As ultrasound-guided cannulation has been reported of use in hospital wards and in children, we tried to assess its efficacy in primary care venipuncture in adults. As this procedure is mostly successful, we focused on patients in whom the first attempt failed.

We tested the technique against the best gold standard available, that is, the venipuncture performed by an expert nurse. So, we decided to evaluate ultrasound-guided venipuncture as a way to reduce the number of attempts and complications and improve patient's satisfaction in primary care. This is the first study that evaluates the use of ultrasound-guided venipuncture in primary care to inform about its utility in clinical practice.

OBJECTIVES

To compare the use of ultrasound-guided venipuncture to traditional venipuncture in primary care and assess the patient satisfaction, evaluate the number of complications, and the number of attempts required.

METHODS

From April to October 2017, we performed a prospective, randomized, consecutive sampling study in primary care patients whose reference doctor requested a venipuncture following usual clinical practice. We carried out our study in the Primary Care Center of San Martin, which serves a population of 45,000 people in Barcelona city area. The patients in need of a second attempt were asked for consent to participate and ascribed either to the intervention group, consisting in ultrasound-guided venipuncture by an expert nurse, or to second attempt performed by the same experienced nurse following anatomical landmarks (control group). We used a pattern of alternate Mondays to ascribe the patients in the groups. That means that every patient in the study in the need for a second attempt was ascribed to ultrasound-guided venipuncture on odd Mondays and to anatomical landmarks venipuncture on even Mondays (See flowchart in figure 1). From the 94 patients in need of a second attempt, five denied participation in the study; forty-two patients were assigned to ultrasound-guided venipuncture, and 47 to traditional blood draw procedure following anatomical landmarks by an experienced nurse.

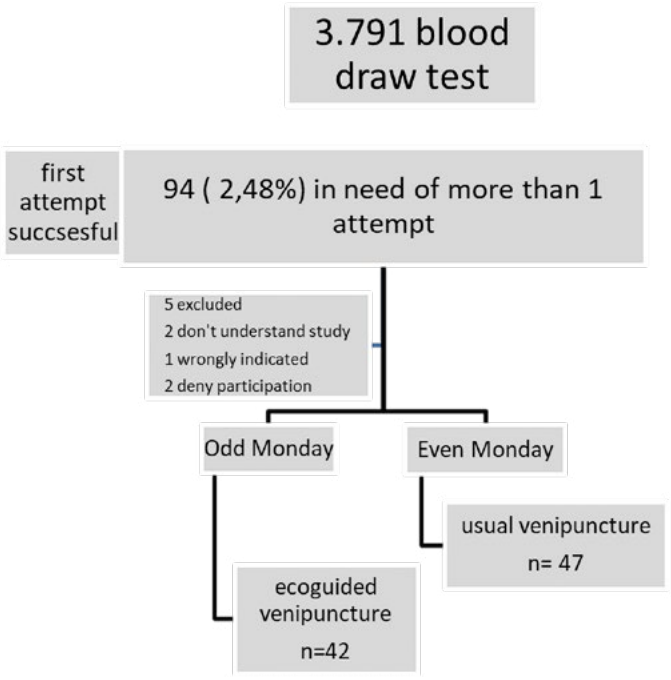

Fig 1. Patients flow chart.
One patient was delivered and already had a successful attempt

The first venipuncture was performed by one of the five nurses on duty on Mondays. The patient in need of a second attempt was explained about the study and asked for consent. Then the patient was referred to the same experienced nurse for the second venipuncture, and she performed it with the help of ultrasound-guided venipuncture on odd Mondays or following anatomical landmarks on even Mondays. To reduce inter-rater variability all punctures, both ultrasound-guided and traditional, were performed by the same experienced nurse. We used a Mindray DC-N3 6D3B001163 with a 7L4A probe as Standard for superficial ultrasound imaging.

The study protocol was approved by the local committee of ethics (IDIAP Jordi Gol, **codi** P17/042) for clinical research and all patients gave written informed consent after recruitment. Exclusion criteria for the study were as follows: negative to participate in the study, age younger than 18 years, and severe psychiatric pathology and / or severe cognitive impairment that makes it difficult for the patient to understand the conditions of the study.

We assessed demographic variables and number of attempts of venipuncture in both groups, subjective characteristics of the veins (hardly palpable, hardly visible, and self-perception of "bad veins", fear of blood draw), and we registered meaningful variables from clinical records as diabetes, obesity, previous burns, injecting drug users (IDU), direct acting oral anticoagulants (DOAC), and chemotherapy.

We determined vessel characteristics in the intervention group using the caliber tool of the Ultrasound System. Cross-sectional vascular diameter, skin-vessel distance and vessel tortuosity (linear distance vessel<1cm) were assessed following the2016 European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) directives on interventional ultrasound[3] Guidelines.

We prepared a questionnaire in a Likert scale from 1 to 5 to record the different elements that have proved relevant according to previous studies, including the following questions: Professionals satisfaction: "Are you satisfied with the professionals that have attended you today?" Technique satisfaction: "Are you globally satisfied with the technique used today?" Recommend to others: "Would you recommend this technique used today to other people with difficult veins?" Less discomfort: "Have you had less discomfort this time than previous venipuncture?" The nurse has found the vein more easily: "Do you think that this time the nurse has found the vein more easily?"

We made telephone contact with all patients the day after the venipuncture to record possible side effects of any of the technique used either the traditional technique or the ultrasound-guided technique, like hematoma, bruises, or pain.

STATISTICAL ANALYSES

Normality tests were performed using the Kolmogorov-Smirnov test. All data were expressed as the mean and Standard deviation, number of subjects (and percentage %) or by interquartile interval (RIC) as appropriate. The Squared Chi test was used to compare proportions, and the Mann-Whitney U test or the Student t test for comparison between groups. We used Fisher's exact test for the comparison of proportions when sample sizes are small.

The acceptable statistical significance was p = 0.05. SPSS® version 13.0 (IBM, Armonk, NY, USA) was employed for statistical analyses.

RESULTS

Baseline demographic characteristics of the 89 patients analyzed were similar regarding to sex, age, veins characteristics (subjective sense of "difficult veins", hardly visible or hardly palpable veins) diabetes, scars, chemotherapy or drug use (Table1). Obese patients were overrepresented in the ultrasound-guided group (61, 9% vs

	Ultrasound-guided	Expert nurse	p
N	**42**	**47**	
Age, years (x ± SD)	57,56± 21,79	59,1± 17,12	0,797
Sex (women)	33,3%	44,7%	0,274
Veins, n	**42**	**46**	
Hardly Palpable	69,0%	74,5%	0,760
Hardly Visible	33,3%	34,0%	0,993
Patients refers "difficult veins"cam	76,2%	63,8%	0,400
Diabetes n,%	42, 33,3%	47, 27,7%	0,561
Obesity n,%	42, 61,9%	47, 36,2%	0,015
Burns or scars n,%	42, 0,0%	47, 0,0%	-
Chemotherapy n,%	42, 19,0%	47, 8,5%	0,146
Inject drug users n,%	42, 0,0%	47, 2,1%	0,342

Table 1. Demographic characteristics within the groups

The total number of attempts required was similar for both groups, with four patients exceptionally requiring a maximum of 4 attempts at the intervention group. (Table 2)

		Intervention group			
		Ecoguided		Experienced nurse	
		n	% (column)	n	%(column)
Number of attempts	1,0	8	19,5%	6	12,8%
	2,0	24	58,5%	34	72,3%
	3,0	6	14,6%	7	14,9%
	4,0	4	9,5%	0	0,0%
n		42		47	
Me (IQR)		2,0 (2,0-3,0)		2,0 (2,0-2,0)	

Table 2: Number of attempts required
Me: median. IQR: interquartilic range

Complications were globally scarce, and slightly less frequent in the ultrasound-guided group (19, 05%) versus 25, 53% in the control group (Table 3). The patients free of complications in both groups exceeded 70%. More patients in the ultrasound-guided venipuncture had more pain than usual during the procedure (2.38%) versus the landmark technique (0% expressed more pain than usually). Hematoma as a complication was less common in the intervention group. No result reached statistical significance.

	Ultrasound-guided	Expert nurse	P (Fisher)
Pain	2,38%	0,00%	0,472
Hematoma	16,67%	25,53%	0,438
No response	14,29%	10,64%	0,75
Free of complications	66,67%	63,83%	0,75

Table 3. Self-reported complications

Remarkably, satisfaction was overall high with no values lower than 3, 5 on the Likert scale. The percentage of non-responders to the questionnaire was similar in both groups. Ultrasound-guided did not improved patient satisfaction (Fig 2). Thirty-eight patients (50%) would recommend ultrasound-guided technique to other patients with difficult veins (90,5%) versus 38 patients (80.9%) in the control group (p=0.29)

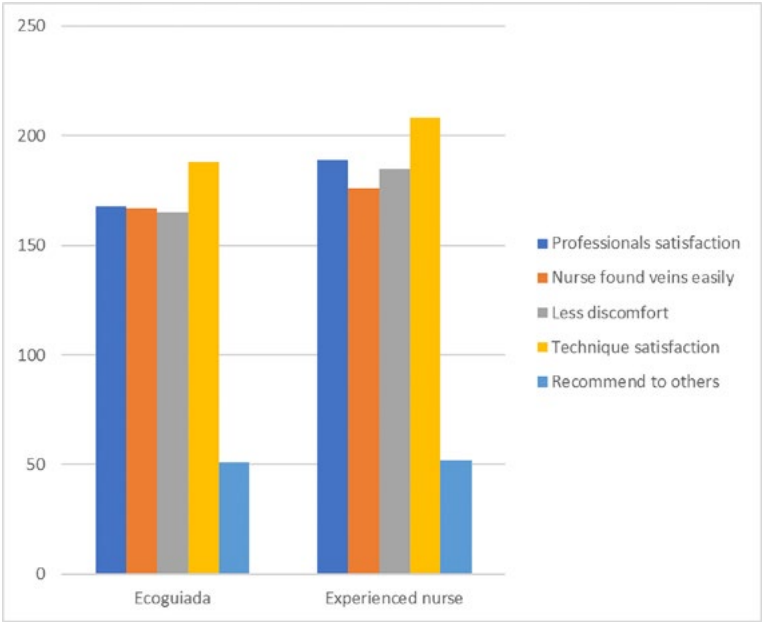

Fig 2. Patient's satisfaction Questionnaire (Sum of variables).

Questions statement: Professionals satisfaction: "Are you satisfied with the professionals that have attended you today?" Technique satisfaction: "Are you globally satisfied with the technique used today?" Recommend to others: "Would you recommend this technique used today to other people with difficult veins?" Less discomfort: "Have you had less discomfort this time than previous venipuncture?" The nurse has found the vein more easily: "Do you think that this time the nurse has found the vein more easily?" Abscises is a Likert scale from 0 to 5. No lower values found under 3, 5. p=0,122

DISCUSSION

This is the first study to assess the use of ultrasound-guided venipuncture in adult patients with a need of more than one venipuncture attempt in primary care. No previous studies on primary care had been performed so far. However, the help of ultrasound in central venous cannulation in hospital settings has been widely studied[4]. There is abundant literature in the case of cannulation in children[5,6], mainly reporting different ways of diminishing the pain in children during venipuncture[7,8], or devices with infrared light for visualization of surface blood vessels[9]. Also cannulation in emergency wards have been tested against ultrasound-guided technique[10]. A meta-analysis by Hind[1] concluded that ultrasound-guided catheterization was quicker and safer than the landmark traditional method in both adults and children. At this respect, the EFSUM Guidelines on ultrasound – guided vascular interventions recommend ultrasound vessel imaging of target vessels with a strong consensus (100 %) either for central vascular access or for peripheral venous access in cases with difficult cannulation conditions[3]. Ultrasound-guided venipuncture had no effect on number of attempts in our study. Other secondary variables as pain, secondary effects or satisfaction did not reach significance, although it should be emphasized that the present trial was not powered to look at these secondary endpoints. This may be due to the experience of the nurse who did all the subsequent venipunctures. One study compared ultrasound-guided arterial cannulation among experienced personnel at the hospital and found that for an expert it is faster to be guided by anatomical landmarks, while less experienced nurses benefit more from the help of the ultrasound-guided technique[2]. Ultrasound-guided radial arterial cannulation[11] increased the first and overall success rates compared to palpation in anesthesia residents in a recent study

Complications were scarce, with less hematoma in the ultrasound-guided group. Interestingly, more patients reported pain in the ultrasound-guided group than in the control group. That can be explained by the way the question was formulated. As the question we used was "have you less pain with the second venipuncture?"; and in the control group, the second venipuncture was performed in the same way as the first, the perceived difference in pain between both techniques should be minimal. Other complications described previously as phlebitis, syncope or paresthesia were not reported.

We chose patients in need of a second attempt as venipuncture is usually a successful technique in primary care settings, selecting those in need of extra help. The high efficiency of primary care nurses on venipuncture makes the percentage of patients in need of a second attempt very scarce (2,48%) and similar to those found on the literature. We cannot exclude the possibility that studying more patients might have revealed statistically significant differences in our secondary end points. We also cannot apply our results in children or other populations / settings.

From the patient's point of view, their satisfaction was globally high with no values lower than 3,5 on the Likert scale, and slightly higher when the scanner was used, with less sense of discomfort during the procedure and more satisfaction with both the technique used and the professionals who attended them, although these differences were not significant.

On the other hand, the ultrasound-guided technique neither increased the number of attempts significantly nor augmented the number of complications. That could make it a helpful assistant in more difficult situations as patients in need of multiple attempts, focusing on obese patients with a sense of difficult veins and previous failed attempts.

In conclusion, based on the findings of the present trial, we reject our hypothesis that ultrasound-guided venipuncture will result in less attempts in venous peripheral blood draw comparing to the traditional landmark technique performed by an experienced nurse. Ultrasound-guided venipuncture was not inferior either, opening the field for its use in the case of less experienced nurses and in certain clinical cases, as in the patient in need of multiple venipuncture attempts.

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KEY POINTS

What is already known about the topic

- Peripheral venipuncture is not always successful.
- Ultrasound-guided cannulation has been tested successfully in Hospital settings
- Some studies have compared the use of ultrasound in venipuncture in children.
- No studies have been published about the use of ultrasound in second attempt venipuncture in adults in Primary Care.

What this paper adds

- This is the first study comparing ultrasound-guided venipuncture versus expert nurse blood draw in primary care
- The use of ultrasound-guided venipuncture did not diminished the number of subsequent attempts compared to an experienced nurse
- Ultrasound-guided did not augment the number of attempts either.
- Ultrasound-guided venipuncture result in less hematoma and more pain as secondary effects, but this did not reach statistical significance
- Testing the technique in less experienced nurses remained uninformed.