

Film for safe stabilization of intravenous catheters - ABRACEFIX*Película para estabilización segura de catéteres intravenosos - ABRACEFIX**Filme para estabilização segura de cateteres intravenosos - ABRACEFIX***Wilza Cabral Rodrigues da Silva¹**

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Abstract

The aim was to characterize and describe the improvement in the design of the new fenestrated adhesive film called by the authors as ABRACEFIX. This is an exploratory field research. Participants were 70 children, undergoing intravenous therapy from July to October 2021. There were 25 (35.71%) female children and 45 (45.71%) male children. Age range: 34 (48.57%) under 1 year old; 22 (31.42%) between 1 and 3 years; The minority, above 3 years. Degree of nursing care, length of stay and stabilization of the IVC in the ABRACEFIX monitoring instrument. They stayed an average of 2.5 days. Most of the films were intact, clean and adherent to the skin. Nursing care, Satisfactory, Level 0 = 79(73.14%); Unsatisfactory, Grade 1 = 25(23.14%); Very unsatisfactory, Grade 2 = 04(3.72%), inadequate fixation. We verified through the care degree scale that the film, embracing the device, kept the catheter safe (fixed), that is, without mobilization inside the blood vessel (inadequate movement) during intravenous therapy.

Descriptors: Phlebitis; Catheter; Pediatric Nursing; Nursing Care; Transparent Adhesive Film.**Resumén**

El objetivo fue caracterizar y describir la mejora en el diseño de la nueva película adhesiva fenestrada denominada por los autores como ABRACEFIX. Esta es una investigación de campo exploratoria. Participaron 70 niños, en tratamiento intravenoso de julio a octubre de 2021. Hubo 25 (35,71%) niñas y 45 (45,71%) niños. Rango de edad: 34 (48,57%) menores de 1 año; 22 (31,42%) entre 1 y 3 años; La minoría, mayores de 3 años. Grado de atención de enfermería, tiempo de estancia y estabilización de la VCI en el instrumento de monitorización ABRACEFIX. Se quedaron un promedio de 2,5 días. La mayoría de las películas estaban intactas, limpias y adheridas a la piel. Atención de enfermería, Satisfactorio, Nivel 0 = 79(73,14%); Insatisfactorio, Grado 1 = 25(23,14%); Muy insatisfactorio, Grado 2 = 04(3,72%), fijación inadecuada. Verificamos a través de la escala de grado de cuidado que la película, abrazando el dispositivo, mantuvo el catéter seguro (fijo), o sea, sin movilización dentro del vaso sanguíneo (movimiento inapropiado) durante la terapia endovenosa.

Descritores: Catéter Intravenoso; Enfermería Pediátrica; Cuidados de Enfermería; Película Adhesiva Transparente.**Resumo**

Objetivou-se caracterizar e descrever o aprimoramento no design do novo filme adesivo fenestrado denominado pelas autoras como ABRACEFIX. Trata-se de uma pesquisa de campo tipo exploratória. Participaram 70 crianças, em terapia intravenosa no período de julho a outubro de 2021. Foram 25 (35,71%) crianças do gênero feminino e 45 (45,71%) masculino. Faixa etária: 34 (48,57%) abaixo de 1 ano de idade; 22 (31,42%) entre 1 a 3 anos; A minoria, acima de 3 anos. Grau de cuidado de enfermagem, o tempo de permanência e estabilização do CIV no Instrumento de acompanhamento ABRACEFIX. Permaneceram em média de 2,5 dias. A maioria dos filmes estava íntegro, limpo e aderente à pele. Cuidado de enfermagem, Satisfatório, Grau 0 = 79(73,14%); Insatisfatório, Grau 1 = 25(23,14%); Muito insatisfatório, Grau 2 = 04(3,72%), fixação inadequada. Constatamos através da escala de grau do cuidado que o filme, abraçando o dispositivo se manteve o cateter seguro (fixo), ou seja, sem mobilização dentro do vaso sanguíneo (movimentação inadequada) durante a terapia intravenosa.

Descritores: Cateter Intravenoso; Enfermagem Pediátrica; Cuidados de Enfermagem; Filme Adesivo Transparente.

Introduction

Intravenous catheterization (IVC) is the most common invasive procedure performed among hospitalized children in clinical practice, being part of the care of approximately half of the children who need intravenous therapy and infusion therapy^{1,2}.

In 2017, the Ministry of Health published Health Care-Related Infection Prevention guidelines with measures for peripheral catheters involving the following topics: Hand hygiene; Catheter selection and insertion site; Skin preparation; Stabilization; toppings; Flushing and maintenance of the peripheral catheter; Catheter insertion and removal site care³.

After the insertion of the VIC, its maintenance is the other moment in which the nurses must pay particular attention and be rigorous in maintaining the aseptic technique, as well as in the careful handling of all the material that will be used and connected to the PVC⁴.

In this study, we will stick to three fundamental stages of intravenous therapy for effective child safety, namely:

a) Ensure the stabilization of the IVC with the improvement of a new model of the adhesive film to be used in coverage and fixation of the IVC site, aiming at its effective maintenance and reduction of risks of loss.

b) Submit the referred new model of the ABRACEFIX adhesive film to the pediatric hospital for standardization.

The IVC needs a cover to secure and stabilize the catheter. Therefore, stabilizing the catheter means preserving access integrity, preventing device displacement and loss.

Thus, catheter stabilization reduces the risk of complications related to intravenous therapy, such as: phlebitis, infiltration, sepsis and displacement of this device³.

There are two types of stabilization for intravenous catheters, namely: a) a catheter with an integrated stabilization mechanism, combined with a polyurethane dressing with reinforced edges, and b) a peripheral venous catheter combined with a specific adhesive device for stabilization. However, any of the two types should not interfere with the evaluation and monitoring of the insertion site or hinder/prevent the infusion of the therapy. Adequate stabilization is important for preventing complications at the VSD insertion site. This step corresponds to the use of a material specifically designed and constructed to control the movement of the catheter hub, thus reducing the movement inside the vessel, the risk of poor positioning of the catheter, accidental losses and associated complications^{5,6}.

The covers are intended to protect the puncture site and minimize the possibility of infection, through the interface between the surface of the catheter and the skin, and to fix the VIC at the inserted site to prevent movement of the device, damaging the blood vessel. Thus, the coverings must be sterile, and can be semi-occlusive (gauze and sterile adhesive tape) or semi-permeable transparent membrane. The materials generally used for the fixation of VSD are adhesive tapes, sterile gauze and transparent film³.

We know from care practice that a well-fixed catheter provides less need for manipulation, reduces the risk of traction, dislocations and complications.

In view of the above, considering innovations to improve the quality of PVC fixation used in intravenous and/or infusion therapies in a pediatric unit, the main contribution of the present study is the presentation of a new model improved by the authors of this article, in relation to the coverage and fixation of the sterile fenestrated transparent adhesive film, aiming at a better immobilization of the catheter, and the consequent reduction of the risk of loss during its use, favoring a better efficacy of the intravenous therapy. For this, it became necessary to carry out an exploratory research on the new fixation model proposed by the authors called ABRACEFIX, in relation to the conventional fixation used by the service.

It should be noted that the authors are nurses from a team with expertise in procedures involving VSD, working in the Venous Access and Infusion Therapy Team (TAVTI), at the pediatric hospital, place of work, referred field of study.

Aware of our daily practice, it is essential to implement nursing care based on scientific evidence, thus promoting qualified, excellent and safe care.

This concern gains amplitude given the awareness that nursing care related to stabilization and coverage of peripheral and central intravenous catheters should be increasingly valued in the care of pediatric patients who are highly vulnerable to displacement and loss during the exchange or manipulation of the venous catheter used.

In this perspective, this study is justified by contributing to the improvement and innovation of a new model of venous catheter fixation, with adhesive film named by the study team with the acronym ABRACEFIX, seeking to remember the comfort and safety to improve the stabilization of infusions in venipunctures and, in intravenous therapy as a whole, from monitoring the stabilization of said catheter performed by the Nursing service, monitoring accidental losses and adverse events through Nursing care indicators.

Therefore, this study aims to: Characterize and describe the improvement in the design of the new fenestrated adhesive film named by the authors as ABRACEFIX for safe stabilization of intravenous catheters; reduce losses of intravenous catheters, standardize the stabilization method of said catheters and register the patent for the new fenestrated adhesive film ABRACEFIX.

Methodology

This is an exploratory field research carried out in a pediatric hospital in the Metropolitan Region of São Paulo, belonging to the State Department of Health – CSRMG/SP. Motivated by the idea of characterizing and describing the improvement of the design of the new adhesive film for stabilization and secure fixation of the intravenous catheter.

Initially, we would apply only in an inpatient unit. Due to the pandemic, we chose to include all inpatient units at the study hospital.

The study included 70 hospitalized children (100%), using intravenous therapy, after insertion of the intravenous

catheter (IVC) by the authors, working in the Venous Access Team and TAVTI infusion therapy.

There were 25 (35.71%) female children and 45 (45.71%) male children, distributed in the following age groups: 34 (48.57%) under 1 year of age; 22 (31.42%) are between 1 and 3 years old; Between 3 and 6 years old, only 4 (5.71%) children participated in the research; From 6 to 9 years, 3 (4.30%) and, above 12 years, 7 (10%). Sampling was for convenience, used according to ease of access, taking into account the availability of subjects to be part of the sample in a given time interval. The follow-up of the children in the study who used ABRACEFIX, by the TAVTI team of nurses, was from July 1, 2021 to October 4, 2021.

Such hospitalized children met the following eligibility criteria: with indication to remain with IVC: without clinical signs of phlebitis, without malformations in the venous network and, that parents and children accepted to participate in the research, signing the terms of consent and assent presented and oriented, respectively. As for the exclusion criteria, they were cases that, even within the clinical eligibility criteria, did not accept to participate in the research.

The children were distributed in the hospitalization units: ICU Ped: 09; ICU NEO 11; Rear: 10; Wards: 40.

All were inserted and fixed with ABRACEFIX film, monitored daily by the TAVTI nursing team, replaced when necessary, making a total of 108 films during data collection.

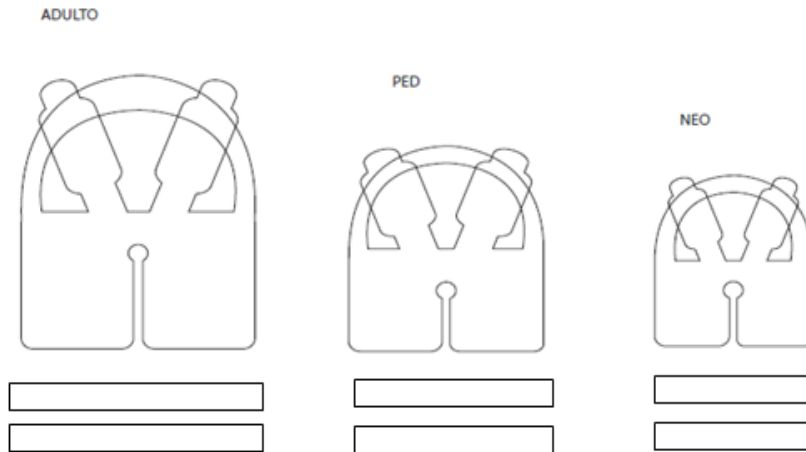
The instrument for data collection was a form (notification form) already used by the local service, adopting the Maddox Scale, including all data obtained on adverse events with the use of IVC or Central catheter, such as: leakage, dirt, obstruction, accidental loss, evasion, patient transfer/death, local pain and suspected infection in patients. Such data are always observed and reported by the Nursing service, and in view of the research they were studied, while using ABRACEFIX.

Caracterização e descrição do design do novo Filme Adesivo fenestrated film ABRACEFIX, improved by the authors, starting from the conventional fenestrated Adhesive Film used in the local service, for the development of the new model and obtaining the relevant information for this study.

The adhesive film, transparent, with polyurethane border, fenestrated, sterile, has two fixed stabilizing strips to embrace the intravenous catheter in "V" (Chevron method), offering greater security in the fixation and, preventing the movement of the catheter inside the vein .

It was cut and assembled from the prototype, idealized by the research authors, and then packed in surgical grade paper, sterilized in ethylene oxide by a specialized company. See characterization of ABRACEFIX, below in Figure 1.

Figure 1. Adhesive film, transparent, with polyurethane border, fenestrated, sterile, with two fixed stabilizing strips (Chevron method), to embrace in a "V" (fix) the intravenous catheter. São Paulo, SP, Brazil, 2021



Note: Measurements: A. Adult = 7.0 cm (height) X 5.0 cm (width); B. Pediatric = 6.0 cm (height) X 5.0 cm (width); C. Neonatal = 5.0cm (height) X 4.0 cm (width).

The length of stay for VSD stabilization was monitored using the ABRACEFIX length of stay follow-up instrument, together with the degree of nursing care for venous access scale.

The degree of nursing care refers to the degree of nursing care for the venous access scale.

It should be noted that the conventionally used sterile transparent adhesive film, also made of polyurethane, only has a fenestra and a separate stabilizing tape. This fixes the catheter and then the film is positioned over the stabilizing tape and the catheter.

ABRACEFIX, on the other hand, has two strips, fenestrated in V, in hypoallergenic acrylic, fixed in the film itself, in transparent polyurethane, providing daily inspection of the insertion site. After insertion of the catheter, the strips are passed over it, providing greater stability within the vein. That is, the adhesive strips embrace the catheter to reinforce its stabilization. Then we position the loose stabilizing tape.

The survey was registered and authorized on the Brazil platform under the number: 3195882030000086. Those responsible for the children agreed and signed the

TCLE. The patent process is being initiated at the National Institute of Industrial Property (INPI).

Results

The adhesive film to stabilize and fix the venous catheter was intact and adherent during intravenous therapy, demonstrating adherence and stability to movements. Regarding registered AEs, there was intervention according to the Standard Operating Procedure (SOP) and replacement of the venous device and ABRACEFIX, after evaluation by the researcher. The insertion site of the venous access was inspected daily. When identifying any adverse event associated with venous therapy (infiltration, extravasation, phlebitis, phlogistic signs or other events). They were replaced by another ABRACEFIX film.

The Adverse Events (AE) registered, NOT related to the stabilization and fixation of the catheters, among them: Infiltration 15 (21.71%), obstruction 06 (5.08%) of them. Humidity/ Leakage/ Dirt (sweating, vomiting, secretion, blood), 22(18.64%), Accidental loss/drawn by the patient (displacement of the device by traction, drawn by the patient); Evasion/ transfer/ death; Suspected infection/pain (pain, edema, redness, local heat) occurred in 03 (2.54%) devices respectively. We now present the descriptions of the reasons for withdrawing the ABRACEFIX films:

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"Full and adherent film after the second day of use. Withdrawn for hospital discharge."

"Film was removed lack of adhesion due to post shower moisture."

"Removed AVP due to obstruction, film with good integrity."

"Film removed due to PICC pulling. It was intact and adherent."

"Shows infiltration at the puncture site, intact and coherent film."

"Film removed due to bloody soiling due to disconnection of the two-way cut-off device."

"AVP permanence time, (07) seven days. ABRACEFIX test film replaced, intact and adherent."

"Whole film. Removed by infiltration in AVP, after 4 days."

"PICC was drawn by patient referring local pain, after 5 days of insertion".

"Film removed on the sixth day, because the patient had intense sweating. wet film."

"Loss of venous catheter. Full and adherent film removed."

Below, the survey results are presented in graphs and tables using absolute and relative numbers.

Table 1. Distribution according to the reason for removing/exchanging the ABRACEFIX film. São Paulo, SP, Brazil, 2021

Reason for removal/replacement of ABRACEFIX		n	%
Discharge/ End of treatment/ Changed (> 7 days of use)		64	55.93
Adverse event - AE	Wet/ Leaking/ Dirt	22	18.64
	Infiltration	15	21.71
	Obstruction	06	5.08
	Accidental loss / Withdrawn by the patient	03	2.54
	Evasion / Transfer / Death	03	2.54
	Uninformed	03	2.54
	Local pain / Suspected infection	02	1.69
TOTAL	118	100	

Source: Silva WCR; Araújo SAN; Costa MC; Vasconcelos AMA; Sousa MWCR. Película para estabilização segura de cateteres intravenosos - ABRACEFIX.

Table 2. Distribution according to the scale of the degree of care related to the stabilization and fixation of the ABRACEFIX film. São Paulo, SP, Brazil, 2021

Level of care	n	%
Level 0	79	73,14%
Level 1	25	23,14
Level 2	04	3,72
Total	108	100

Source: Silva WCR; Araújo SAN; Costa MC; Vasconcelos AMA; Sousa MWCR. Película para estabilização segura de cateteres intravenosos - ABRACEFIX.

To carry out this study we used 16(14.83%), adhesive films, adult size 18(16.66%), neonatal and 74(68.51%) pediatric. Among the catheters used during intravenous therapy, we had: PICC 34(31.48%); AVP 68(62.96%); CVC 06 (5.55%), where they remained 172 days with the devices, making an average of 2.5 days. The children received: antibiotics 53 (75.71%), serum therapy 10 (14.28%), corticosteroids 06 (8.57%), and NPP 01 (1.42%).

As for the conservation of the films, most remained intact, clean and adherent to the skin during use, demonstrated by satisfactory nursing care, Level 0 = 79(73.14%); Presented unsatisfactory nursing care, Level 1 =

25(23.14%); Very unsatisfactory nursing care, Level 2 = 04(3.72%), inadequate device fixation.

Discussion

Two billion intravenous catheters (IVCs) are used around the world each year, but the optimal methods of securing these devices are not well established. IVCs are the most commonly used vascular access devices, with approximately 330 million sold each year in the US alone. Studies show that 70% of hospitalized patients will at some point make use of this resource⁷.



In Asia-Pacific, the demand for intravenous catheters grew due to the increase in surgical procedures, US\$ 4.28 billion was spent in 2018. With technological advances, it is estimated that the use of this device will reach US\$ 7.52 billion by 2027⁸.

In France, up to 25 million CVPs are entered each year. It is estimated that in the United States of America (USA) around 200 million catheters are used annually and in Spain, approximately 50% of hospitalized patients receive an intravenous catheter, 95% of which are peripheral⁹⁻¹¹.

For the Commission on Safety and Quality in Health Care (CSQHC), in Australia, there are 7.7 million peripheral intravenous catheters inserted each year. Once inserted, there is a risk of complications, some of which are serious. IVC insertion is an unavoidable experience for the patient. However, there is a high failure rate of 40% for first-time insertions and a high rate of problems, with up to 69% of cannulas needing to be removed due to complications¹²⁻¹⁴.

Risk factors for IVC, in the pediatrics of 278 hospitals (47 countries), 4,206 children used polyurethane dressings to stabilize the devices 2,822 (67.1%); many were not clean, dry 715 (17.1%) and 526 (8%) of them were idle (not in use). Local complications have been reported in children over 2 years of age. Bad integrity of the dressing draws attention 778.88(5.4%) and the average permanence time was 1.9h¹⁵.

Adverse events associated with PVC use include accidental catheter removal, phlebitis, occlusion, infiltration, extravasation, hematoma, and patient infections¹¹.

When the steps related to the management of these devices, which range from the insertion, maintenance and removal of the catheter, do not meet the recommendations of scientific evidence, they potentially increase the possibilities of complications related to their use. Factors related to the handling of these devices directly interfere with the occurrence of AEs¹⁶.

High failure rates and associated complications have been recognized internationally for their contribution to patient harm and increased health care costs. Intravenous catheters (IVC) are the most used invasive devices in hospital procedures¹⁷.

The incidence of adverse events related to the use of peripheral venous catheters of 52.3%. The main adverse events found were phlebitis 20.1%, followed by hematoma 17.7%. Infections accounted for only 0.4%. The most frequent mechanical AEs were PVC obstruction/occlusion 12.4%. The incidence of post-removal AE was 21.7%. Peripheral venous catheter with inadequate fixation was the main risk factor found¹¹.

A randomized study with 300 adult patients using peripheral venous catheters fixed with a transparent polyurethane film with a border (top), demonstrated inadequate stabilization or fixation to the skin, as it provided micromovement in 207 (69%) of the PVCs inside the vein. Causing displacement of the PVC within the vein, local infection, phlebitis, thrombosis, impairing the permanence time of the referred device. However, the patients participating in the aforementioned research were satisfied with using the transparent polyurethane film with a border⁹.

Intravenous therapy is commonly stopped before the drug infusion is completed. This is because the device is not properly adhered to the skin, allowing the catheter to dislodge, leading to complications such as phlebitis (irritation or inflammation of the vein wall), infiltration (leakage of fluid into surrounding tissues), or occlusion (blockage)¹⁸.

The displacement of this device before the conclusion of the treatment or the infusion of a drug is a concern among nursing professionals, as it occurs in 33-69% of hospitalized patients. In part, this is due to inadequate stabilization or attachment to the skin, which allows for micromovement of the catheter within the vein⁹.

As for partial displacement and accidental removal, these are some of the reasons for the failure of intravenous therapy. Authors¹⁹ consider that the most effective fixation method to prevent accidental removal remains unclear.

An improperly secured catheter also increases the risk of catheter-related bloodstream infection because the piston action (back and forth motion in the vein) of the catheter may allow migration of organisms along the catheter and into the bloodstream¹⁸.

Despite the many adhesive films for dressings and fixation devices available, the impact of different fixation techniques to increase the residence time of PVC remains unclear; there is a need to provide scientific evidence to healthcare professionals with systematic review of current studies¹⁸.

According to a study²⁰, the degree of nursing care can be changed with the time the device remains in situ, and after the second day of installation, there is a compromise in the quality of care, as noted. Commitment may be associated with the lack of observation of signs and symptoms of possible complications by the nursing team.

Current dressing and fixation methods are commonly associated with poor durability of the VSD. Cost is currently the main factor that determines product choice. Innovations are urgently needed to achieve effective and durable dressings and fixations and randomized clinical trials that evaluate their effectiveness. Furthermore, it is unclear whether any dressing or fixation device is better than any other at securing peripheral venous catheters. There is a need for other high-quality independent tests to evaluate the many traditional and newer high-use products. Given the large cost differences between some different dressings and fixation devices, future testing should include a robust cost-effectiveness analysis^{18,21}.

Despite the many adhesive films for dressings and fixation devices available, the impact of different fixation techniques to increase the residence time of PVC remains unclear; there is a need to provide scientific evidence to healthcare professionals with systematic review of current studies¹⁸.

Among the seven topics on Bloodstream Infection Prevention measures, for peripheral catheters, none of them can be neglected. When we deal with the coverage item, research shows that the use of non-sterile adhesive tapes and microporous tapes should not be used for the fixation and stabilization of catheters, since these materials provide

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relationships between business and business, between business and research centers, and between business and government"²⁸.

Regarding the limitations of the research, data collection was carried out after construction of the ABRACEFIX films, by the researchers from a roll of transparent polyurethane film and a roll of hypoallergenic adhesive tape. The study makes an important contribution to practice, highlighting the need to apply safe care in relation to the stabilization of the intravenous catheter.

Relevance to practice: potential arises to use adhesive film to keep the IV catheter fixed (immobile) until replacement.

Conclusion

We found that the format of the film, embracing the device, kept the catheter safe (fixed), that is, without mobilization inside the blood vessel (inadequate movement) during intravenous therapy. ABRACEFIX can prolong the IVC permanence time in pediatric patients without increasing the rate of adverse events.

In order to build a solid conclusion that leads us to recommend an ABRACEFIX adhesive film, we consider it necessary to deepen multicenter and/or comparative studies to test technological innovations related to stabilization and fixation of intravenous catheters. There is superiority and quality of the new ABRACEFIX film in terms of safety and a lower risk of adverse events in children treated at the study site.

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the interface between the skin and the surface of the catheter, which is, therefore, recommended the use of sterile, semi-occlusive coverings, such as gauze and adhesive tape, provided they are sterile or transparent semi-permeable covering, emphasizing that the use of sterile gauze and adhesive tape is only recommended when the prediction of use for the catheter is less than 48 hours^{22,23}.

The Intravascular Catheter-Associated Infections (CDC) Prevention Guidelines recommend routine and frequent assessment of patient conditions, insertion site, skin and vessel integrity, duration and type of therapy prescribed, device integrity and patency, coverage and stabilization sterile²⁴.

We know that understanding the aspects related to its use is essential for nursing to carry out the evaluation, indication and maintenance of dressings, contributing to the safety of patients who need the use of CVC or any other intravenous catheter - IVC, be it AVP or PICC²⁵.

It is necessary that the professional responsible for its planning and execution be trained and understand the factors that may compromise the procedure. In this context, the Nursing team must be aware and prepared technically and scientifically to ensure the prevention of adverse events, including the risk of phlebitis^{26,27}.

So let's embrace this innovation with the new standard to consider how we can all do better"¹¹. Understanding innovation as "introduction of novelty or improvement in the productive or social environment that results in new products, processes or services", it is perceived that it involves much more than simple changes in technology. Innovation "involves connections, interactions and influences of many and varying degrees—including

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