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Research Article

Rigenase® and Polyhexanide Combination for Wounds Treatment and Management of Small Wounds in Dermatologic Practice : The Survey 2024

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Abstract

The management of wound lesions and small wounds in dermatologic practice is well characterized and the monitoring of treatments that are already in the market is crucial in order to verify the correct therapeutic approach, confirm its effectiveness and avoid the use of inappropriate products, as antibiotic if not necessary. In this regard, several molecules with different indications have shown beneficial effects in promoting wound healing. Through these molecules, a most recent and effective one is represented by Rigenase®, a peculiar patented triticum vulgare extract which in association with polyhexanide, an antiseptic that doesn't give any resistance to bacteria, characterizes the Fitostimoline® Plus formulations. Rigenase®, consists of a mix of oligosaccharides, having consolidated activities in the wound healing process. Polyhexanide is an antiseptic that has specific activities on bacteria, fungi and some viruses. The Fitostimoline®Plus formulations are present in the form of gauzes, guzes advnace, spray and cream and all represent a valid and safe alternative for the treatment of various type of wounds, including burns, abrasions, ulcers, lesions and of office skin procedures, such as electrodesiccation, laser therapy, superficial peelings, curettage, cryotherapy, and incisional.

In this trial, we evaluated through a survey on a large population of patients, the efficacy and tolerability of the Fitostimoline® Plus formulations considering which one is the eligible product for each specific indication, in order to help the physicians to choose among the various types of these medical devices

Introduction

Wounds are a significant health problem worldwide. Unfortunately, 15% of the wounds cannot recover 1 year after presentation. [1] Chronic wound formation is a challenging problem for both patients and caregivers.[2] Beyond the physical, mental, and social aspects, productivity loss in the workforce together with expensive medical interventions for wound management creates an economic burden on the health care system.[3,4] Delayed wound healing in specific populations might be prevented or improved with appropriate therapies.[3,4] Wound healing is a physiologic, very complex phenomenon that occurs when skin integrity is lost and consequently also the barrier function of the skin is impaired. This may occur quite often since the skin is much exposed to external insults and the need to avoid systemic infections drives a rapid defense mechanism [5]. Through physiologic healing, the normal status of the skin can be fully recovered although only a maximum of 70% of previous tensile strength is usually achieved [6].

The standard wound-care practice for impaired wound healing includes control of the infection together with debridement, off-loading to relieve pressure, and maintenance of a moist wound bed. One of the first aims in the treatment of chronic wounds is in fact to prevent the occurrence of infection and to clean the area from non-viable tissue material. Infections can easily occur due to the loss of the innate barrier constituted by the skin layer and pathogens accumulating in the wounded area may further interfere with the healing process. On the contrary, the removal of debrides and non-viable tissue, or debridement, allows exposure of healthy tissue where cells can migrate and proliferate to repair the wounded area [7]. Since the sequence of events of impaired wound healing is well characterized, the possibility to identify drugs that are already in the market and that are known to target one or, even better, many of the described molecular events can be taken into account. In this regard, several molecules with different therapeutic indications have shown beneficial effects in promoting wound healing. Through these molecules, a most recent and effective one is represented by Rigenase®, a peculiar patented triticum vulgare extract which in association with polyhexanide, an antiseptic that does not induce bacterial resistance, characterizes the Fitostimoline® plus formulations. Rigenase®, consists of a mix of oligosaccharides, having consolidated activities in the wound healing process. Polyhexanide is an antiseptic that has specific activities on bacteria, fungi and some viruses.

The Fitostimoline® plus formulations are present in the form of gauzes, advance gauzes, spray and cream and all represent a valid and safe alternative for the treatment of various type of wounds, including burns, abrasions, ulcers and lesions. Here, we evaluated through a survey on a large population of patients, the efficacy and safety of the Fitostimoline® plus formulations considering which one is the eligible product for each specific indication, in order to help the physician to choose among the various types of this medical device.

Materials and Methods

Survey Design and Participants

This post-marketing clinical follow-up (PMCF) survey starts from the medical need to understand the best clinical practice in managing wound healing. For this reason, in January 2023, we designed a questionnaire based on the National Recommendations for the Pharmacovigilance on Medical Devices, which needs to be repeated every year. Our research group included 16 key opinion leaders belonging to different Italian Regions and a group of 100 general practitioners (GP) (please see appendix) who participated in actually administering the PMCF survey to patients. The questionnaire was revised by the key opinion leaders and shared with the GPs in order to enroll the highest number of patients. The PMCF survey included two visits, one at the enrollment and one at the end of the follow-up. In the enrollment visit, GPs reported patient age, sex, indication for the treatment (ulcers, sores, lesions, first and second degree burns, abrasions), type of product, posology and duration of the prescribed treatment.

In the follow-up visit GPs collected efficacy and safety data (dosage used, therapeutic effects and adverse reactions) by asking the patients whether the product was painful or there was any side effect. Furthermore, patients were asked to indicate on a scale from 1 to 10 (where 1 is not satisfied at all, and 10 is completely satisfied) their satisfaction for the evolution of the lesion after the prescibed treatment with no more than 45 day duration. In addition, data were collected on safety and customer satisfaction through a judgement on the product itself considering indication, composition, formulation and improvement of the patient quality of life.

The survey was compiled by the GP who the same number of patient for each medical device, in order to obtain four groups basing on the type of formulation used: 1) Fitostimoline® plus gauzes; 2) Fitostimoline® plus cream; 3) Fitostimoline® plus spray 4) Fitostimoline® plus gauzes advance.

Inclusion and Exclusion Criteria

Eligible patients were men and women who were at least 18-year-old, screened by applying the following eligibility criteria:

Inclusion Criteria: Presence of the following conditions: first or second degree burns, ulcers, sores, abrasions, lesions.

Exclusion Criteria:

• Refusal to participate;

• History of intolerance to triticum vulgare extract or polyhexanide;

• Presence of lesions other than first and second degree burns, ulcers, sores or abrasions

Ethical Aspects: A clear and informative description of the survey and an explanation of how collected data would be used were given to respondents; participation was voluntary. According to the Italian regulatory framework, all of the data were anonymized and aggregated, and no personally identifiable information was collected.

Results of the Survey

733 patients were enrolled and successfully completed the survey, as shown in the flow chart in Figure 1.

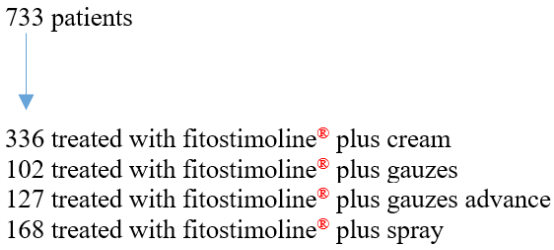

Figure 1: Flow chart of the study population enrollment.

There were no significant differences in terms of sex and age between the groups treated with different formulations. The average age was 60 years. Tables 1&2 shows the type of lesions treated with each Fitostimoline formulation. The cream was found to be preferred in case of the topical management of skin lesions following electrodesiccation, laser therapy, superficial peelings, curettage, and cryotherapy, while the gauzes were preferred in case there was a need of keeping the medication in situ for more than one day, like for sores and ulcers. The recently launched Fitostimoline® plus gauzes advance formulation was used in case of sores, ulcers and burnes with mild-moderate exudate (type ulcerative pressure ulcers, surgical wound dehiscence, foot amputation wound). The spray instead was favored in case of treatment of pediatric patients for diaper rash and abrasions/skin lesions following dermatological treatment. All the formulations were found to be effective in their indications and well tolerated (Tables 3-5) and the customer Satisfaction was very good.

	Fitostimoline® plus gauzes	Fitostimoline® plus cream	Fitostimoline® plus spray	Fitostimoline® plus gauzes advance	p-value
N	102	336	168	127	-
Male Sex %	51	50	49	48	0.4
18-34 years %	2	3	6	0	-
35 - 50 years %	8	7	6	5	-
51-64 years %	20	70	80	15	-
65-80 years %	60	10	4	75	-
>80 years	10	10	2	5	-

Table 1: Main characteristics of the three populations.

Number of cases over 733 patients	Indication	Fitostimoline® plus cream	Fitostimoline® plus gauzes	Fitostimoline® plus spray	Fitostimoline® plus gauzes advance	p
	Abrasions %	5	0	85	0	<0.001
	Ulcers %	10	48	1	80	<0.001
	Sores %	40	15	2	10	<0.001
	First degree burns %	5	5	5	0	<0.001
	Second degree burns %	30	32	2	10	<0.001

	Lesions%	10	0	5	0	-

Table 2: PMCF results indications.

Efficacy	Fitostimoline® plus cream	Fitostimoline® plus gauzes	Fitostimoline® plus spray	Fitostimoline® plus gauzes advance	p
Healing %	86	87	90	88	-
Pain%	0	1	1	1	-
Satisfaction score	9.5	9	9.6	9.8	-
Side effects No	0	1	1	1	-

Table 3: PMCF Efficacy results.

	Fitostimoline® plus cream	Fitostimoline® plus gauzes	Fitostimoline® plus spray	Fitostimoline® plus gauzes advance	p
Leaflet Indications clarity %	90	95	90	90	-
Safety %	98	98	90	90	-

Table 4: PMCF safety results.

	Fitostimoline® plus cream	Fitostimoline® plus gauzes	Fitostimoline® plus spray	Fitostimoline® plus gauzes advance	p
Product texture	good	Very good	good	Very good	-
Product grade	good	good	Excellent	Very good	-
Product improvement of the quality of life (QoL) %	95%	94%	95%	95%	-

Table 5: Customer satisfaction.

Discussion

The size and location of the wound must be considered in the choice of any product, particularly for topical use. Wound healing located over a pressure point in most cases cannot be achieved without appropriate offloading. Many products are incompatible with others and should not be used in an infected wound. Effective, yet costly, treatment options should be avoided in situations where patient non-adherence may prejudice the effects of the therapy. Careful discussion with the patient and a clear understanding of their social situation and personal goals are required to assure that an appropriate product is used. In order to solve all these questions it is required that physicians are well aware and prepared about the characteristics of the medication and the judgments and complains expressed by patients that have used that type of dressing for the same pathologic condition. The present survey was aimed to obtain such information for the four formulations containing Rigenase® and Polyhexanide in different forms: gauzes, cream and spray. These distinct forms indicate a different type of application: the gauzes for located ulcers and burns, the cream of smaller skin areas and the spray for lesions or abrasions more extended on the skin. These different applications of the formulations guarantees their efficacy. In fact, all the formulations were considered efficacious and safe in their specific indications.

Study limitations

We do reckon that our research is not exempt from limitations. We recognize that therapeutic indications should be based on placebo-controlled randomized trial more than on the results of a survey, but strengths of this survey include the large population enrolled and the fact that the questionnaires were administered in multiple centers throughout Italy. Furthermore, albeit we do not have full clinical data for all patients, our conclusions are corroborated by the fact that patients were enrolled by physicians who had prescribed the different medical devices on the basis of a complete knowledge

of the clinical characteristics of their patients. Further dedicated interventional studies are warranted to endorse our findings.

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