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Impact of non-adherent Ibuprofen foam dressing in the lives of patients with venous ulcers

Impacto do curativo de espuma não aderente com Ibuprofeno na vida dos pacientes com úlcera venosa

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ABSTRACT

Objective: *to evaluate pain in patients with lower limb venous ulcer who used non-adherent Ibuprofen foam dressing (IFD).* **Methods**: *we conducted a prospective study of patients with lower limb venous ulcers treated from April 2013 to August 2014. We used the Numerical Scale and McGill Pain Questionnaire, performing the assessments at the moment of inclusion of the patient in the study and every eight days thereafter, totaling five consultations. We divided the patients into two groups: 40 in the Study Group (SG), who were treated with IFD, and 40 in the Control Group (CG), treated with primary dressing, according to tissue type and exudate.* **Results**: *at the first consultation, patients from both groups reported intense pain. On the fifth day, SG patients reported no pain and the majority of CG reported moderate pain. Regarding the McGill Pain Questionnaire, most patients of both groups reported sensations related to sensory, affective, evaluative and miscellaneous descriptors at the beginning of data collection; after the second assessment, there was slight improvement among the patients in the SG. After the third consultation, they no longer reported the mentioned descriptors. CG patients displayed all the sensations of these descriptors until the fifth visit.* **Conclusion**: *non-adherent Ibuprofen foam dressing is effective in reducing the pain of patients with venous ulcers.*

Keywords: *Varicose Ulcer. Lower Extremity. Pain Measurement. Ibuprofen. Quality of life. Patient-Centered Care.*

INTRODUCTION

Venous ulcers are a consequence of chronic venous insufficiency, due to venous hypertension caused by valvular incompetence of the superficial and deep veins, venous obstruction or a combination of these factors[1,2]. They most commonly affect the lower limbs and commit about 5% of the adult population in Western countries, with a prevalence of 0.3%. Their occurrence increases with age, being higher than 4% in individuals over 65 years old[1,3]. They may present exudate and odor, with the need to change dressings several times a day, with an impact on the lifestyle. It is common for the patient to present frustration and hopelessness related to treatment, since some of these lesions can take months to heal[4-7]. They cause pain, edema, loss of mobility and withdrawal from work, often leading to disability retirement. As a consequence of the pain, which aggravates or causes difficulty in locomotion, and restriction of activities of daily living and leisure, venous ulcers can lead to changes in quality of life and self-esteem, and determine anxiety and depression, which may contribute to delay the ulcer healing process[8-15].

The Ibuprofen foam dressing (IFD) is a non-adherent dressing, formed by foam attached to a semipermeable polyurethane film that allows Ibuprofen release into the wound by the presence of fluids or exudate. It is an innovative technology that promotes better control of the exudate, ensures a minimum risk of leakage or maceration of the skin, brings pain relief during the use time and during its exchange and promotes a humid environment[16-18].

This study aimed to evaluate the impact of non-adherent Ibuprofen foam dressing in pain control of patients with venous ulcers.

METHODS

We carried out a controlled, randomized, analytical and prospective study at the São João Ambulatory of the Dr. José Antônio Garcia Coutinho

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Faculty of Health Sciences, after approval by the Ethics in Research Committee under number 534,263.

We studied 80 patients, divided into two groups with 40 patients each: Study Group (SG), treated with IFD, and Control Group (CG), treated with primary dressing, according to tissue type and exudate. Inclusion criteria were: age equal or above 18 years, ankle/arm ratio between 1.0 and 1.4, patients who were taking pain medication and who were not being treated with compressive therapy. Exclusion criteria were: patients whose wounds presented clinical signs of infection, allergy to Ibuprofen or presence of erysipelas adjacent to the lesion. We excluded patients who missed the outpatient visits, those who were taking pain medication during the study and patients who, during the study, showed clinical signs of infection or allergy.

We performed the study from April 2013 to August 2014. We collected the first data at the time of inclusion of the patient in the study, and then every eight days, totaling five visits. In these consultations, we evaluated the wound and changed the primary dressing, but the patients were instructed to change the secondary dressing whenever saturation occurred.

We randomized patients by sealed and opaque envelopes, which were stored at the randomization central. An independent individual generated a sequence of random numbers, placing them one by one in the sealed envelopes. Patients were drawn consecutively, through withdrawal of the envelope and allocation in one of the groups.

Participants answered a questionnaire on sociodemographic and clinical data. To quantify the intensity of pain, we used the Numerical Pain Scale, graded from 0 to 10, where 0 means absence of pain and 10, the worst pain eve felt. Pain intensity was classified as painless (0), mild pain (1-3), moderate (4-6), and severe (7-10)[19,20].

We evaluated the pain quality with the application of the McGill Pain Questionnaire. This questionnaire consists of words known as descriptors, as they describe the sensation of pain that the patient may be feeling. The descriptors are organized into four major groups and into 20 subgroups. Each set of subgroups evaluates a group. The descriptors cover the areas: sensory (subgroup of 1 to 10), affective (subgroup of 11 to 15), evaluative (subgroup 16) and miscellaneous (subgroup of 17 to 20)[19,20]. The sensory-discriminative group (subgroups 1 to 10) refers to the pain's mechanical, thermal, vivid and spatial properties; the affective-motivational group (subgroups 11 to 15) describes the affective dimension in the aspects of tension, fear and neurovegetative responses; The descriptors of the cognitive-evaluative component (subgroup 16) allow the patient to express the overall evaluation of the pain experience. Subgroups 17 through 20 comprise miscellaneous items. Each subgroup consists of two to six qualitatively similar descriptors, but with nuances that make them different in terms of magnitude. Thus, for each descriptor a number indicates its intensity.

The McGill questionnaire can render the number of descriptors chosen and the pain index. The number of descriptors chosen corresponds to the words that the patient chose to explain the pain. The highest possible value is 20, since the patient can only choose at most one word per subgroup. The pain index is obtained with the sum of the intensity values of the chosen descriptors. These indices can be obtained in total and for each of the four components of the questionnaire: sensitive, affective, evaluative and miscellaneous subgroup.

We performed the statistical analysis with SPSS 11.5, using the Mann-Whitney and Chi-square tests. For all statistical tests, we considered significance levels of 5% ($p \leq 0.05$).

RESULTS

The sociodemographic variables of the participants can be seen in table 1. We verified that the majority of the participants of both groups were white, female, aged over 60, retired and smokers. With regard to schooling, 18 participants (45%) of the SG were illiterate and 29 patients (72.50%) of the CG had only elementary education.

Regarding the lesion, table 2 shows that the majority of patients in both groups had lived with the ulcer for six to ten years and the lesions presented exudate and odor.

Table 1. *Sociodemographic variables of the study participants.*

Variables	Group				p-value
	Study Group		Control Group		
	n	%	n	%	
Race					
White	33	82.50	28	70.00	
Black	07	17.50	12	30.00	* 0.001
Total	40	100.00	40	100.00	
Age Group					
< of 50 years	01	2.50	2	5.00	
50 to 59 years	03	7.50	01	2.50	
60 to 69 years	31	77.50	35	87.50	* 0.002
70 to 79 years	05	12.50	01	2.50	
> of 80 years	00	00	01	2.50	
Total	40	100.00	40	100.00	
Gender					
Female	28	70.00	26	65.00	
Male	12	30.00	14	35.00	* 0.003
Total	40	100.00	40	100.00	
Smoker					
No	11	27.50	11	27.50	
Yes	29	72.50	29	72.50	* 0.003
Total	40	100.00	40	100.00	
Schooling					
Literate	00	00	18	45.00	
Complete elementary school	04	10	01	2.50	
Incomplete elementary school	29	72.50	13	32.50	
Incomplete high school	02	5.00	03	7.50	0.067
Complete high school	04	10.00	05	12.50	
College level	01	2.50	00	00	
Total	40	100.00	40	100.00	
Profession					
Unemployed	00	00	05	12.50	
Retired	22	55.00	26	65.00	
Housewife	10	25.00	09	22.50	
Housekeeper	06	15.00	00	00	0.087
Caregiver	01	2.50	00	00	
Craftsman	01	2.50	00	00	
Total	40	100.00	40	100.00	

*Chi-square test of Pearson; * Level of statistical significance p≤0.05.*

Table 2. *Wound-related variables.*

Variables	Group				p-value
	Study Group		Control Group		
	n	%	n	%	
Time of injury					
< of 12 months	04	10.00	02	5.00	
1 to 5 years	06	15.00	03	7.50	
6 to 10 years	25	62.50	31	77.50	* 0.001
> from 11 years	05	12.50	04	10.00	
Total	40	100.00	40	100.00	
Exudate					
Yes	22	55.00	32	80.00	
No	18	45.00	08	20.00	* 0.001
Total	40	100.00	40	100.00	
Odor					
Yes	23	57.50	31	77.50	
No	17	42.50	09	22.50	* 0.001
Total	40	100.00	40	100.00	

*Chi-square test of Pearson; * Level of statistical significance p≤0.05.*

Table 3 shows that the majority of patients in both groups had diabetes *mellitus*, hypertension, but no heart disease.

Table 4 shows that in the first data collection, patients in both groups reported intense pain; in the second, the majority of SG patients reported moderate pain. In CG, 20 (50%) reported moderate pain and 19 (47.50%) had severe pain. In the third data collection, the majority of SG patients reported mild pain and CG patients reported moderate pain. In the fourth assessment, most SG patients reported no pain. In CG, most reported moderate pain. At the fifth visit, most SG patients reported no pain. In CG, most reported moderate pain.

Table 5 shows that the majority of patients in both groups reported sensory, affective, evaluative and miscellaneous descriptors. CG individuals continued to report these descriptors until the fifth visit, with a slight improvement, but SG patients showed significant improvement during the first and even in the fifth data collection.

DISCUSSION

In Brazil, chronic venous disease is the 14th cause of temporary withdrawal from work. These data represent a serious public health problem, affecting several age groups, different ethnicities, both genders, reflecting public spending and interference in the quality of life of patients and their families. It was found that the majority of the patients were smokers and with a low level of education, data that are similar to those of other studies [5-7,17,21,22]. Among the study participants, women predominated. It is inferred that the occurrence of venous ulcer in the female gender is associated with hormonal factors, pregnancy, puerperium and the higher incidence of varicose veins, which may favor the onset of chronic venous insufficiency. This predominance is also due in part to female longevity, since up to the age of 40 the number of cases is evenly distributed between both genders[23-25].

Table 3. *Disease-related variables.*

Variables	Group				p-value
	Study Group		Control Group		
	n	%	n	%	
Diabetes *Mellitus*					
Yes	08	20	03	7.50	
No	32	80	37	92.50	* 0.001
Total	40	100.00	40	100.00	
Arterial Hypertension					
Yes	14	35	20	50	
No	26	65	20	50	* 0.001
Total	40	100.00	40	100.00	
Cardiopathy					
Yes	10	25	05	12.50	
No	30	75	35	87.50	* 0.001
Total	40	100.00	40	100.00	

*Chi-square test of Pearson; * Level of statistical significance $p \leq 0.05$.*

With regard to smoking, it impairs tissue oxygenation, decreases the body's resistance, makes it more susceptible to infections and delays healing. In addition, smoking alters collagen synthesis, hampering wound healing. Nicotine produces vasoconstriction, which increases the risk of ischemia and the development of ulcers, and ulcers, when already present, have difficulty in healing. In these cases, the cellular process is interrupted and abnormal functions of the healing process derive from systemic or local factors, or both[26].

Wound pain results from tissue injury and the perception of pain depends on numerous factors related to the patient, type of wound, quantity and intensity of external stimuli[19,20]. The skin is richly innervated, which gives it the ability to capture various types of stimuli, and the presence of infection and necrosis aggravates the wounds' painful process. Chronic pain can be considered as the perpetuation of acute pain, has no biological function of alertness and generates suffering. In general, neurovegetative responses such as those found in acute pain do not occur, resulting from the adaptation of neuronal systems[27].

Pain is one of the main causes of suffering for any sick person. National and international studies report that approximately 80% of people's demand for health services is pain-motivated. Chronic pain affects 30 to 40% of Brazilians and is the main cause of absenteeism, sick leave, health-related retirements, workers' compensation and low labor productivity[28,29]. Pain is a very common symptom in patients with venous ulcers and its prevalence varies between 80 and 96% in this group. It may be persistent and/or exacerbated during dressing changes. Pain can also negatively influence healing, as the painful stimulus is associated with the release of inflammatory mediators, which potentially reduce tissue repair and regeneration[16,30-32].

In the present study, all patients in the two groups reported severe pain at the beginning of data collection, but the participants of the SG, who were treated with the non-adherent Ibuprofen foam dressing, showed significant pain improvement in the second week of treatment. Regarding the CG, after the fourth consultation, the patients reported moderate pain, while SG patients reported no pain.

Table 4. *Total score of the numerical pain scale.*

Numeric pain scale	Group				p-value
	Study Group		Control Group		
	n	%	n	%	
1st Assessment					
0 (absence of pain)	00	00	00	00	
1 to 3 (mild)	00	00	02	5.0	
4 to 6 (moderate)	06	15.00	05	12.50	
7 to 10 (intense)	34	85.00	33	82.50	* 0.001
Total	40	100.00	40	100.00	
Average	7.88		8.25		
Standard deviation	1.871		2.619		
2nd Assessment					
0 (absence of pain)	00	00	00	00	
1 to 3 (mild)	07	17.50	01	2.50	
4 to 6 (moderate)	30	75.00	20	50.00	
7 to 10 (intense)	03	7.50	19	47.50	* 0.001
Total	40	100.00	40	100.00	
Average	4.53		6.80		
Standard deviation	1.320		2.451		
3rd Assessment					
0 (absence of pain)	00	00	00	00	
1 to 3 (mild)	38	95.00	01	2.50	
4 to 6 (moderate)	02	5.00	26	65.00	
7 to 10 (intense)	00	00	13	32.50	* 0.001
Total	40	100.00	40	100.00	
Average	1.90		6.12		
Standard deviation	0.900		2.178		
4th Assessment					
0 (absence of pain)	34	85.00	00	00	
1 to 3 (mild)	06	15.00	02	5.0	
4 to 6 (moderate)	00	00	28	70.00	
7 to 10 (intense)	00	00	10	25.00	* 0.001
Total	40	100.00	40	100.00	
Average	0.15		5.18		
Standard deviation	0.362		1.470		
5th Assessment					
0 (absence of pain)	39	97.50	03	7.50	
1 to 3 (mild)	01	2.50	10	25.00	
4 to 6 (moderate)	00	00	22	55.00	
7 to 10 (intense)	00	00	05	12.50	
Total	40	100.00	40	100.00	* 0.001
Average	0.03		4.43		
Standard deviation	0.158		1.079		

*Mann-Whitney test. * Level of statistical significance p≤0.05.*

Table 5. *Total score of the McGill Pain questionnaire descriptors.*

	McGill Pain questionnaire				
	Descriptors				
	Sensory	Affective	Evaluative	Miscellaneous	p-value
Type of group	n (%)	n (%)	n (%)	n (%)	
First assessment					
Control	40 (100)	40 (100)	39 (97.50)	40 (100)	* 0.0001
Study	22 (55.00)	27 (67.50)	27 (67.50)	28 (70)	
Second assessment					
Control	30 (75.00)	34 (85.00)	21 (52.50)	40 (100)	* 0.0001
Study	20 (50.00)	13 (32.50)	11 (27.50)	19 (47.50)	
Third assessment					
Control	29 (72.50)	11 (27.50)	16 (40)	35 (87.50)	* 0.0001
Study	7 (17.50)	4 (10.00)	5 (12.50)	4 (10.00)	
Fourth assessment					
Control	18 (45.00)	24 (60.00)	29 (72.50)	10 (25.00)	* 0.0001
Study	4 (10.00)	2 (5.00)	1 (2.50)	3 (7.50)	
Fifth assessment					
Control	44 (88.00)	44 (88.00)	15 (30.00)	15 (30.00)	* 0.0001
Study	1 (2.50)	00 (00.0)	00 (00.0)	1 (2.50)	

*Mann-Whitney test. * Level of statistical significance p ≤0.05.*

In a study with non-adherent Ibuprofen foam dressing, the authors concluded that this it was effective in relieving pain[16]. In our study, patients treated with IFD also showed significant improvement after the first week of treatment.

A study in which the authors described the characteristics of pain in patients with chronic foot ulcers, applied the numerical scale and McGill Pain Questionnaire to 90 patients. The mean pain intensity reported was 7.56 and the sensitive descriptors were more frequently used to describe the pain. The authors concluded that it is necessary for the professionals, when evaluating the patients with such wounds, to use an instrument to evaluate the pain and elaborate a care plan so that they can have an improvement in pain and quality of life[33,34].

The McGill Pain Questionnaire assesses the sensory, affective, and evaluative aspects of pain, describing the patients' painful experience. The sensory-discriminative dimension evaluates the temporal-spatial, mechanical and thermal aspects of pain; the affective-motivational dimension involves aspects of tension, fear, self-punishment and neurovegetative responses; and the cognitive-evaluative dimension evaluates the overall situation of the individual and represents a judgment based on sensory and affective characteristics, previous experience and the meaning of the situation[19,20,35].

In another study with 24 pain patients, the authors investigated the effect of non-adherent Ibuprofen foam dressing. Persistent pain in the wound presented a decrease of a mean of 6.3±2.2 to 3.0±1.7 after 12 hours and remained low thereafter. Pain during dressing change also declined and remained low. As we did, the authors concluded that the non-adherent Ibuprofen foam dressing reduced the pain of patients with chronic venous ulcers[36].

RESUMO

Objetivo: avaliar a dor em pacientes portadores de úlcera venosa de membros inferiores que utilizaram curativo de espuma não aderente com Ibuprofeno (CEI). **Métodos**: estudo prospectivo de pacientes portadores de úlceras venosas de membros inferiores tratados no período de abril de 2013 a agosto de 2014. Foram utilizados os questionários Escala Numérica e Questionário de Dor de McGille, as avaliações eram feitas no momento da inclusão do paciente no estudo e a cada oito dias, totalizando cinco consultas. Os pacientes foram divididos em dois grupos: 40 no Grupo Estudo (GE), que foram tratados com CEI, e 40 no Grupo Controle (GC), tratados com curativo primário, conforme o tipo de tecido e exsudato. **Resultados:** na primeira consulta os pacientes de ambos os grupos relataram dor intensa. No quinto dia os pacientes do GE relataram ausência de dor e a maioria do GC relatou dor moderada. Com relação ao Questionário de Dor de McGill, a maioria dos pacientes de ambos os grupos, no início da coleta de dados, relataram sensações relacionadas aos descritores sensorial, afetivo, avaliativo e miscelânea, sendo que entre os pacientes do GE houve discreta melhora após a segunda consulta. Após a terceira consulta já não referiram os descritores citados. Os pacientes do GC manifestaram todas as sensações desses descritores até quinta a consulta. **Conclusão:** o curativo de espuma não aderente com Ibuprofeno é eficaz na redução da dor de pacientes portadores de úlceras venosas.

Descritores: Úlcera Varicosa. Extremidade Inferior. Medição da Dor.Ibuprofeno. Qualidade de vida. Assistência Centrada no Paciente.

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