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RESEARCH

SAFETY AND EFFICIENCY OF CARBOXIMETHYLCELLULOSE HYDROGEL 2% IN LEG ULCERS

SEGURANÇA E EFICÁCIA DO HIDROGEL DE CARBOXIMETILCELULOSE À 2% EM ÚLCERAS DE PERNA*

EVALUACIÓN DE LA SEGURIDAD Y EFICACIA DEL USO DEL HIDROGEL À 2% EN ULCERAS DE PIERNAS

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ABSTRACT

Objective: The aim of this study is to assess the efficiency and safety on using hydrogel carboxymethylcellulose 2%, handled at university pharmacy in treatment of patients with leg ulcers. **Method:** A non-controlled prospective clinic study with 20 patients took place from January to October 2010. **Results:** The efficiency assessment was performed through the wound area reduction and wound bed tissue alteration; the safety was assessed through observation and report of adverse events. The data showed that 33.3% of the lesions presented total healing. Regarding the safety, only 2 patients reported pain, increase of the exudate and wound infection as possible adverse reaction to the use hydrogel as dressing, according to the Naranjo algorithm. **Conclusion:** The results let us consider that the hydrogel 2% can be considered efficient and safe for this type of lesion. **Descriptors:** Nursing, Leg ulcers, Safety, Efficiency, Hydrogel.

RESUMO

Objetivo: Avaliar a eficácia e a segurança do uso do hidrogel a 2%, manipulado na farmácia universitária, no tratamento de pacientes com úlceras de perna. **Método:** Estudo clínico, prospectivo, não controlado, incluindo 20 pacientes no período de janeiro a outubro de 2010. A avaliação da eficácia foi realizada através da redução e da alteração tecidual do leito da ferida. A segurança foi avaliada por observação e relato dos eventos adversos. **Resultados:** Os dados mostraram que 33,3% das lesões apresentaram cicatrização total. Quanto à segurança, apenas 2 pacientes apresentaram dor, aumento de exsudato e infecção da ferida como reações adversas possíveis, segundo o algoritmo de Naranjo, ao uso do hidrogel 2% como curativo. **Conclusão:** Os resultados permitem considerar que o hidrogel de CMC a 2% mostrou-se eficaz e seguro para o tratamento desse tipo de lesão. **Descritores**: Enfermagem, Úlcera de perna, Segurança, Eficácia, Hidrogel.

RESUMEN

Objetivo: Es evaluar la eficacia y la seguridad del uso del Hidrogel 2%, manoseado en una farmacia docente, en el tratamiento de enfermos con úlceras de pierna. **Método:** El estudio clínico, no controlado, incluyó 20 pacientes en el periodo entre enero y octubre de 2010. **Resultados:** La evaluación de su eficacia fue comprobada por la reducción de la herida y de la alteración de la piel en su interior. La seguridad fue evaluada por observación y el relato de los eventos adversos. Los dados han evidenciados que 33,3% de las lesiones presentaron cicatrización total. Cuanto a la seguridad, solamente dos pacientes presentaron reacciones previsibles al uso del Hidrogel 2% como curativo. **Conclusión:** Se puede concluir que el Hidrogel 2% se muestra eficaz y seguro para el tratamiento de esto tipo de lesión. **Descriptores:** Enfermería, Úlceras de pierna, Seguridad, Eficacia, Hidrogel.

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INTRODUCTION

Leg ulcers are considered an important public health problem worldwide, being responsible for considerable economic impact, permanent pain and limitation, and various psychosocial problems, such as isolation, loss of self-esteem and away from work.[1-3] The main causes of chronic ulcer of lower extremity venous diseases are responsible for about 60 to 70% .[4]

Multiple products are available varying in relation to the physical and chemical characteristics, what influences in their effects. Several of them are registered and approved for the use in Brazil, which makes it important to verify the existence of clinical studies and accompanying information of pharmacovigilance to ensure the effectiveness and safety of these products. The efficacy of hidrogels for the treatment of wounds has been demonstrated in several studies.[5-12] Adverse effects are divided into immediate and late and can range from mild edema and erythema to the lesional flatbed necrosis.[13]

The search for new technologies and non-invasive methods for correction of skin changes related to wounds and dressings is increasingly significant trend. The carboxymethylcellulose is a polymer used in the treatment of wounds in the form of Hydrogel. Such preparations are classified as primary dressings, showing excellence for hydration and maintaining a moist environment at the wound. The hydrogels have the property of absorbing, scaling and debride necrotic tissue and fibrotic.[14-16]

GOAL

Evaluate the effectiveness and safety of the 2% of CMC Hydrogel produced masterfully in the Fluminense Federal University Pharmacy as a product for the treatment of chronic injuries of the leg ulcers.

METHODOLOGY

Study of therapeutic intervention, prospective, uncontrolled clinical trial on the safety and efficacy of the 2% of CMC Hydrogel produced in University pharmacy for the treatment of wounds in patients with leg ulcers. The Research Ethics Committee of the Fluminense Federal University of Medicine College (n^0 0154.0.258.000-08) approved the study. Data collection occurred from January to October 2010. Have been admitted in the study 20 patients, according to random probability sampling, among those who were already in Outpatient monitoring of Tissue Repair. The main inclusion criteria for the study were: patients over 18 years; they had indication for the use of CMC Hydrogel to 2%; absence of an infectious process in the injury; chronic leg injury present in one or both lower limbs, with stable or evolution in the process of increase of the lesion; had cognitive conditions so they could follow the recommended guidelines during the study period. The study showed a loss of 20% of the sample group (04), for the following reasons: occurrence of local and systemic infection (N=1) requiring the exchange of treatment; by request due to frequent pain complaints (N=1); for changing the psychic state (N=1); for health complications requiring hospitalization and remoteness of the study (N=1). Thus, 16 volunteers were accompanied by ninety days for the collection of data of each patient.

The CMC Hydrogel 2% was produced in the Pharmacy College of Pharmacy University of Fluminense Federal University following the formulation of an amorphous gel and non-sterile. Its composition was 2% carboxymethylcellulose, 0.1% methylparaben, 20% propyleneglycol and 77.9% purified water in bottles of 100 g. The production of a non-sterile

gel requires means of control of quality and effectiveness of the product periodically, thus the CMC Hydrogel 2% spent by Physical-Chemical Control processing and microbiological control. All the tests applied to the study product obtained satisfactory results. There is no impediment to its use in the study volunteers.

The evaluation of the effectiveness of the CMC Hydrogel 2% came through the measurements of wounds evaluated routinely according to the protocols of research, having as parameters to reduce the size of the wounds and the changes of the tissue characteristics in four times: beginning of the treatment, 30, 60 and 90 days through biweekly registry of lesions with digital photography and decal. The technique of the overlay is accomplished through perimeter contour, sheets of transparent acetate; on the top sheet is drawn the outline of the wound, while who was in contact with the wound is overrated. The stroke is transferred to graph paper. The presence of epithelization, granulation, yellow slough and necrosis were evaluated using an ordinal scale validated for the study (table 1). Safety was evaluated by the report and observation of immediate adverse events/late mild, moderate or severe, such as erythema, pruritus, edema, infection, exudation, necrosis and pain.

ORDINAL SCALE TISSUE CLASSIFICATION	
Tissue Presence of tissue %	Granulation: (1) 0 (2) 1 - 25 (3) 26 - 50 (4) 51 - 75 (5) 76- 100
	Epithelization: (1) 0 (2) 1 - 25 (3) 26 - 50 (4) 51 - 75 (5) 76- 100
	Yellow Slough: (1) 0 (2) 1 - 25 (3) 26 - 50 (4) 51 - 75 (5) 76- 100
	Necrosis: (1) 0 (2) 1 - 25 (3) 26 - 50 (4) 51 - 75 (5) 76- 100

Image 1: Ordinal Scale Tissue classification. Niterói/RJ, 2010.

RESULTS AND DISCUSSION

20 patients were treated with ages between 40 and 84 years, predominantly female (n = 10). After 90 days of treatment with the CMC Hydrogel to 2%, there was a change in the depth of the lesions in 43.7% of volunteers, with the absence of exudation in 25% and with moisturizing the edges of lesions in 56.25%. The results were excellent because 25% of patients had complete healing and 75% had reduced the size of the lesion or tissue change of the bed of the wound (table 1).

Table 1-Clinical characteristics of injuries of leg ulcers treated with CMC Hydrogel to 2% on the initial visit and after 90 days. Niterói/RJ, 2010

Injury clinic		Initial		After 90 days	
		N	%	N	%
Depth of the lesion	Superficial	4	25.00	7	43.75
	Partial	12	75.00	5	31.25
	Total	0	0.00	0	0.00
	Missing	0	0.00	4	25.00
Edema	Missing	11	68.75	16	100.00
	Discreet (+1)	0	0.00	0	0.00
	Moderate (+2/+3)	4	25.00	0	0.00
	Intense (+4)	1	6.25	0	0.00
Pain	Missing	11	68.75	12	75.00
	Light	0	0.00	0	0.00
	Moderate	3	18.75	1	6.25
	Intense	2	12.50	3	18.75
Type of exudate	Serous	9	56.25	8	50.00
	Serosanguinolent	6	37.50	4	25.00
	Purulent	1	6.25	0	0.00
	Missing	0	0.00	4	25.00
Amount of exudate	Small	6	37.50	7	43.75
	Average	5	31.25	3	18.75
	Great	4	25.00	2	12.50
	Missing	0	0.00	4	25.00
Smell	Missing	14	87.50	16	100.00
	Present	2	12.50	0	0.00
Edge	Macerated	9	56.25	6	37.50
	Hydrated	1	6.25	9	56.25
	Desquamated	5	31.25	0	0.00
TOTAL		16	100.0	16	100.0

Security

After an interval that varied from 7 to 30 days from the application of CMC Hydrogel to 2%, was observed in 2 volunteers, undesirable reactions, which, however, occur commonly in the treatment of chronic wounds, that is, they are predictable, such as pain after application, increased exudation and local infectious process (table 2). The Naranjo algorithm has classified

these reactions, as possible adverse reactions. There were no late reactions or cutaneous or systemic adverse events.

Table 2- Distribution of the number of volunteers in accordance with the type of adverse reaction to treatment with CMC Hydrogel to 2%. Niterói/RJ, 2010.

Types of reactions	Immediate Reaction		Late Reaction	
	Yes	Not	Yes	Not
Edema	1	19	-	20
Severe Pain	1	19	-	20
Erythema	-	20	-	20
Infection	1	19	-	20
Pruritus	-	20	-	20

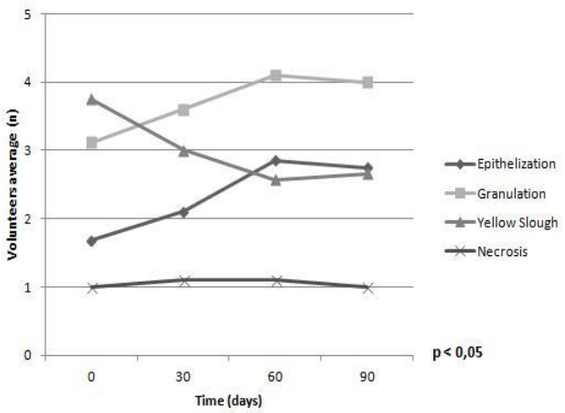

Image 2- Evolution of wound bed tissue treated with CMC Hydrogel to 2% in 90 days of treatment. Niterói/RJ, 2010

This study showed that the 2% of CMC Hydrogel was effective and safe for the treatment of leg ulcers improving the tissue bed and promoting healing of the lesions.

It was found that in the first evaluation, namely at the beginning of treatment with the Hydrogel the CMC 2%, the higher prevalence in the wound bed was the yellow slough, by averaging 3.75 ± 1.2 (image 2). After 90 days of treatment with the Hydrogel of CMC to 2%, was a reversal of the prevalence of tissue in wound bed type. The granulation tissue began to prevail in the wound bed with an average of 3.12 ± 1.0 (n = 8) and the development of the fabric of epithelization with 1.68 ± 0.7 (n = 4) of presence in bed tissue. These results showed a degree of significance with p-value of 0.0416 confirming this relationship inversely proportional. Other studies corroborate with what was found in this study according to the prevalence of lesions showing liquefy necrosis, granulation and fibrin to the detriment of granulation and epithelization and in another study it was found that 100% of surveyed have granulation tissue, 35% had woven epithelization, and 95% had fibrin and necrotic liquefying in your injuries.[17-18] To several authors, the reduction of leg ulcers in the first three or four weeks of treatment is an important predictor of healing, indicating a good prognosis for most patients.[19-20] Still, were detected in patients in which there was no reduction of fibrin, most remained with their wounds until the 12th week of treatment, which reinforces the assertion that studies identify the presence of fibrin in 50% or more of the wound surface leads to injury to a worse prognosis. Still, say, hardly patients with unsatisfactory evolution of the bed will have their healed lesions, since the presence of non-viable tissues, as well as encourage infections, does not allow the formation of granulation tissue and proper good reepithelization.[21-22] It is reasonable to assume that the satisfactory progress observed in the study can be attributed to the Hydrogel of CMC to 2%, since the gel promotes reduction of fibrin, through the autolytic debridement, as well as promote epithelization of the wound by wound bed maintenance hydrated.[1.3 -4; 23-4]

In this study, there were no late reaction type. To achieve good results without serious complications is important that nurses learn to use and get to know the product and select the patient properly. It is essential to know the possible complications, identify them and treat them as early as possible.

CONCLUSION

Although it is a clinical study without control, the methodology employed allowed to estimate both the answer and the safety in the use of CMC Hydrogel to 2%. The results suggest that the use of Hydrogel of CMC to 2% handled masterfully in the pharmacy university contributed to acceleration of the healing process, showing to be effective and safe for the treatment of leg ulcers. However, the use of a product in the treatment of chronic wounds cannot be considered an isolated factor, and stimulate the adherence and patient involvement in self-care activities, as well as the provision of systematic assistance on the basis of the best scientific evidence.

As the CMC Hydrogel to 2% is a cheap product (currently with the amount of R$ 8.00), its use can contribute to ensure patient compliance with leg ulcer treatment, since the access to the product is facilitated.

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