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Incidence and adverse events of hypodermoclysis in the elderly in palliative care

Incidência e eventos adversos da hipodermóclise no idoso em cuidados paliativos

Incidencia y eventos adversos de hipodermoclisis en ancianos en cuidados paliativos

ABSTRACT

Objective: to estimate the incidence, time of occurrence of adverse events and time of permanence of hypodermoclysis in the elderly. **Method:** Research carried out with 127 elderly people in Palliative Care. Assessment of hypodermoclysis was performed every 24 hours until the event occurred. Descriptive analysis was performed, proportions and incidence rate were calculated per 100 punctures/patients. **Results:** The incidence rate of adverse events was 22.8% for hypodermoclysis and 27% for individuals using hypodermoclysis. The catheter remained for an average of 4 days, with a minimum of 1 day and a maximum of 15 days; the chance of adverse events on the 1st day was 6%, 28% on the 5th day and 48% on the 10th. **Conclusion:** The incidence of adverse events was small and localized; mean time of catheter permanence at the insertion site was 4 days and the probability of presenting complications increased over the days.
Descriptors: Palliative Care; Subcutaneous Absorption; Health of the Elderly; Hypodermoclysis; Nursing Care

RESUMO

Objetivo: estimar a incidência, tempo de ocorrência de eventos adversos e tempo de permanência da hipodermóclise no idoso **Método**: Pesquisa realizada com 127 idosos em cuidados paliativos. A avaliação da hipodermóclise foi realizada a cada 24 horas até a ocorrência do evento. Realizou-se análise descritiva, calculando as proporções e a taxa de incidência por 100 punções/pacientes. **Resultados**: A taxa de incidência dos eventos adversos foi de 22,8% para a hipodermóclise e 27% para os indivíduos em uso de hipodermóclise. O cateter permaneceu em média quatro dias, sendo no mínimo um dia e no máximo 15 dias; a chance de eventos adversos no primeiro dia foi de 6%, de 28% no quinto dia e 48% no décimo. **Conclusão**: Incidência de eventos adversos foi pequena e localizada; tempo médio da permanência do cateter no local de inserção foi de quatro dias e as probabilidades de apresentar complicações aumentaram no decorrer dos dias.
Descritores: Cuidados paliativos; Absorção subcutânea; Saúde do idoso; Hipodermóclise; Cuidados de enfermagem

RESUMEN

Objetivo: estimar la incidencia, tiempo de ocurrencia de eventos adversos y tiempo de permanencia de la hipodermoclisis en ancianos **Método:** Investigación realizada con 127 ancianos en Cuidados Paliativos. La evaluación de la hipodermoclisis se realizó cada 24 horas hasta que ocurrió el evento. Se realizó análisis descriptivo, se calcularon proporciones y tasa de incidencia por 100 punciones/pacientes. **Resultados:** La tasa de incidencia de eventos adversos fue del 22,8 % para la hipodermoclisis y del 27 % para los individuos que usaban la hipodermoclisis. El catéter permaneció en promedio 4 días, con un mínimo de 1 día y un máximo de 15 días; la probabilidad de eventos adversos el primer día fue del 6 %, del 28 % el quinto día y del 48 % el décimo. **Conclusión:** La incidencia de eventos adversos fue pequeña y localizada; el tiempo medio de permanencia del catéter en el sitio de inserción fue de 4 días y la probabilidad de presentar complicaciones aumentó con el transcurso de los días.
Descriptores: Cuidados Paliativos; Absorción Subcitanéa; Salud del Anciano. Hipodermoclisis; Atención de Enfermería

Raquel Eustaquia de Souza[1]
0000-0002-8980-2784

Isabel Yovana Quispe Mendoza[1]
0000-0002-7063-8611

Clarissa Jesus Ferraciolli[1]
0000-0002-4229-337X

Giovana Paula Rezende Simino[1]
0000-0002-9814-3004

Vania Regina Goveia[1]
0000-0003-2967-1783

Gilberto de Lima Guimarães[1]
0000-0001-6027-372X

[1]Universidade Federal de Minas Gerais (UFMG), Campus Saúde- MG, Brasil.

Corresponding author:
Raquel Eustaquia de Souza
E-mail: raquel.souza.enf@hotmail.com

INTRODUCTION

Hypodermoclysis is the administration of fluids and medications subcutaneously (SC), being an alternative used mainly in geriatric clinics and palliative care, scenarios in which patients present health conditions that preclude the proper maintenance of hydration, nutrition, and symptom control[1]. Therefore, it may be considered a route of choice for fluid and electrolyte replacement and administration of some drugs in elderly patients [1-2].

The mechanism of hypodermoclysis is the administration of solutions and drugs in the subcutaneous space, and its absorption occurs by simple diffusion and depends on the blood and lymph capillaries present in the septa of the hypodermis[1]. Among the benefits it offers, the following are reported: simple, low-cost, comfortable technique, and several anatomical sites for catheter insertion. In addition, it constitutes an alternative for solution and drug administration in the home environment [3]. Nevertheless, its use in clinical practice is still incipient among health professionals [4].

Hypodermoclysis is a safe and effective procedure. However, adverse events of two types may occur, namely: local adverse events at the catheter insertion site and systemic adverse events. Information regarding the incidence of adverse events resulting from hypodermoclysis is scarce in the literature. Some studies report only the proportion of the most frequent local events: edema (3%), abscess (2.1%) and erythema (1.7%)[5]; cellulitis (2%)[6], erythema (1.7%), edema (5.3%)[7], hyperemia (9.1%)[8] and extravasation (25.9%)[9].

Concerning the length of stay of the catheter, there are recommendations to change the catheter every 96 hours[10], every five days, depending on the type of catheter[1]. According to the Brazilian National Health Surveillance Agency, catheter permanence should be seven days for drug administration and every 48 hours or after infusion of 1.5 liters, at the insertion site[10].

In a study carried out with elderly patients within the home environment, diagnosed with cancer, the length of catheter stay was 11.42 (± 23.90) days longer, according to the authors, the use of hypodermoclysis at home provided comfort to the elderly during the last days of life.[5] In a study carried out with adult patients under palliative care, the authors stated that the length of catheter stay varied from less than 24 hours to six days, with a mean of 3.5 days, the main reason for removal of the catheter was the standard time at the institution, which was five days [9].

Thus, it is evident the discrepancy regarding the length of catheter stay, which can hinder the decision-making of health professionals in the management of hypodermoclysis. The time of occurrence of adverse events is unknown in the literature, as well as the incidence of adverse events at the site of insertion of hypodermoclysis. Therefore, knowledge of these variables may favor the planning of care actions focused on the prevention of new adverse events, provide scientific subsidies for their use by the health team, and constitute an indicator of the quality of care.

Therefore, this study aimed to estimate the incidence, time of occurrence of adverse events, and length of stay of the catheter in the insertion site of hypodermoclysis in the elderly.

METHOD

This is a longitudinal prospective study with a quantitative approach involving elderly patients, developed in a palliative care unit of a university hospital in Belo Horizonte (Minas Gerais), located in the southeastern region of Brazil. The institution serves exclusively patients of the Unified Health System (UHS) and has 340 beds. Out of these, 18 are destined for the palliative care ward. The care is provided through inter-consultation with other sectors of the hospital. The clinical staff is made up of doctors, nurses, physical therapists, social workers, psychologists, and nutritionists.

Data were collected from August to November 2019. A structured form was used, containing demographic and socioeconomic data: age (ordinal qualitative variable, 60 to 69 years, 70 to 79 years, 80 to 89 years, and over 90 years)

sex (dichotomous qualitative variable, male and female); clinical variables: puncture site (categorical variable, vastus lateralis thigh, abdomen, deltoid, infra scapular, subclavicular), reasons for catheter removal (categorical variable, death, discharge, accidental loss, hypersensitivity); length of catheter stay (dichotomous variable, less than seven days and more than seven days); the adverse event which was considered in days and also categories (dichotomous variable in yes or no).

Patients with a medical prescription for drugs and infusion of solutions via hypodermoclysis, age ≥ 60 years, of both genders were considered eligible for the study. Elderly patients without a companion who were unable to answer the collection of information and sign the consent form were excluded.

After verifying the established inclusion criteria, as soon as there was a prescription for hypodermoclysis in the patient's medical record, the unit nurse performed the hypodermoclysis technique based on the Manual of the Brazilian Society of Geriatrics and Gerontology 2017[1], the Manual on Measures for Prevention of Health Care-Related Infection of the Brazillian Health Regulatory Agency - ANVISA[13] and the protocol of the Hospital Infection Control Committee of the institution. It is noteworthy that the device used for hypodermoclysis was the non-needled catheter No. 20.

For this study, the outcomes of interest were the incidence rate and time of occurrence of adverse events and the length of catheter stay at the site of hypodermoclysis insertion. Adverse events were considered as those that occurred at the catheter insertion site from the beginning until days after infusion of solutions and drugs, namely: edema, erythema, ostium cellulitis, induration, hematoma, necrosis, obstruction, hypersensitivity to the polyurethane film.

Due to the lack of studies that substantiate the timing of adverse events, in this study, an initial assessment (D1) was performed to ensure that the outcome variable is not present. The hypodermoclysis puncture site assessment was performed every 24 hours until the event occurred (D2, D3, ...). The evaluation of adverse events at the catheter insertion site was performed solely by the main researcher of the study. The instrument used for evaluation was developed by the researchers.

The sample size was calculated considering the occurrence of adverse events of 25%[11], with a significance level of 5%, a power of 90%, a mean effect size (d=0.50) that equals an odds ratio of 2.5, that the multiple correlation coefficient would be 0.50 thus, a minimum of 126 subjects should be included. The study participants were selected by convenience sampling, which requires choosing the participants who are most accessible at the time of data collection. The study comprised 127 elderly individuals followed up with hypodermoclysis, but due to the fact that a participant could be punctured in more than one anatomical site, a total of 184 hypodermoclysis punctures were used for the analysis.

SPSS software (IBM, v. 25.0) was used for data analysis. Descriptive statistics were used to present the characteristics of the study participants. To determine the overall incidence rate of adverse events, we considered in the numerator the number of elderly with hypodermoclysis who presented adverse events resulting from its use and, in the denominator, the total number of elderly with hypodermoclysis and exposure to the same characteristics, multiplied by 100.

To exploratively verify the distribution of time to complication in the elderly with hypodermoclysis, the Kaplan-Meier estimator was used. In addition, the mean survival time, including 95% confidence intervals (CI), was determined. Hypodermoclysis without adverse events, accidental loss, death, and discharge were considered censoring, and failure (event) was defined at the time of the first identification of the occurrence of the investigated outcome.

All stages of the study were guided by Resolution No. 466 of 2012 - National Health Council, for Scientific Research on Human Beings

in Brazil. Data collection occurred after project approval by the Ethics and Research Committee of the Federal University of Minas Gerais with Opinion No. 4,328,959. Informed consent was obtained from all study participants by signing the Free and Informed Consent Term.

RESULTS

A total of 127 elderly people were eligible for the research follow-up, with a predominance of females and a mean age of 78.48 (±9.3). Regarding the procedure, 184 hypodermoclysis punctures were considered for analysis. Of these, 56.5% were performed in the lateral vastus of the thigh, in 22.8% presented adverse events at the puncture site, with obstruction and edema being the most frequent adverse events (46.5% and 34.8%, respectively). In most cases of hypodermoclysis (88.6%), the length of stay was equal to or less than seven days (Table 1).

Table 1 – Sociodemographic and clinical characteristics of the study participants. Belo Horizonte, Minas Gerais, Brazil, 2020.

Variable	Sex	n	%
Sex (127)	Female	73	60.8
	Male	47	39.2
Age (127)	60 to 69	20	15.7
	70 to 79	44	34.6
	80 to 89	51	40.2
	90 +	12	9.5
Adverse event (43)	Obstruction	20	46.5
	Edema	15	34.8
	Cellulite	02	4.6
	Pain	02	4.6
	Hardening	01	2.3
	Erythema	01	2.3
	Hematoma	01	2.3
	Hypersensitivity	01	2.3
Other causes of catheter removal (117)	Death	52	44.4
	Discharge	37	31.6
	Accidental Loss	28	23.9
	Others	24	20.5
Puncture site (184)	Lateral thigh vastus	104	56.5
	Abdomen	47	25.5
	Deltoid	23	12.5
	Infrascapular	06	3.3
	Subclavicular	04	2.2
Length of stay (184)	Less than 7 days	163	88.6
	More than 7 days	21	11.4

Source: Research data

The incidence rate of adverse events (n=184 hypodermoclysis punctures) was 22.8%, and when individuals (n=127 elderly) were considered, it was 27% (Table 2).

Table 2 – Incidence rate of adverse events resulting from hypodermoclysis. Belo Horizonte, Minas Gerais, Brazil, 2020.

	N	Incidence rate	95% CI*
Hypodermoclysis Punctures	184	42(22.8)	[1.71 – 1.83]
Participants	127	34(27.0)	[0.20 – 0.35]

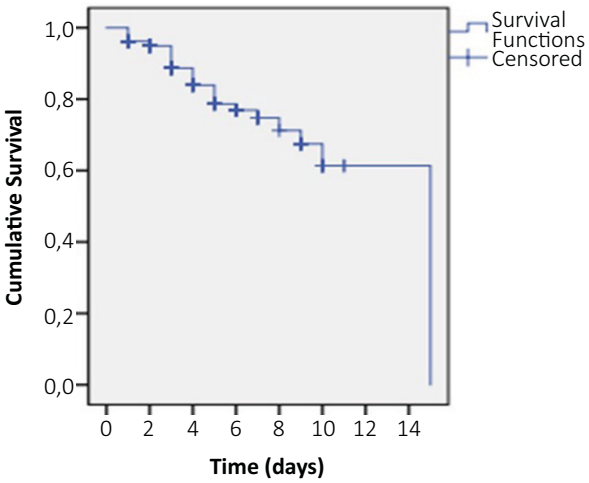
*CI: Confidence Interval. Source: Research data.

The average length of stay of the catheter was four days, with a minimum of one day and a maximum of 15 days. The probability of presenting complications increased over the days, so on day 1, the probability of not presenting adverse events was 94%, on day 5, 72%, and on day 10, 52% (Table 3, Graph 1).

Table 3 – Probability of occurrence of adverse events at the insertion site of hypodermoclysis in the elderly, obtained through the Kaplan-Meier estimator. Belo Horizonte, Minas Gerais, Brazil. 2020.

Time Days	N	Probability of survival	95% CI*
1	184	0.94	[0.9;0.97]
2	149	0.87	[0.82;0.92]
3	122	0.83	[0.77;0.89]
4	93	0.80	[0.74;0.87]
5	64	0.72	[0.64;0.81]
6	45	0.70	[0.62;0.80]
7	36	0.68	[0.59;0.78]
8	21	0.65	[0.55;0.77]
9	19	0.58	[0.45;0.73]
10	11	0.52	[0.39;0.71]
15	1	0.00	-

*CI: Confidence Interval. Source: Research data.



Graph 1 – Kaplan-Meier curve- Probability of non-occurrence of adverse events due to hypodermoclysis in the elderly. Belo Horizonte, Minas Gerais, Brazil. 2020

DISCUSSION

Hypodermoclysis is a simple procedure that can be used more frequently in the elderly in palliative care. In recent decades it has been shown to be a safe, easy, and acceptable procedure for the administration of medications and infusions. It is a procedure that involves and generates less cost than the intravenous route[7]. However, it is still underused, in a study of cancer patients 200 punctures were performed, of which only 10% were hypodermoclysis punctures and 90% were peripheral venous punctures[9].

The administration of solutions and medications has been associated with low rates of adverse events[7]. In this study, the incidence of adverse events was 42 (22.8%); in the literature, a meta-analysis study was identified in which participants reported 90 adverse events per 1000 infusions[7]; another review study pointed out that of 13 selected articles, 61% reported adverse events[9]. In the studies cited, the authors provide data on the frequency of adverse events in a heterogeneous manner, which does not allow comparison with the results of this study.

Among the adverse events at the hypodermoclysis puncture site, obstruction and edema were the most frequent. The latter was also identified in other studies[5,7] and is presented

as an adverse event of minimal risk, without changes in therapeutic attitudes or worsening of the clinical picture, being resolved by changing the infusion point, i.e., a new puncture.

Clinically, after fluid infusion, edema is expected at the catheter insertion site for up to four hours; in this study, edema was considered an adverse event after the fourth hour. It is believed that edema may have occurred due to saturation of the subcutaneous tissue, it is worth noting that most participants had subcutaneous folds of less than 1.0 cm. It is known that drugs and solutions administered by hypodermoclysis are absorbed through the mechanism of capillary diffusion. Thus, patients who present edema may have their therapy impaired [12].

When it comes to edema as an adverse event of hypodermoclysis, different factors may interfere with fluid absorption: a) albumin levels, an essential protein for the correct distribution of body fluids between the compartments[7]. b) infusion rate, which varies according to the medication and patient characteristics. Authors recommend the use of slower infusion rates to allow the gradual transfer of fluid into the intravascular space[7]. c) subcutaneous tissue, the larger the area of subcutaneous tissue, the greater the absorption. d) circulation, in places where blood circulation is more intense, absorption tends to be faster. It is clear from the factors listed that studies that address these variables are necessary because in the literature there are no studies that establish these relationships.

Regarding catheter obstruction, the result of this study is discrepant from the literature data. Catheter obstruction was identified in only one patient in a geriatric hospital in Germany[10], but the percentage was not reported. Obstruction is due to catheter malfunction, which leads to an inability to deliver solutions, most often due to a blood clot, mechanical problems, or intraluminal precipitation of lipids or drugs, resulting in their removal [13].

It is recommended that in bolus infusion, after medication administration, 0.5 mL of 0.9% saline solution (SS 0.9%) be infused to ensure that the volume of medication is totally infused and, consequently, to prevent catheter obstruction[14]. The institution where the study was conducted has a protocol that recommends the administration of 0.9% saline solution after medication administration; however, for this study, it was not verified whether this recommendation was followed.

Although edema and obstruction are classified in studies as minor adverse events, they can generate discomfort, cause pain, limit the patient's mobility, and consequently impact the patient's quality of life [9].

The average length of stay of the catheter was four days, with a minimum of one day and a maximum of 15 days. Survival analysis shows that, as the days go by, there is a greater risk of developing adverse events at the catheter puncture site. The results show that, until the fourth day, there is an 80% chance of the patient not presenting adverse events resulting from hypodermoclysis.

The mean and maximum lengths of stay of the catheter in this study are higher than the results found in a review study, in which the length of stay was 93.5 hours for the SC route and 42.8 hours for the IV route[7]. Another study showed that the average catheter stay was 3.5 days, with a maximum of up to six days; the authors reveal that, at the institution, it was standardized that catheters should remain in place for no more than 96 hours[9].

The institution where this study was conducted has a hypodermoclysis protocol, which determines that the catheter should be changed every five days. However, the elderly who participated in the study were followed until the occurrence of the event (adverse events). Although the average time of catheter stay was 4.11 days, it was possible to identify that the catheter can remain in the patient for up to 15 days, i.e., longer than what is foreseen in the care protocols, a fact that must be justified by the clinical particularities of each patient.

Finally, hypodermoclysis is a poorly explored route in clinical practice. Studies on the administration of drugs and solutions through the SC route as an alternative route are still limited, and it is believed that the lack of institutional protocols and staff awareness limits its use. However, even in the presence of adverse events, hypodermoclysis is a safe alternative route of drug and fluid administration, provided that the nursing staff is trained.

As contributions to the area, the results of this study may provide subsidies to permeate clinical guidelines, protocols, and standard procedures in patient care, in order to reduce the occurrence of adverse events and thus provide qualified assistance to the elderly in palliative care. However, further studies are needed to elucidate the influence of risk factors for the development of adverse events of the use of hypodermoclysis in the elderly in palliative care.

A limitation of the study is the fact that it was conducted in a single hospital.

CONCLUSION

This study shows that the incidence of adverse events was 22.8% for hypodermoclysis as a procedure and 27% for individuals using hypodermoclysis. The average time from catheter stay until the occurrence of adverse events was four days, minimum time of one day and a maximum time of 15 days. The rate of adverse events is higher in males when compared to females. The probability of presenting adverse events on day 1 was 6%, 28% on day 5 and 48% on day 10.

Edema at the puncture site and catheter obstruction were the most prevalent adverse events. It is worth noting that the adverse events identified are reversible and have a low potential to cause harm to an elderly patient in palliative care.

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