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Ernesto García Herrera

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Via Bassini, 41 - 20133 Milano
Tel. 0270608091/0270608060 - Fax 0270606917
E-mail: scriman@tin.it
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A comparative study of the wound healing action of Triticum vulgare acqueous extract-soaked gauzes vs Asiaticoside-soaked gauzes in the treatment of 2nd degree burns

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Former Head of the Division of Burned in the Coyoacan Children's Hospital, Mexico

Summary

A comparative study of the wound healing action of Triticum vulgare acqueous extract-soaked gauzes vs asiaticoside-soaked gauzes in the treatment of 2nd degree burns

Introduction: The literature reports the wound-healing benefits of Centella asiatica (Ca) ascribable to its epithelializing action, as its triterpenes stimulate the extracellular matrix through the genetic expression of skin fibroblasts. Asiatic acid is responsible for collagen synthesis through the activation of kinase TGF-β receptors.

Furthermore, clinical trials with Triticum vulgare (Tv) acqueous extract have provided evidence of a stimulation of granulation and epithelization, as well as of a tissue regeneration activity rapidly restoring the skin layers that had been traumatized by thermal aggression.

Materials and Methods: A prospective, randomized, comparative study was carried out on 60 patients of both sexes, divided into two groups of 30 patients with second-degree skin burns, with the aim of assessing the efficacy and tolerability of Tv acqueous extract (Italdermol, Italmex - Mexico) soaked gauzes versus Ca-soaked gauzes. Patients were selected in sequence from the outpatients of a Mexican Public Hospital. All enrolled patients presented with second-degree thermal burns the severity and extension of which did not require intensive care and which did not impair the patients' quality of life. Patients received one of these two types of treatment: either 10 x 10 cm Tv-soaked gauzes applied every 12 hours locally, or asiaticoside-soaked gauzes for a maximum of 60 days. Once the critical state of the lesions was assessed, patients were taken care of through the outpatient clinic.

Statistical analysis: This was conducted by the chi-square method and the Student's t-test, a value of $p < 0.05$ being considered to be significant.

Results: A total of 60 patients were studied, 30 of whom were included in the Tv group and 30 in the Ca group. The percentage of body surface area affected by burns was 11.5% in the first group and 11.6% in the second group. Patients treated with Tv did not require the use of pain-killers, tranquillizers were used in 10% of patients and antibiotics in 20%, whereas in the Ca group 20% required pain-killers ($p = 0.003$), 25% tranquillizers ($p = 0.041$) and 20% antibiotics (0.393). In the Tv group neither gauze adherence nor skin bleeding was observed, while in the Ca group gauze adhered to the granulation tissue in 84% of the cases and bleeding occurred in 85% ($p = 0.0001$). In the first group healing time was 14.8 ± 1.4 days, whereas in the second group it was 20 ± 1.9 days ($p = 0.029$).

Conclusions: The conclusion was that therapeutic response to Tv acqueous extract was much greater than the response to asiaticoside. Pain sedation was much more rapid and prolonged and no gauze-adherence to the granulation tissue was observed with the Tv extract. The final analysis of the results demonstrated that the Tv-soaked gauzes are superior to those soaked with Ca in the treatment of patients with second-degree burns.

Key words: *Triticum vulgare extract, Wound healing, Epithelization, Granulation, Burns.*

Introduction

Burns are defined as tissue destruction caused by a thermal, electrical, chemical or radioactive agent [1-2].

In the United States alone, it is estimated that, every year, 1.25 million people are treated for some kind of burn and approximately 50,000 patients require hospitalization, with an approximate hospital stay of one day for every 1% of body surface area affected by burns; and a mortality of 4%. In Mexico, the average national burn rate as reported by INEGI is 107.26 every 100,000 inhabitants, which is tantamount to a yearly average of 113,531 burn patients in the past 5 years [2-4].

The most frequent causes of burns include household accidents, accounting for 59.3% of the cases, and accidents at the workplace (30%), these being the situations that more frequently give rise to flames and scalding liquids [2].

Burns are classified into three degrees according to their depth, first and second-degree burns being the most frequent. The latter can involve variable portions of the dermis. The wound healing process for superficial second-degree burns requires 14 days and in the case of deep burns it requires more than 18 days, which leads to bad quality scars, with the development of keloids, hyper or hypopigmentation and skin retractions [2].

The main objectives of the treatment of second-degree burns include maintaining a favorable environment for cell regeneration, vascularization, elimination of necrotic tissue and the prevention of bacterial proliferation, which interfere with wound healing processes [2].

For the above reasons, the appropriateness of wound treatment is important and urgent in a patient with burns, as it reduces the probability of infection and improves the survival of patients and, in the long term, it also determines the scar result. Hence the importance of a skilled and experienced general physician, who is the first contact for most patients [4].

A wide variety of remedies for topical use is available for both burn protection and, therefore, the anatomic-functional recovery of affected skin; however, in their composition, not all of them contain factors capable of stimulating tissue regeneration.

Triticum vulgare acqueous extract (ITALDERMOL, *Italmex - Mexico)* is indicated in the form of soaked gauzes and cream, in the treatment of skin lesions requiring the stimulation of the reparation of processes (e.g., ulcerous-dystrophic processes, burn damage, delayed wound healing) [1, 3, 5-7].

The *Triticum vulgare* extract considerably accelerates the tissue repair processes as it stimulates chemotaxis and fibroblast maturation.

Furthermore, the presence of 2-phenoxyethanol in the product guarantees an efficient antiseptic action [3].

In this study, two different formulations, namely *Triticum vulgare* and *Centella asiatica*-soaked gauzes, were compared in the treatment of second-degree thermal burns with the aim of assessing their efficacy in wound healing and their tolerability among the Mexican population.

Materials and methods

A prospective, randomized, comparative study was carried out on 60 patients of both sexes and of any age, referred to a first contact Public Hospital with second-degree thermal burns with an evolution of less than 36 hours.

The study only included patients with second-degree burns by the *Wallace scale* with a body surface area (BSA) smaller than 15% in adults and 10% in children without serious issues, multiple lesions not involving the organs of the face, neck, palms, genital areas or important joints, nor the closed spaces where, in addition to skin thermal trauma, the laryngotracheal region had been affected, with the risk of causing glottis or larynx edema. Patients with chronic diseases such as type-2 diabetes, arterial hypertension, neoplasias, immunocompromised and pregnant patients were excluded. Two adult patients were accepted with burns exceeding 15% of the body surface area (20 and 22%), without a hemodynamic impairment.

Enrolled patients were randomly assigned to receive either *Triticum vulgare* (*Tv*) or *Centella asiatica* (*Ca*) by means of medicated gauzes. The treatment was applied every 12 hours over a maximum period of 60 days, first during hospitalization and later through the outpatient clinic. The 10 x 10 cm gauzes, soaked in a substance of slightly fatty appearance containing the active principle on an ethylene glycol

monophenyl ether substrate in a water-soluble excipient, were applied to the lesions, after disinfection with saline solution, removal of necrotic material and management of flyctens (they were perforated and cut if larger than 2 cm). In some cases, a medium-compression sterile dry dressing was applied on top of the gauzes by using an elastic bandage, also sterilized. A prophylaxis against tetanus was conducted on dirty wounds of the lower limbs.

During hospitalization, blood biometry, blood chemistry and general urine tests were carried out. During treatment, pain-killers and anti-inflammatory drugs were administered according to need. Finally, as a complementary action to treatment, all patients received a hyperproteic nutritional supplement.

Statistical analysis: The results are expressed as simple relative frequency measures for category variables, and as mean values with their standard deviations for numerical variables; the statistical analysis was carried out according to the chi-square test for category variables and by the Student's t-test for numerical variables, considering as significant a p value < 0.05, with a 95% confidence interval.

Table 1.
Baseline characteristics of the population.

	Years of age			Sex (n. pz)		Waist in cm			Weight (kg)		
	M	Mn	Mx	Ma	Fe	M	Mn	Mx	M	Mn	Mx
Triticum vulgare	16	8/12	61	15	15	140	62	182	43	8	96
Centella asiatica	18	2	56	15	15	156	70	179	56	12	105

Table 2.
Skin surface (BS) with initial burns and time of healing.

	Triticum vulgare	***Centella asiatica***	
BS with burns %	11.5	11.6	
Time of healing - days	14.8 ± 1.4	20 ± 1.9	p = 0.0295

Table 3.
Use of additional medication for pain management.

Medication group studied	***Triticum vulgare***		***Centella asiatica***		
	Yes	**No**	**Yes**	**No**	**p**
Antibiotics	6	24	6	24	Not adm.
Tranquillizers	3	27	7	23	0.041
Pain-killers	--	30	6	24	0.003

Table 4.
Localization of burns.

Study group (*Triticum vulgare extract*)			**Control group (*Asiaticoside*)**		
Localization	**n. of cases**	**%**	**Localization**	**n. of cases**	**%**
Hands*	16	53	**Hands***	15	50
Thigh-leg	4	14	**Thigh-leg**	6	20
Forearm-arm	3	10	**Forearm-arm**	5	17
Trunk	3	10	**Trunk**	2	6
Face*	2	6.5	**Face**	1	3.5
Feet	2	6.5	**Feet**	1	3.5
Total	30	100	**Total**	30	100

** Presenting with other sites in addition to the specified one, which was the main one.*

Results

A total of 60 patients were studied at the *Children's Hospital of Coyoacán* randomized into two groups: 30 patients (50%) were included in the *Tv* group and 30 patients (50%) in the *Ca* group. No differences were found in the demographic and baseline characteristics (Table 1).

The percentage of body surface area affected by burns was homogeneous in both groups. It was 11.5% on average in the first group and 11.6% in the *Ca* group.

Healing time in the *Tv* group was 14.8 ± 1.4 days, while in the *Ca* group it was 20 ± 1.9 days (p = 0.029) (Table 2).

The lesions mainly involved housewives in 53% of the cases, followed by children (16%) and cooks (10%). The distribution was similar in both groups.

The *Tv* group did not require the use of pain-killers, while the *Ca* group pain-killers were used in 6 patients (p = 0.003), tranquillizers in 3 and 7 patients of the first and second group (p = 0.041) and antibiotics were used in 6 patients of both groups (p = 0.39) (Table 3).

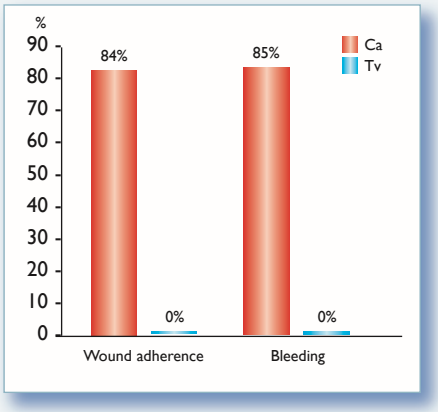
In both groups, lesions more frequently affected the hands (53% in the *Tv* group and 50% in the *Ca* group), followed by the legs in 14% and 20% of the cases respectively (Table 4).

As can be observed in Figure 1, in the *Tv* group gauzes did not adhere to tissue nor was there any bleeding along the edges.

In the *Ca* group, however, gauzes adhered to tissue in 84% of the cases and bleeding occurred in 85% (0.0001) respectively.

There was infection of the lesions in 3.4% and 6.7% of the patients in the *Tv* and *Ca* groups respectively (p = 0.207).

Figure 1.
Clinical behavior to treatment with Tv vs Ca.



Discussion

The application of *Tv* extract on burns has been widely used for more than 20 years for its tissue regeneration activity [5-7]. The availability of various formulations on the market allows their use on different kinds of skin lesions. In a double blind, randomized, controlled study, the efficacy of *Tv*-soaked gauzes on second-degree burns was significantly greater than in the case of placebo [8].

This study compared the effect of *Tv*-soaked versus *Ca*-soaked gauzes on second-degree burns.

The result was that the *Tv* extract is an excellent product with a tissue regeneration activity which rapidly restores the tissue layers traumatized by thermal aggression. In the second-degree lesions under study, tissue damage not only involves the epidermis, but also the dermis, where as is known the hair follicles and sweat glands are to be found, which play an important role in skin regeneration. Their lesions produce severe pain due to the compression of nerve terminations with irritation and hypersensitivity.

Tv appears to reduce nerve compression, while resolving the edema; thus, hypersensitivity markedly decreases, thereby allowing to avoid the use of painkillers which are difficult to manage in this type of burns. Neither of the two groups required surgical procedures.

In terms of safety, this study observed a better local tolerability and fewer adverse effects in the *Tv* group as neither gauze adherence to wounds nor bleeding signs were observed.

To confirm a better efficacy and tolerability profile, the assessment of symptom improvement was significantly in favor of *Tv*.

In conclusion, the results of this study have shown that the clinical efficacy and safety of *Tv*-soaked gauzes in patients with second-degree burns are greater than those of *Ca*-soaked gauzes.

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