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# Observational Study on the Treatment of Skin Complications in Lymphedematous Limbs with the association of a Spray of Rigenase® Plus Polyhexanide

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## Introduction

One of the most frightening complications of Chronic Peripheral Lymphedema is represented by Lymphangitis. It may be caused by different bacteria (mostly gram positive cocci) and can be divided in Truncular Lymphangitis and diffuse Reticular Lymphatigitis (so called Erysipela). The latest is caused by Streptococcus beta-hemolytic group A and represents the most serious clinical feature. The clinical manifestations include high fever, shaking chills, septic status, and a whole accompanying symptomatology, characterized by nausea, vomiting, headache, diffuse pain, confusional state, marked sweating, exhaustion, oliguria. Some of these patients need assistance in an intensive care unit and in infectious wards.

Clinical features of Erysipelas include: diffuse and demarcated skin erythema, edema, heat, pain, major skin changes and functional impotence of the limb. There is also a marked proximal lymph node reaction (inguinal, for the lower limb, and axillary, for the upper limb), with marked increase in the volume of the lymph nodes and signs of acute inflammation.

Another frequent dermatological complication in lymphedematous limbs, most often localized in the lower limbs, is non-necrotizing dermo-hypodermitis and like lymphangitis, is often due to streptococci. Although there is currently no consensus on the treatment of these infections, it is generally recognized that bacterial necrotizing dermohypodermitis and lymphangitis are serious infections that can be life-threatening and require timely treatment. Treatment includes 3 aspects; antibiotic therapy, treatment of lymphatic stasis and care of the bacterial port of entry. The treatment of lymphedema includes conservative and operative (lymphatic microsurgery) procedures, properly integrated to give the best possible clinical results [1-3].

The aim of this study is to assess the efficacy of the association of the elastic compression bandage with the use of a novel spray formulation based on a particular extract of triticum vulgare (Rigenase®). This spray consists of a transparent formulation containing polyhexanide, thus the product is particularly indicated for the treatment of wounds or burns which are at risk of being infected.

## Materials and Methods

We enrolled 100 patients affected from complicated lower limb chronic lymphedemas, randomly divided in two groups, one treated with zinc oxide multilayer bandage alone and one group with the same bandage and the use of a spray based on a particular extract of triticum vulgare (Rigenase®) and polyhexanide. The two groups were equally divided between males and females with an average age of 42 years the first group and 41 the second group. Patients were equally distributed between those who had dermo-hypodermatitis and lymphangitis. Visits were performed at time zero (basal) and after 30 days of treatment with elastic compression bandage containing Zinc Oxide (2 bandages per week, 8 bandages altogether, for both groups). 50 patients were also treated with the spray based on Rigenase® and Polyhexanide, which was applied to the skin twice a week, before the bandage, on the entire affected surface of the leg, leaving it to dry for a few minutes. Besides, the spray was used on the toes and interdigital spaces (daily application), in order to repair any small skin abrasions, create a protective film and reduce the risk of further bacterial contamination. The remaining 50 patients were only treated with Zinc Oxide multilayer bandage twice a week.

The symptomatology of skin redness, burning, paresthesias (itching, burning pain, tingling) were evaluated at pre-treatment time and after 1 month, with a scale value from 1 to 10, where 1 was absent or light and 10 are severe. Limb volumetric reduction was assessed in the two groups as well.

## Results

After 30 days, in the group treated with Rigenase and Polyhexanide, there was a much more marked improvement in clinical symptoms related to skin redness, sense of heat, compressive tenderness and paresthesias (Figures 1-6). There was no difference in limb volume reduction in the two study groups: stage 3, reduction varying from 10% to 15%; in advanced stage 2, from 15% to 20%; in early stage 2, 20%-25%.

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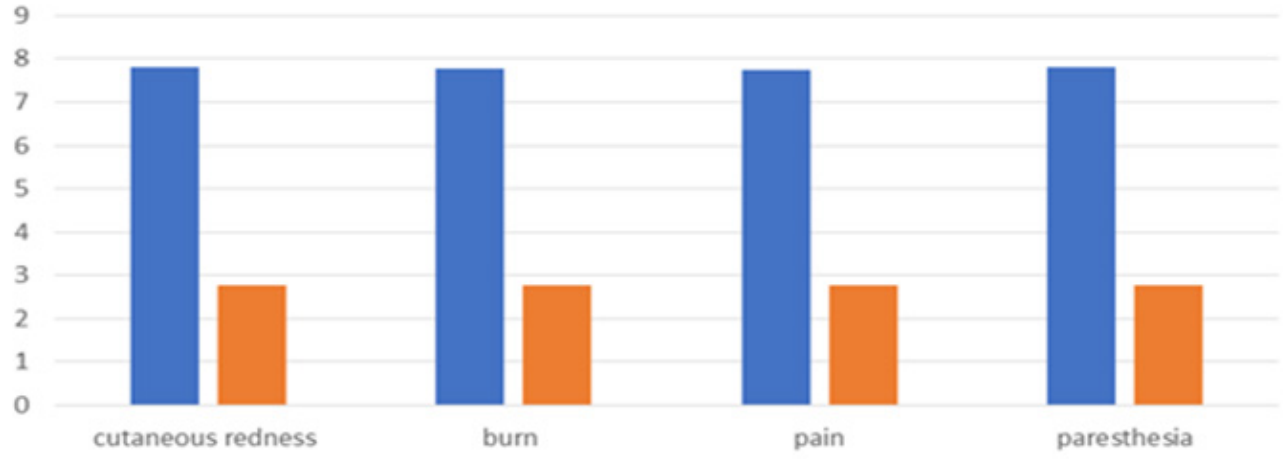


**Figure 1.** Patients treated with Fitostimoline plus spray. Note: ( ) Pre ( ) Post

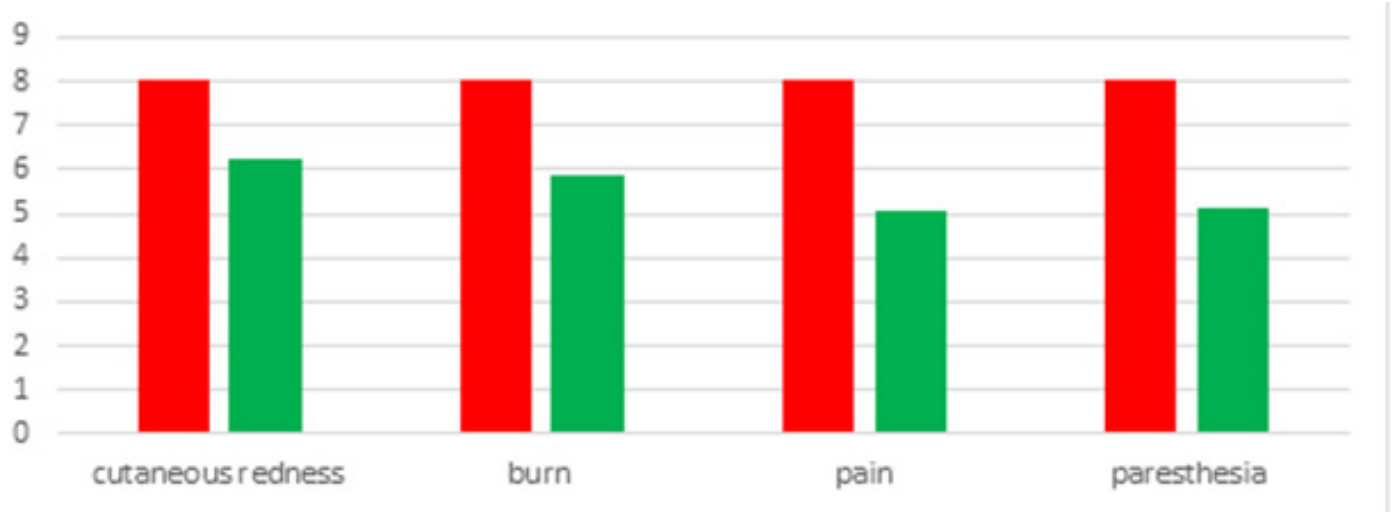


**Figure 2.** Patients treated without Fitostimoline plus spray Note: ( ) Post; ( ) Pre.


**Figure 3.** A. Secondary lymphedema of the right lower limb with extensive dystrophic-ulcer-erosive skin areas, especially in the foot and fingers with pain and functional impotence; B. Treatment with Fitostimoline Plus gauzes, after application of a film of Fitostimoline Plus spray.

**Figure 4.** Almost complete resolution of the clinical picture with good functional recovery, skin re-epithelialization, absence of ulcerative/erosive lesions.

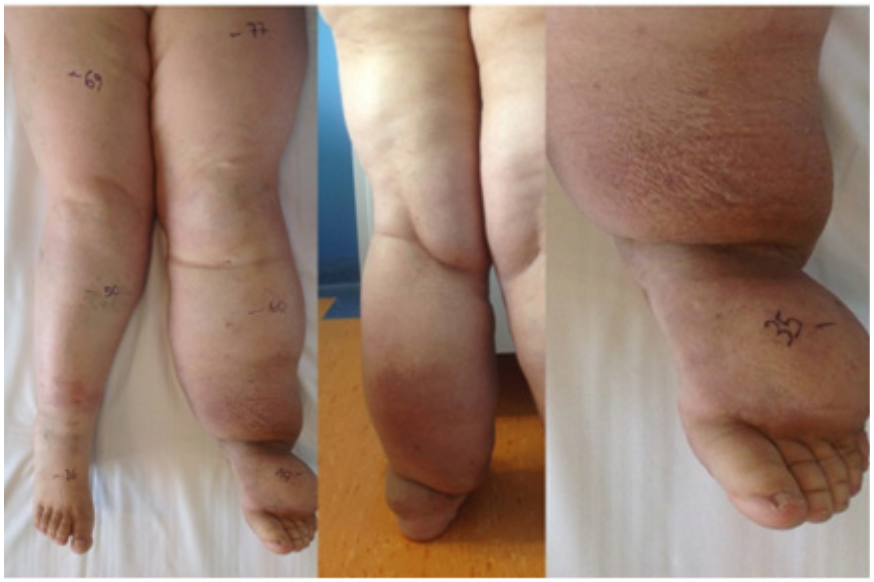

**Figure 5.** Lymphedema with chronic exacerbating dermohypodermatits, skin lesions, inflammation and episodes of bacterial superinfection.

**Figure 6.** Use of Fitostimoline Plus spray in combination with microsurgical treatment of lymphedema. Marked improvement of skin, reduction of signs of inflammation, absence of bacterial contamination, re-epiteliazation of erosive lesions.

## Conclusion

Our results suggest that Fitostimoline® plus spray is a new medical device that can be useful in the treatment of inflammatory and infectious dermatological complications like lymphangitis and dermo-hypodermatitis, together with other methods of treatment.

## Conflict of interest

The Authors have no conflict of interest to declare.

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