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Complications related to peripheral venipuncture and hypodermoclysis in cancer patients under palliative care

Complicações relacionadas à punção venosa periférica e à hipodermóclise em pacientes oncológicos sob cuidados paliativos

Complicaciones relacionadas con la venopunción periférica y la hipodermoclisis en pacientes oncológicos en cuidados paliativos

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Abstract: Objective: to identify complications related to peripheral venipuncture and hypodermoclysis in cancer patients hospitalized under palliative care. **Method:** this is a descriptive and longitudinal study. A questionnaire was used for the sociodemographic and clinical characterization of participants, a script for puncture assessment and monitoring. The data were ran through descriptive statistics. **Results:** seventy patients participated in the study, 54.3% (n=38) of whom were female and with a mean age of 68.8 years (SD = 15.0), whose main underlying oncological diseases were head cancer and neck and lung. Furthermore, 90% of assessed punctures were intravenous and the most frequent complications were localized pain, extravasation and a bent or pulled catheter. **Conclusion:** the complications observed during the study period were related only to venipunctures. There was a predominance of peripheral venipuncture due to the subcutaneous route, a viable and recommended alternative for cancer patients under palliative care.

Descriptors: Palliative Care; Hypodermoclysis; Infusions, Subcutaneous; Catheterization, Peripheral; Medical Oncology

Resumo: Objetivo: identificar complicações relacionadas à punção venosa periférica e à hipodermóclise em pacientes oncológicos hospitalizados sob cuidados paliativos. **Método:** estudo descritivo e longitudinal. Foi utilizado questionário para caracterização sociodemográfica e clínica dos participantes, roteiro para a avaliação e acompanhamento da punção. Os dados foram analisados por meio da estatística descritiva. **Resultados:** participaram do estudo 70 pacientes, sendo 54,3% (n=38) do sexo feminino e com idade média de 68,8 anos (DP = 15,0), cujas principais doenças oncológicas de base foram câncer de cabeça e pescoço e de pulmão. Ademais, 90% das punções avaliadas foram endovenosas e as complicações mais frequentes foram dor local, extravasamento e cateter dobrado ou tracionado. **Conclusão:** as complicações observadas no período do estudo foram relacionadas

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apenas às punções venosas. Houve predominância da punção venosa periférica em detrimento da via subcutânea, uma alternativa viável e recomendada para os pacientes oncológicos sob cuidados paliativos.
Descritores: Cuidados Paliativos; Hipodermóclise; Infusões Subcutâneas; Cateterismo Periférico; Oncologia

Resumen: **Objetivo:** identificar las complicaciones relacionadas con la venopunción periférica y la hipodermoclisis en pacientes con cáncer hospitalizados bajo cuidados paliativos. **Método:** estudio descriptivo y longitudinal. Se utilizó un cuestionario para la caracterización sociodemográfica y clínica de los participantes, un guión para la valoración y seguimiento de la punción. Los datos fueron analizados utilizando estadística descriptiva. **Resultados:** en el estudio participaron 70 pacientes, de los cuales el 54,3% (n=38) eran mujeres y con una edad media de 68,8 años (DE=15,0), cuyas principales patologías oncológicas de base fueron cabeza y cuello y pulmón. Además, el 90% de las punciones evaluadas fueron intravenosas y las complicaciones más frecuentes fueron dolor local, extravasación y catéter doblado o tirado. **Conclusión:** las complicaciones observadas durante el período de estudio se relacionaron únicamente con las punciones venosas. Predominó la punción venosa periférica en detrimento de la vía subcutánea, alternativa viable y recomendada para pacientes oncológicos en cuidados paliativos.
Descriptores: Cuidados Paliativos; Hipodermoclisis; Infusiones Subcutáneas; Cateterismo Periférico; Oncología Médica

Introduction

Palliative care (PC) is mainly offered to people who are at the end of their life, with no age restriction, who, due to serious illnesses, face intense health-related suffering. The purpose of PC is to offer active holistic care and improve the quality of life of patients, their families and their caregivers.[1] Considering the growth of the elderly population and chronic-degenerative diseases, such as cancer, discussions on methods alternatives for medication administration and rehydration solutions have grown, such as subcutaneous route use, when the intravenous and oral routes are limited, and invasive procedures, such as venous dissection and insertion of catheters, when they are contraindicated.[2]

Peripheral venipuncture (PPV) is an intravenous therapy routinely performed in hospital care using technological devices, including peripheral intravenous catheters.[3] It is a technique indicated for the administration of medications, fluids, blood and nutritional components, used in patients who need intravenous therapy to treat pathologies in different circumstances. The most used catheter is the peripheral venous catheter (PVC), which allows the application of medications or solutions, parenteral nutrition, blood products and blood collection.[3-4] Despite being widely used,

PVC can lead to the development of localized and systemic complications, with evidence of the high incidence of localized reactions after its insertion, especially phlebitis and infiltration.[4]

Hypodermoclysis, on the other hand, consists of medication and fluid administration in the subcutaneous space, continuously or intermittently.[2] It is described as a simple, safe procedure without serious complications, but it is still a little known technique and used in the hospital setting, there are questions regarding its use, which drugs and fluids can be safely administered, in what volume and infusion rate, among other aspects.[5-6]

Complications related to the subcutaneous route use are rare when the correct use of the puncture procedure, dilution and infusion of drugs is adopted.[7] According to an integrative review on the adverse effects found in hypodermoclysis performed in adults, the most reported reactions in the studies were pain and edema at the puncture site, cellulitis and insufficient absorption of the solution with accumulation of fluid at the site. The risks mentioned are reversible and of little clinical importance, which can be treated with localized massage, a decrease in the infusion rate and change of puncture site. In Brazil, there are still few studies and protocols on the use of hypodermoclysis, requiring the development of research that address the proposed method as an alternative for patients, including issues related to adverse effects, patient safety, effectiveness of the technique and its impact on patients' quality of life.[6,8-9]

Given the above, the aim was to identify complications related to PPV and hypodermoclysis in cancer patients hospitalized under PC.

Method

This is a descriptive and longitudinal study, carried out in two medical clinic wards of a secondary-level hospital in the countryside of the state of São Paulo. The population of this research corresponded to cancer patients hospitalized under PC, accompanied by inter-consulting PC teams. The inclusion criteria were to be patients over 18 years of age, diagnosed

with oncological disease, hospitalized under PC (with the ICD 10 – Z51.5 record in the medical record) and with the need for puncture for parenteral drug therapy. The exclusion criterion was the absence of a family member or caregiver to respond for patients in cases where he/she is unable to respond to the collection instruments.

Potential participants were invited to participate in the research through a direct approach carried out by the researcher. After they agreed, the Informed Consent Form (ICF) was read in duplicate. A copy was delivered to patients, and the other was filed by the researcher after consent and signature. In situations where patients were not able to consent to participate in the study (drowsiness, sedation), consent and signature of an ICF were obtained from their legal guardians.

Data collection was carried out from September 2019 to February 2020, through an interview with patients and/or their legal guardian, medical record consultation, direct puncture assessment and daily monitoring (venous or subcutaneous), from its acquisition to the moment when there was no longer an indication for puncture or patient discharge/death. Instruments were used to obtain patients' sociodemographic and clinical data and a script for puncture assessment and monitoring.

To obtain the sociodemographic aspects, the following data were collected: age, sex, marital status, complete years of formal education, main caregiver, degree of kinship with patient and complete years of formal education of caregivers. For clinical characterization, the following information was obtained by consulting the medical records: admission date, reason for admission, underlying oncological disease, exclusive PC indication date, modifying treatment of the disease to which patients were previously submitted, onset dates and end of modifying treatment, purpose of PPV or hypodermoclysis, and drugs prescribed for parenteral administration.

Daily and direct puncture assessment and observation was performed by graduate students, nurses or duly trained teachers, through a script created by the study authors, containing puncture type (venous or hypodermoclysis), number of puncture attempts, puncture date, puncture site, catheter and gauge type, presence or not of catheter stabilization tape, coverage type, puncture

identification (considered present when containing date and time of performance, name of the professional who performed it and gauge of the catheter used), signs of infection at the catheter insertion site (pain, local heat, hyperemia, edema, existence of secretion in the catheter insertion), need for puncture change and reason, infeasibility of puncture maintenance.

Data were structured in Microsoft Excel spreadsheets, undergoing double typing and a validation step to minimize transcription errors. For the sociodemographic and clinical characterization, descriptive statistics were used, in order to summarize the information of interest. Qualitative variables were described in terms of frequency and percentage, and quantitative variables, using measures of central tendency (mean) and dispersion (standard deviation).

Data were processed and analyzed using the statistical program IBM Statistical Package for Social Sciences (SPSS), version 24.0, for Windows. The project was prepared in accordance with the precepts of Resolution CNS 466/12 and was approved by the Institutional Review Board of the *Universidade de São Paulo* at *Escola de Enfermagem de Ribeirão Preto*, on September 20, 2018, under Opinion 2.912. 046 and CAAE 91320318.1.3002.5440.[10]

Results

The sample consisted of 70 participants, whose sociodemographic characteristics are shown in Table 1. In all, 86 patients who met the inclusion criteria were invited to participate in the study; however, there were 16 refusals, most of them related to the fact that patients were feeling unwell at the time or not wishing to take part in the research.

Table 1 - Sociodemographic characterization of cancer patients under palliative care. Ribeirão Preto - SP, 2019. (n=70)

Variables	Mean (SD)	n	%
Age	68.8 (15.0)		
Sex			
Female		38	54.3
Male		32	45.7
Marital status			

Married/Consensual union		38	54.3
Widow		13	18.6
Separated/Divorced		10	14.3
Single		9	12.9
Years of formal study (n=64)	5.8 (4.3)		

The clinical characterization of participants is shown in Table 2. The main underlying oncological diseases were head and neck (11.4%; n=8), lung (11.4%; n=8), breast (10.0%; n=7) and colorectal (10.0 %; n=7). The most prevalent metastases were pulmonary (25.7%; n=18), bone (24.3%; n=17) and liver (21.4%; n=15). Among the main comorbidities are hypertension (HP) (47.1%; n=33), diabetes mellitus (27.1%; n=19) and dyslipidemia (14.3%; n=10).

Table 2 - Clinical characterization of cancer patients under palliative care. Ribeirão Preto - SP, 2019. (n=70)

Variables	n	%
Underlying cancer disease		
Head and neck	8	11.4
Lung	8	11.4
Breast	7	10.0
Colorectal	7	10.0
Prostate	6	8.6
Esophagus	5	7.1
Other	27	39.9
Metastases		
Lung	18	25.7
Bone	17	24.3
Liver	15	21.4
Lymph nodes	8	11.4
CNS	6	8.6
Other	30	42.6
Comorbidities		
Hypertension	33	47.1
DM	19	27.1
Dyslipidemia (DLP)	10	14.3
Hypothyroidism	9	12.9
COPD	6	8.6
Other	17	24.3

Note.: CNS – Central Nervous System. HP – Hypertension. DM – Diabetes Mellitus
COPD - Chronic Obstructive Pulmonary Disease

During the study period, 200 punctures were assessed, among which 180 (90.0%) were peripheral venous punctures and 20 (10.0%) were subcutaneous punctures (hypodermoclysis). The characteristics of assessed punctures are presented in Table 3.

Table 3 – Characteristics of punctures in cancer patients under palliative care. Ribeirão Preto - SP, 2019. (n=70)

Variables	n	%
Puncture type		
Peripheral venipuncture	180	90.0
Subcutaneous puncture	20	10.0
Number of venipuncture attempts		
1	69	55.7
2	34	27.4
3	12	9.7
4	5	4.0
5	4	3.2
Intravenous puncture site		
Dorsal metacarpal	38	20.8
Cephalic	33	18.0
Basilic	24	13.1
Cubital median	31	16.9
Brachial	31	16.9
Dorsal plexus	15	8.2
Subcutaneous puncture region		
Anterolateral thigh	12	60.0
Abdominal	5	25.0
Deltoid	3	15.0
Catheter type		
Abocath® non-needled (Teflon)	192	93.7
Intima® non-needled (Teflon)	13	6.3
Catheter gauge		
22	139	69.5
20	46	23.0
24	15	7.5
Catheter stabilization tape (if venipuncture)		
Yes	128	73.1
No	47	26.9
Coverage type		
Sterile transparent film	189	91.3
Coverage association	17	8.2
Surgical tape	1	0.5
Puncture identification		

Incomplete	171	84.7
Yes	26	12.9
No	5	2.5
Purpose of puncture		
Antibacterial	33	11.8
Analgesia	32	11.4
Hydration	12	4.3
Dyspnea control	11	3.9
Nausea and vomiting control	8	2.9
Neurological symptom control	3	1.1
Constipation improvement	1	0.4

Table 4 shows the main medications used by the study participants. The most indicated class of drugs was analgesics, with dipyrone as the most prescribed drug (12.1%; n=34), followed by serum therapy for hydration (10.7%; n=30), corticoid dexamethasone (7, 9%; n=22) and ondansetron antiemetic (6.4%; n=18).

Table 4 – Medicines most used by cancer patients under palliative care. Ribeirão Preto - SP, 2019. (n=70)

Medication	n	%
Dipyrone	34	12.1
Serum therapy for hydration	30	10.7
Dexamethasone	22	7.9
Ondansetron	18	6.4
Ceftriaxone	13	4.6
Morphine solution in continuous infusion pump	11	3.9
Bromopride	8	2.9
Morphine boluses	8	2.9
Meropenem	8	2.9
Others	61	22.1

The reasons for hospitalization are shown in Table 5, with the main reasons being related to respiratory changes (6.8%; n=19), such as dyspnea, respiratory distress and oxygen dependence, and pain (6.8%; n=19), followed by symptoms related to adynamia (3.6%; n=10).

Table 5 – Main reasons for hospitalizations among cancer patients under palliative care. Ribeirão Preto - SP, 2019. (n=70)

Reason for admission	N	%
Dyspnea/Respiratory discomfort	19	6.8
Pain	19	6.8
Adynamia/Lowering or altered level of consciousness/Responsiveness/Prostration/Drowsiness	10	3.6
Fall/Worsening of general condition	9	3.2
Nausea/Vomiting	9	3.2
Pneumonia	8	2.9
End of antibiotic therapy	6	2.1
Asthenia/Loss of strength	6	2.1
Fever	5	1.8
Others	49	18.2

Throughout the study, 85 complications were observed, all related to PPV, the main ones being localized pain (30.5%; n=26), extravasation (25.9%; n=22), kinked catheter (24.7 %; n=21) and a pulled catheter (18.8%; n=16). Complications related to hypodermoclysis were not identified.

Discussion

Other studies that assessed PVC and associated complications showed participants with characteristics similar to those in the present study, especially those related to gender, average age over 50 years, incomplete primary education and arterial hypertension as the main comorbidity.[3,11-13]

Regarding the underlying diseases presented by the research participants, the similarity with data from the National Cancer Institute (INCA) can be seen, in which the most incident types of cancer, in both sexes, are estimated for 2020 (except skin non-melanoma), were colon and rectum (9.1% in men and 9.2% in women), followed by trachea, bronchus and lung (7.9% in men and 5.6% in women).[14]

The most common cancer type in men is prostate (29.2%), and in women, breast (29.7%).[14] In a prospective study carried out with 10 patients under PC diagnosed with cancer, seven patients were

diagnosed with lung cancer, one patient with breast cancer, one with prostate cancer and one with gastrointestinal cancer, showing similarity between oncological diseases found in this research.[8]

The data collected showed a high prevalence of HP among participants (47.1%). Chronic non-communicable diseases (CNCDs) account for 63% of the causes of death in the world, equivalent to the main cause of morbidity and mortality. About a third of global deaths are caused by cardiovascular disease, with hypertension being the most prevalent.[15] In Brazil, self-reported HP predominates in the Southeast, with 23.3%.[16] These data justify HP as the main comorbidity among research participants.

Diabetes Mellitus was the second most common comorbidity in the study patients. About 80% of the world population with Diabetes Mellitus lives in low- and middle-income countries. According to descriptive research that used data from laboratory tests from the Brazilian National Health Survey (PNS - *Pesquisa Nacional de Saúde*) between 2014 and 2015, the prevalence of Diabetes Mellitus is higher among women and increases with age.[17]

In the present article, performing PPV was superior to performing subcutaneous puncture. The clinical characteristics of patients with PC and elderly patients, who have the natural aging process of the veins and loss of skin elasticity, making it difficult to obtain venous access, especially in patients over 80 years old or in those who have already undergone chemotherapy, point to the indication of hypodermoclysis.[6] However, despite this, adherence to the performance of hypodermoclysis (subcutaneous puncture) was low in this study.

The PPVs obtained with only one attempt were 55.7%, and 44.3% were obtained with two or more attempts. According to the literature, the chances of success in the first attempt are between 10% and 55%, being considered a challenging technique for professionals who perform it.[18] Thus, the result of this research finds data similar to those in the literature.

An integrative review that identified the factors that hinder PPV in adults concluded that the difficulty in obtaining it is associated with demographic aspects such as sex and age; clinical data, such as comorbidities, nutritional status, visibility and palpability of the venous network;

device-related issues such as catheter gauge and model; and elements related to professionals' ability.[19] In the present study, due to participants' clinical conditions, the skill of the professionals who performed the procedure was a differential for the success of punctures obtained in the first attempt, giving patients less discomfort related to numerous pricks.

The main place of choice for PVC insertion was the dorsal metacarpal vein (20.8%), which is in agreement with other findings on PPV, which indicate the back of the hand as the most used site for insertion of venous catheters.[12-13] Regarding the subcutaneous puncture site, 60.0% were performed primarily in the anterolateral region of the thigh, followed by the abdominal region (25.0%) and the deltoid region (15.0%). In a research carried out in Curitiba, Paraná, with patients being monitored by the PC team in outpatient and/or home care, from a total of 30 hypodermoclysis, 28 were carried out in the infraclavicular region, and two in the abdominal region, which regions differed from the regions chosen by the professionals in this article, also considered adequate and safe.[3,9]

The most used catheter was Abocath® non-needled Teflon catheter (93.7%). Research carried out comparing types of intravenous catheters concluded that the cumulative risk rates for the development of phlebitis, infiltration and traction are lower with the use of Intima® non-needled Teflon catheter.[20] However, Intima® non-needled catheter was the least used, a fact probably related to the catheter cost and because it is a public health service with scarce resources.

Among the catheters, the most used gauge was 22G (69.5%), followed by 20G (23.0%) and 24G (7.5%). In a surgical service, where 58 patients with peripheral venous punctures admitted to a hospital in northern Portugal were analyzed, the most used gauge was 18G (70.5%), followed by 20G and 24G.[11] Another study identified the prevalence in the use of 22G (60.0%) and 20G (37.7%) gauges, followed by 18G (2.3%) and 24G (0.4%).[12] In two other studies of the same nature, there was a prevalence of the use of 20G catheters.[3,11]

A randomized clinical trial carried out with 169 participants indicates that the use of the 20G gauge reduces the risk of complications, when compared to the 22G gauge, due to the lower

incidence of infiltration.[20] However, smaller gauge catheters should be selected, as they reduce the occurrence of phlebitis due to irritation of the vein wall by the cannula and reduce the obstruction of blood flow within the vessel.[21]

Thus, 73.1% of intravenous punctures had catheter stabilization tape. Catheter stabilization preserves access integrity and prevents its displacement and loss.[21] Inadequate stabilization can lead to poor PPV adherence to the skin, which allows for partial or complete displacement, due to movement of the catheter in and out of the vein.[22] It is possible that this fact has led to the occurrence of complications, such as catheter traction, in the present study.

The predominant coverage type was the sterile transparent film (91.3%). All coverage used for peripheral catheters must be sterile and transparent or semi-occlusive in order to protect the puncture site, minimize the possibility of infection and secure the device to prevent movement and damage to the vessel.[22] In a hospital in Portugal, 110 patients with PVC were analyzed regarding the presence of phlebitis or infiltration, the most used dressing type was also the sterile transparent film (88.8%).[12] Another study carried out in Portugal identified the low adherence to the use of sterile, waterproof and transparent dressings among the nursing staff. This fact contradicts the measures to prevent phlebitis and infection, making it difficult to assess the catheter insertion site, requiring the fixation system exchange daily to allow visualization and assessment of insertion site, which, in several situations, resulted in catheter accidental exteriorization and the need for a new venipuncture.[23]

Only 12.9% of venous or subcutaneous punctures were complete, 84.7% of identifications were incomplete and 2.5% had no identification. Adequate identification is considered to include information such as the name of the professional who performed the procedure, date and time.[24] In this definition, catheter type and gauge was not included, since the transparent film allows this visual identification. The practice of non-identification can expose patients to

risk of infection and adverse reactions, due to inadequate installation and maintenance, which can result in an increase in length of stay and in the cost of hospitalization.[24]

In this research, the main purposes of punctures were antibiotic therapy, present in 33 cases (11.8%), followed by analgesia (11.4%) and hydration (4.3%). Despite these results, the most prescribed class of drugs in the present study was analgesics, with dipyrone being the most prescribed drug (12.1%), followed by serum therapy for hydration (10.7%).

Bibliographic research listed the main medications used in PC, showing that the main symptom treated is pain, with opioids and analgesics being the main classes of medications,[25] a result similar to that of this study, in which the main pharmacological class prescribed was of analgesics.

The main reasons for hospitalization were dyspnea, followed by pain, adynamia, worsening of general condition and nausea and vomiting. In southern Brazil, 213 cancer patients, hospitalized between 2005 and 2008, were approached in order to describe the structure and work process of the Interdisciplinary Home Care Program (*Programa de Internação Domiciliar Interdisciplinar*). The reason for hospitalization of these patients was investigated, identifying, among the most frequent symptoms, anorexia, pain and asthenia, in addition to dehydration, nausea and vomiting and dyspnea, reasons also present in the results of this research.[26]

Dyspnea is one of the most common symptoms in the context of oncological patients under PC, affecting 21 to 90% of patients, with or without pulmonary involvement, and it is important to carry out a thorough assessment of situation.[27] Pain was the second most frequent symptom in research participants, with a high prevalence. In a qualitative study carried out with 14 caregivers of people with advanced cancer, it was reported that 71% of patients had pain.[28] According to the concept of total pain, it is not only composed of the physical component, it also includes psychic, social and spiritual pain. Thus, adequate pain treatment is complex and individual, as it is subjective.[29] In this research, 85 complications were identified, all related to

PPV. The main complications presented among the participating patients were localized pain (30.5%), extravasation (25.9%), bent catheter (24.7%) and tractioned catheter (18.8%).

A large university hospital in Curitiba, Paraná, analyzed the distribution of complications from PVCs, finding phlebitis (18.34%) as the main complication, followed by infiltration (11.83%), obstruction (11.24%) and traction (9.47%).[20] Analysis performed with a sample of 92 catheters showed phlebitis (36.54%), infiltration (23.08%), accidental catheter traction (17.31%), obstruction (15.38%), localized infection (3.85%), extravasation (1.92%) and thrombophlebitis (1.92%) as the main complications related to PVC.[3] Thus, all complications related to PVC found in the present study are present in other studies of a similar nature.

The present study found the absence of complications related to hypodermoclysis, but analyzes describing such occurrences are found in the literature. An integrative review identified 13 articles that addressed the adverse effects of hypodermoclysis in adults. The most reported adverse effects in the analyzed studies were considered to be of minimal risk, reversible and of little clinical importance, such as pain and edema at the puncture site, cellulitis and insufficient absorption of solution with accumulation of fluid at the site. The adverse effects mentioned can be treated through local massage, puncture site reduction and change. Such occurrences are frequently reported after three days of treatment in a single subcutaneous site, and may also be caused by erroneous puncture. Therefore, it is recommended that the technique be performed by trained professionals, with the insertion site being inspected regularly and with a permanence time between 48 and 96 hours. Thus, according to the review, the adverse effects caused by hypodermoclysis in adult patients are, in most cases, minimal and reversible and do not cause serious damage.[6]

One limitation observed was the low number of hypodermoclysis included in this study, due to the reduced time to perform data collection.

The findings allow us to identify the need to disseminate knowledge of the benefits of hypodermoclysis and its impacts on the quality of life of cancer patients under PC, who undergo several painful interventions so that there is greater adherence to the procedure by the health professionals who assist them.

Conclusion

The rate of complications related to PPV was high, not being observed in subcutaneous punctures. There was the predominant use of PPV in detriment to the subcutaneous route use, even though this is a viable and recommended alternative for cancer patients under PC.

The present study did not obtain a significant amount of hypodermoclysis, reaffirming it as a technique still little used by health professionals, however, when performed, it did not present adverse effects, being characterized as a safe technique without serious complications.

The main complication found in the present study was localized pain, easily resolved by changing puncture site. Thus, in general, the risk of complications presented was minimal and of little clinical importance, and could be easily treated and resolved.

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3 – Fabiana Bolela de Souza
Conception or design of study/research, data analysis and/or interpretation, final review with critical and intellectual participation in the manuscript.

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