Reliability study of Visual Infusion Phlebitis Score Portuguese European version

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Abstract

Phlebitis is the most frequent complication associated with the use of Short Peripheral Catheters. The Visual Infusion Phlebitis Scale is a tool used to access the catheter insertions site and surrounding area, providing a score. The goal of this study was to translate and culturally adapt the VIP scale to European Portuguese in order to achieve a reliability score. Intra and inter-observer reliability studies were performed. The study was conducted at one Portuguese Hospital in a sample of 23 participants. The reliability score was assessed using Kendall's Tau = 0.925, Spearman's Rho = 0.926 and Cohen Kappa = 0.918.

Introduction

Inserting a Short Peripheral Catheter (SPC) into the patient veins likely to be the most practiced procedure in a hospital environment. Whenever a SPC is introduced into a patient the risk of an extra lumen infection is present, as the catheter piercing the human skin allows for bacteria and pathogens to make their way into the bloodstream. Other factors, such as bad asepsis during the SPC's manipulation increases the chances of infection as well. (1, 2)

An infection caused by the insertion of SPCs increases the patient's hospital stayfrom seven days up to twenty days, in addition to the substantial economic costs accrued by the hospital. For example, in the United States, such a procedure cancost up to forty-eight thousand dollars. (1)

Introducing SPCs increases the risk of Healthcare-Associated Infections (HAI), as doing so breaches the skin's continuity solution and its protection function is therefore altered due to permanent microflora accessing the bloodstream. The HAIcausedby inserting SPC are complex and varied, especially when using antibiotics, asthese damage the vein walls.This means there are several sources for SPC contamination: the resident microbial flora of the patient, the tip of SPC that gets contaminatedwhen puncturing, contamination of the lines, shutters and bad hand hygiene of health professionals. (3)

Phlebitis in its turn is an inflammatory process of the intimate tunica, the most internal wall of the veins made of endothelial tissue, and the most complicatedin terms of SPCs' use. The SPC predisposes the development of phlebitis and venous stasis along with the formation of blood clots that may migrate to the bloodstream and form thrombophlebitis therein. The vascular net is a sensible structure and multiple attempts to introduce a SPC compromises the short and long term success rateof obtaining new venous accesses. It is estimated that a quarter of all SPCs inserted get obstructed or accidentally removed, which can lead to extravasation of the solution to be infused with edema formation. Physically, although there is no agreement within the scientific community, it is characterized by local redness, swelling, pain, heat, and formation of a palpable venous cord along the vein. (1–6)

Phlebitis can also be classified according to its etiology: (a) mechanic, related to the fabrication material of SPCs, improper fixing and incorrect handling of the SPCs during its use; (b) chemical: caused by the substance to be infused, such as some antibiotics, example - vancomycin and ceftriaxone - are aggressive to the endothelial wall; (c) bacterial: when there is microbial colonization due to lack of asepsis, either from the

patient or health professional or even from non-optimization regarding the access itself; finally (d) post-infusion: between 48 hours to 96 days after removal, there is risk of developing phlebitis. (7)

The North American Infusion Nursing Society, a group of Nurses who regulate and publish guidelines and standards aiming to achieve the best practices dealing with infusion therapy, defined the acceptable limit for the incidence of phlebitis to be equal to or less than 5%. Notwithstanding, the care provided in several hospitals and clinics all around is different. (8)

In an enquiry performed by Nobre [9], the observer team stated that in 221 observations related to 78 SPCs introduced in 58 patients worldwide, the incidence of phlebitis was 36.7%. In another study conducted by Urbanetto et al [10], 231 further patients had a 24.7% incidence rate of phlebitis. In another study with 155 introduced SPCs, Magerote and her team [11] revealed an incidence of 25.8%.

Considering the epidemiology related to the development of phlebitis in Portugal, Oliveira[5] stated that in 19 studies focused in venous accesses, the dimension and incidence of phlebitis in Portuguese healthcare providers ranges from 3.7–64.6%. In fact, the results of the Portuguese National Infection Prevalence Survey indicate that SPC is the most relevant extrinsic factor for the occurrence of nosocomial infections in blood flow and HAI. The same enquiry applied in 2012 showed us an 11.7% prevalence rate of phlebitis due to SPC usage. (5)

Nurses in Portugal do not have a reliable and valid tool to perform SPC monitoring. Furthermore, there is no agreement on howNurses shouldrecord relevant information of SPC's usage, by means of standardized and systematic terminology, such as the International Classification for Nursing Practice™. (12)

In order to bridge the gap between the need to have accurate records and a missing standardized system for this purpose, we propose a capable and appropriate tool, which will provide Portuguese Nurses with the help they need regarding the status quo of record taking and keeping.

Since Nurse teams are familiar with the complications of using an SPC device, phlebitis' incidence is now seen as a quality indicator of the care provided. Therefore, the goal is to achieve an optimized practice (13).

A process of translation and cultural adaptation of the original VIP scale into European Portuguese was conducted, according to the country specifications and healthcare scenario. Also, reliability tests were performed according to data previously obtained from a representative sample. Therefore, the goal of this study is to translate and culturally adapt the VIP scale to European Portuguese in order to achieve a reliability score.

Background

The SPC placement process is defined by the introduction of a small and flexible catheter into a peripheral vein in a way that it accesses the venous network. Their caliber ranges from 14 to 24 Gauge, biggest to smallest in diameter. SPCs are used with thegoal of infusing medication, fluids, nutrients,and blood products

into the bloodstream. Despite its utility, the introduction of an SPC is not innocuous for the patient (5, 7, 14, 15).

According to Lynn[16] there are many types of complications associated with the use of SPCs: phlebitis and thrombophlebitis, bacteremia and soft tissue infections, such as cellulitis. The pathophysiology and the reason why this happen, is due to the fact that every time a patient gets punctured the risk of an extra lumen infection occurs, caused by the catheter piercing the skin, which allows bacteria and pathogens access to the bloodstream. Therefore, the risk of bloodstream infections is present (2, 12, 17).

From the moment a strange object is present in the venous network of a patient, the catheter starts to get colonized by bacteria followed by biofilm formation. Manipulation and usage without proper hygiene protocols for SPCs manipulation can lead to the above mentioned complications (16).

Nurses are responsible for the introduction of the SPC and all the maintenance procedures. Since ¼ of all SPC introduced gets obstructed or removed accidentally, leading to perfusion liquid extravasation with edema formation, Nurse actions can determine the success of SPC placement and patient safety. A series of bundles, standard procedures and recommendations are updated every year in order to prevent SPC use related BSI (5, 8, 17).

However, the act of puncturing a vein for SPC placement has physiological implications for the patient. This procedure is a source of anxiety, fear and a focus of pain which can be followed by symptoms, such as increase of the heart rate, nausea, vomits, sweating and syncope. In fact, it activates a physiological reaction of the sympathetic nervous system that initiates a vasoconstriction response in the peripheral veins. This leads to a more difficult SPC placement and there is a higher chance that a second attempt to place the SPC might be needed (18, 19).

In the systematic review performed by Ray-Barruel et al[2] 71 record assessment instruments for phlebitis related with the SPCs were identified. In Table 1 we can see the list of the main phlebitis assessment tools.

Not all scales are equal, some refer to updates of existing scales which are modified with no mention to the original author. Only 13 scales refer to already having some kind of psychometric test performed. The same author states four as the main phlebitis assessment tools available in literature, namely:

VIP is the most used and recommended scale by countries such as the United States of America and United Kingdom. The VIP scale consists in the on-site evaluation of the CVAD inserted into the patient's vein network. The score ranges from 0–5 in order of a series of signs and symptoms present or absent. The same scale suggests a certain action to take in order to prevent future phlebitis complications. (4, 8, 17, 20)

The Infusion Nurse Society scale (21), which has suffered significant changes over time, was developed in 1998 in the United States and it stands as a progressive score from 0 (no presence of symptoms) to four (all symptoms are present: edema, pain, erythema, palpable venous cord greater than 2.54cm and presence of pus). In spite of its usage over the years and its multiple versions, this scale has internal problems and has been under scrutiny for its psychometric measures. Reliability or validity have not been proven over time with extended testing in order toverify its efficiency. (2)

Maddox (22) and Baxter (23) are positive instruments but lack reliability, validation and further studies. Both scales define phlebitis by the presence of the following symptoms: erythema, edema, stiffness, pain, and a palpable venous cord. They also provide a score rated from 0 to 5. There are studies where inter observer reliability was accessed but nor data or validation studies were referenced.

Table 1
List of main phlebitis assessment tools

Scale	Scale definition / Primary Result	Sensitivity to diagnose phlebitis	Validation Studies
VIP	Scale with scores from 0–5. Phlebitis is defined by local symptoms evaluated: pain, redness, heat, edema, presence of pus, palpable venous cord.	On 851 inserted CVP, 6.2% developed phlebitis.	Validity shown informally. Reliability but inconclusive test records.
Infusion Nurse Society	Phlebitis results from inflammation of the vein, with the following symptoms: pain, erythema, edema, hardening of the puncture site, palpable venous pathway, drainage of pus. Scale with a score from 0 to 4, 0 = no phlebitis; 1–4 with varying degrees of phlebitis.	In 182 patients, 18.3% had grade 1 phlebitis. Formula for calculating incidence.:	The authors report acceptable inter-observer reliability. Validity was convergently tested.
Maddox	Phlebitis symptoms defined by: erythema, edema, stiffness, pain, and palpable venous cord. Score is rated from 0–5.	In a sample of 514 patients: 22.6% had grade 1 phlebitis, 17.3% had grade 2 phlebitis.	Inter-observer reliability recorded but no data provided.
Baxter	The scale defines the severity and incidence of phlebitis, contributing factors, length of stay, future complications. Identified signs and symptoms: pain, erythema, edema, stiffness, palpable venous cord. Phlebitis rated from 0 to 5	In a sample of 90 patients, 26% had phlebitis.	Inter-observer reliability recorded but no data provided.

Materials And Methods

• Visual Infusion Phlebitis Scale

The VIP Scale (4,20) is the most used assessment tool by healthcare professionals in order to evaluate a phlebitis grade. Mainly used in North America and in the United Kingdom, this instrument has proven its validity and reliability since it was developed in 1998 by Nurse Andrew Jackson and suffered its final modification by Gallant[4]. Being a visual score, in clinical usage, makes it advantageous as compared to other assessment tools, mainly because of its ease of use.

The latest VIP scale is graded from 0 to 5 and each score is followed by a group of symptoms characterizing each stage and also an action to take place to each score. Its application is simple. Every day or whenever it

may be appropriate, a Nurse checks the SPC insertion site and fills the scale according to her observation:

- Grade 0 is a representation of a normal and healthy insertion site with no sign of phlebitis - must be kept under observation;
- Grade 1 is given in the presence of one of the following symptoms: slight pain or redness near the SPC insertion site – the first signs of phlebitis are present and no removal of SPC is recommend, but it must be kept under observation;
- Grade 2 when two of the following are evident: pain near the SPC insertion site, erythema and swelling - early stage of phlebitis has occurred. Removal and reposition of SPC required;
- Grade 3, when all of the following symptoms are evident: pain along the path of canula, erythema and induration - it represents the medium stage of phlebitis with necessary removal, reposition of SPC and direct treatment;
- Grade 4, where all the following symptoms are evident and also extensive: pain along canula path, erythema, induration and palpable venous cord - this is considered an advanced stage of phlebitis or the early stage of thrombophlebitis and the procedure recommended above, in the previous stage, applies here as well;
- Grade 5 is scored in the presence of an advanced stage of thrombophlebitis and all of the above-described symptoms have presented themselves and are extensive: pain along the canula path, erythema, induration and palpable venous cord and pyrexia - the same procedure described in the previous stage is recommended.

• Translation and Cultural Adaptation

In order to perform a translation and cultural adaptation process to the European Portuguese language, the authors followed the Isis Outcomes Translation and Linguistic Validation Process. This translation method allows researchers to translate foreign language documentation in their mother tongue in a phased, concise and clear manner, ensuring integrity throughout all translation stages. (24)

We started to translate the scale from English to European Portuguese by having two bilingual specialists follow the criteria: translator one must have an idea of and a background in healthcare in order to bring the translation as close as possible to its original meaning. Translator two should not have any healthcare background nor related to the topic being translated. This brings the translated document to its original meaning, reducing, as much as possible, any translation bias.

Finally, with the final translated document we reverted the translation to its original language and reached a consensus between the researcher's and the original author.

• Target population and sample studied

The study was undertaken at a hospital located in Aveiro, Portugal, at a surgical care unit. All ethics permissions were granted before the study took place. A target sample of twenty-three individuals were chosen to test the scale reliability between two observers. The same was calculated based on similar studies and the exclusion and inclusion criteria were established as described in Table 2. (26–28)

Table 2 - Inclusion and Exclusion Criteria to the population sample

Inclusion Criteria
Patients admitted to the Hospital's Surgical Care Unit;   Patients aged 18 years or over;   Patients who have a blocked SPC; and   Patients with SPC who are receiving intravenous therapy.
Exclusion Criteria
Patients who are admitted to the unit but   SPC has already been removed; and   Patients with a SPC in place for less than 24 hours.

The sample collection was conducted by two specialist Nurses with ten years of work experience. The scale was applied in two consecutive moments with a minimal interval of 24 hours and maximum 48 hours, by the two Nurses to the same patient, independently/at different moments.

Alongside the reliability studies, a questionnaire was put in place to collect data that would allow for the characterization of the participants in the study. This collection was performed by the same nursing professional of the surgical specialties' service who applied the scale. The questionnaire's structure included questions to collect the patients' clinical history as well as data characterizing the SPC placement process.

- ## Data analysis

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS) software in its twenty-fifth version for Windows 10 operating system (Armonk, NY: IBM Corp), where the collected data were categorized and sorted in the database, ready to be statistically analyzed. To perform the reliability analysis and internal consistency of the new VIP scale applied to the study participants, specific and appropriate statistical tests were used.   The statistical tests that assess the reliability and interobserver agreement of a scale are: Cohen's Kappa, Spearman's Correlation Coefficient and Kendall's Correlation Coefficient. (25,26)

Results

We obtained a duly translated scale that was applied together with the socio-demographic questionnaire to the selected sample.

The results of the participants' sociodemographic characterization can be seen in Table 3 with a similarity in terms of gender of the participants, given that 43% are male and 57% are female. With regard to the age stratification of the participants, it appears that there is homogeneity between the age groups presented, with a predominance of the 71–80 range (26%).

Table 3 - Sociodemographic Characterization of Participants (n = 23)

Qualitative Variables	
Gender (n (%))	
Male	10 (43%)
Female	13 (57%)
Status (n (%))Professional	
Not answered	14 (53%)
Unemployed	1 (4%)
Domestic	1 (4%)
Retired	7 (39%)
Quantitative Variables	
Age (years n (%))	
< 50	6 (26%)
51–80	15 (65%)
> 81	2 (9%)

It was possible to obtain data about the type of SPC that was introduced. Table 4 shows that, at 26%, themost common insertion place was the back of the hands, both the left and right sides, followed by the left forearm with 22% of insertions .

Table 4
Sample Characterization

Anatomic Location of SPC	n (%)
Right Forearm Flexure	1(4%)
Left Forearm Flexure	2(9%)
Right Forearm	3(13%)
Left Forearm	5(22%)
Back of right hand	6(26%)
Back of left hand	6(26%)
SPC Caliber (G)	**n (%)**
22 G	1(4%)
20 G	9(39%)
18 G	13(57%)
SCP Status	**n (%)**
Saline locked	11(48%)
With EV infusion	12(52%)
Type of EV Infusion	**n (%)**
NaCl 0,9% + Glucose 5%	1(4%)
Simple Polyelectrolytic	3(13%)
Polyelectrolytic with Glucose	3 (13%)
NaCl 0.9 %	4(17%)
Without EV Infusion	11(48%)
EV Infusion rate	**n (%)**
63 ml/h	1 (4%)
80 ml/h	1 (4%)
Ad Libitum	21 (92%)
SPC fixing	**n (%)**
Hypoallergenic Adhesive	7 (30%)
Transparent Dressing (*"Tegaderm"*)	16 (70%)
SPC optimization	**n (%)**

Anatomic Location of SPC	n (%)
Twice a day	23 (100%)

The most CVP caliber used was 18G with 57% alongside 20G with 39%. About 48% of the CVP were filled, and 52% had some type of infusion, the main solution was NaCl 0.9% (17%), followed by Simple and Glucose Polyelectrolytic (13%).

In terms of the infusion rate, 92% had an *ad libitum* prescription, with only 4% at 63 ml / h and 80 ml / h. When providing care for the CVP insertion site, the attachment was done with an opaque dressing ("Tegaderm") 70% of the time and 30% with a hypoallergenic dressing. Finally, it was also observed that the optimization was done every day.

Regarding the application of VIP PT-PT scale, it was conducted by two independent Nurses in consecutive days as shown in Table 5. The result obtained after application of the VIP PT-PT scale ranges from 0 to 2, the most prevalent being 1.

In Table 5 there were three moments where the two Nurses' observations differ. In one case, a potential sign of phlebitis was identified, while the other observer disagrees with the existence of an early-stage phlebitis. In another scenario, there was a progression of the scale score from the first day to the second by one of the observers, while the second observer did not identify any sign of phlebitis on the first day, but ended up validating her colleague's opinion the following day.

Table 5
Results of application of VIP PT-PT^{z,1} scale to the sample (N = 23).

NurseAday1		NurseBday1		NurseAday2		NurseBday2	
0		0		0		0	
1		1		1		1	
0		0		0		1	
0		0		1		1	
1		1		1		1	
0		0		0		0	
0		0		0		0	
0		0		1		1	
1		1		1		1	
0		0		1		1	
0		0		1		1	
0		0		0		0	
0		0		0		0	
1		1		1		1	
0		0		1		1	
0		0		0		0	
0		0		1		1	
0		1		2		2	
0		0		0		0	
0		0		1		1	
0		0		0		0	
0		1		1		1	
0		0		0		0	
	Total	%	Total	%	Total	%	Total	%
Result = 0	19	83%	17	74%	10	43%	9	39%
Result = 1	4	17%	6	26%	12	52%	13	57%

	NurseAday1		NurseBday1		NurseAday2		NurseBday2	
Result = 2	0	0%	0	0%	1	4%	1	4%
Total	23	100%	23	100%	23	100%	23	100%

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Reliability is defined by the absence of measurement errors in the evaluation instrument. Reliability immediatelyrefers to concepts such as stability, since the collected data will always be the same; security and the information collected will not be compromised; and predictability, given by the reliability to an instrument. Reliability is the major parameter toassess the quality of an evaluation instrument. In Table 6 we can see the application of reliability tests to the VIP PT-PT Scale according to the results obtained. (26)

Table 6
Results of reliability tests performed

Cohen Kappa	Value		Sample Size
	0.918		N = 23
Kendall Tau			
	NurseBday1	NurseBday2	
NurseAday1	.772	.311	
NurseAday2	.557	.925	
Spearman Rho			
	NurseBday1	NurseBday2	
NurseAday1	.772	.317	
NurseAday2	.567	.926	

The calculated Cohen's Kappa was 0.918, as shown in Table 6, which according to Santiago's value interpretation framework(26), translates into almost perfect reliability between two observers for a category of nominal data.

The statistical tests Tau de Kendall and Rho de Spearman were also calculated in order to find out if two different observers have the same interpretation on similar days, applying the scale to the same participant. The results for Kendall's Tau were 0.772 for day 1 and 0.925 for day 2, which translates into a strong and very strong correlation, respectively, as described in Table 6.

Under Spearman's Rho Test, the values presented in Table 6 of 0.772 for day 1 and 0.926 for day 2, represent an almost complete agreement between the two observers.

Discussion

The most common comorbidities found with the social demographic characterization application were arterial hypertension, type 2 diabetes mellitus, and hypercholesterolemia. This datais inaccordance with the data provided according to the report of the Portuguese Ministry of Health (27) and, as such,contributes to the degradation of the venous network, increasing the likelihoodof developing phlebitis when SPC is used. (28)

The most frequent site for introducing the SPC was the dorsum of the left and right hands, followed by the left forearm. This is because the ward where the study was carried out is a surgical unit, with a high number of surgical procedures and, for convenience reasons, the left upper limb is preferred for puncturing the patient in the operating room.

The 18G caliber was the most commonly used catheter, despite international guidelines (8) always recommending the use of a lower caliber upon introduction of a PV. The use of 18G caliber SPC in this ward is related to the specificity of the surgical ward where the infusion of high volume of solutes might be needed, as well as that of vasopressor drugs or blood products. The high attention that Portuguese Nurses apply in the SPC placement should be noted, as well as throughout its maintenance and removal. This means that the SPC is optimized twice a day on all patients (100%) using (70%) transparent sterile fixation material, such as "Tegaderm".

Regarding the reliability of VIP PT-PT scale, statistical tests were chosen according to reliability studies on the main phlebitis assessment scales developedthus far. The methodology described in Santiago's work (26) was followed, which refers to the application of Cohen's Kappa, with data reinforced by Kendall's Tau and Spearman's Rho.

The data obtained demonstrates the reliability that this instrument offers when applied. This "almost perfect" reliability obtained by two observers under the same scenario is in line with what Gallant (4) wrote in their study on the assessment of the clinical use of VIP, when they found an interobserver reliability higher than 0.85. The incidence of phlebitis was 0.04%, which is in accordance with international guidelines (8) when referring to a recommended phlebitis rate of 5% or lower in all hospital units.

The study of the occurrence of phlebitis associated with SPC insertion has been a topic which has been questioned and has been worrying the scientific community for decades. What is intriguing to Nurses and also to physicians, is that despite the plethora of assessment tools there is still no consensus; first, for a

definition of phlebitis that is widely accepted, and second, what signs and symptoms make up that definition. This is the variance seen in the different scales produced. (2)

The choice for the VIP Scale, originally by Jackson(20) and modified by Gallant[4], is due to the fact that it is the assessment instrument that gathers the greatest consensus among the community. For some authors, Marsh et al.(29), it is even considered the current gold standard for phlebitis' risk assessment, because it is the only instrument that suggests an action based on the assessment result. It is also the scale recommended by the Royal Nursing College, in the United Kingdom, and it is widely used in the United States of America and recognized by the Infusion Nursing Society. (8)

In Portugal, several thesis has been developed focusing on nursing care related to the insertion of PVCs. Recommendations and protocols are well defined in Portuguese literature by contributions from Oliveira[14] and Reis[3]. The application in the ward in question demonstrated good practices in terms of SPC maintenance.

Some limitations and difficulties were encountered in undergoing the study. The VIP Scale translation process took place according to the methodology proposed by Isis Outcomes Translation and Linguistic Validation Process. (24)

However, there were some difficulties in translating certain terms from the original language into European Portuguese. The fact that only one of the translators had a degree in healthcare sciences meant that there was not harmony in the final product achieved. During the retroversion process, it also suffered some grammatical adjustments in order to generate consensus with the original version, with what would be measured by the scale.

The Nurse ward where the questionnaire was applied has some specificities, as it is a surgery service with a high surgical activity, therefore obtaining the sample was not. Difficulties were found in the inclusion and exclusion criteria defined, and in the Nurse's availability to collaborate with the study and meet all the prerequisites defined.

The definition of the inclusion and exclusion criteria, and the availability of Nurses to collaborate with the project and also the guarantee that they would be fulfilling all the defined prerequisites, constituted a difficulty.

Conclusions

This study answered all the objectives initially proposed by the researchers. Throughout this endeavor, it was possible to translate and culturally adapt VIP to European Portuguese and a value has been obtained to characterize the scale in terms of inter-observer reliability.

From the point of view of translating the scale into European Portuguese, we consider that the final version is validated and culturally adapted to the reality of healthcare provided by Nurses. The inter-observer

reliability assessment was first calculated by using Cohen's Kappa, who concludes that the scale has almost perfect reliability and interobserver agreement was guaranteed by Spearman's Rho and Kendall's Tau.

This work is one of many steps already done and to be done to ensure that the scientific community in Portugal has a readily available and reliable tool to assess, monitor in a standardized manner the SPC placement, maintenance and removal. All to improve vigilance on phlebitis and other major complications.

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