



## Topical Treatment of Oral Mucositis in Cancer Children with *Triticum vulgare* (*Triticum* L. 1753) Extract: A Case-Series

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### Authors' contributions

This work was carried out in collaboration between both authors. Author EMLE conducted the study and wrote the first draft of the manuscript. Author GS checked the data, managed the literature researches and revised the manuscript. Both authors read and approved the final manuscript.

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Case Report

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### ABSTRACT

**Aims:** The clinical effects of a *Triticum vulgare*-containing mouth gel on oral mucositis were evaluated.

**Presentation of Cases:** Five children suffering from oral mucositis due to chemo/radiotherapy were treated with a *Triticum vulgare*-containing mouth gel, spreaded three times in a day as thin layer on the mucosal lesions for 14 days. Control visits were conducted at the days 4th, 7th and 14th. During each visit both the capability of ingesting solid food and beverage were evaluated, as well as the pain intensity - judged by VAS (Visual Analog Scale, graded 0-10). Before the treatment, the pain intensity was ranging from 8 to 10 in all subjects; at the day 4th the mean VAS value decreased to 4.6 and at the day 7th to 1.3 At the day 14th no pain was referred by all patients. At the day 4th, 4/5 patients were able to ingest liquids and food.

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**Conclusions:** The results show that the *Triticum vulgare*-containing mouth gel may be a safe and effective treatment for the oral mucositis in children with cancer.

*Keywords:* Children; oral mucositis; chemoradiotherapy; *Triticum vulgare* extract.

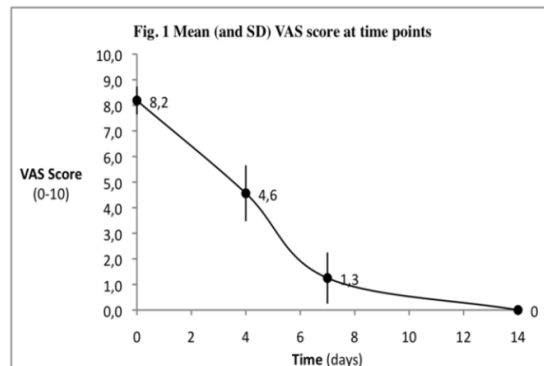
## 1. INTRODUCTION

Oral mucositis is the most common complication of chemotherapy in patients with cancer. It was reported that 303 out of 599 patients (51%) receiving chemotherapy for solid tumors or lymphoma developed oral and/or gastrointestinal mucositis [1]. Oral mucositis can be extremely painful and can significantly affect nutritional intake, mouth care and quality of life [2-3]. Infections associated with the oral mucositis lesions can cause life-threatening systemic sepsis [4]. The management of oral mucositis include nutritional support [5], pain control [6], oral decontamination [7], palliation of dry mouth [8], management of oral bleeding [9] and therapeutic interventions. Several agents have been tested to reduce the seriousness of or prevent mucositis. They include cryotherapy [10,11], growth factors [12], anti-inflammatory agents [13], antioxidants [14], low-level laser therapy [15]. A number of topical mucosal bioadherent agents are also available [16]. The watery extract of *Triticum vulgare*, the active principle of a commercially available mouth gel (*Fitostimoline gel*; Farpag Ltda, Bogotá, D.C.; excipients: 2-phenoxyethanol; Carbopol 940; triethanolamine; ethanol; PEG 40; mint flavour; sorbitol; distilled water), improves the healing processes both in cutaneous and noncutaneous tissues [17,18]. Recent clinical studies showed that the watery extract is a safe and effective treatment for the oral lesions of various origin [19] and for the oral mucositis in cancer patients [20].

## 2. CASES PRESENTATION

Five children (3 male), aged 9-12 years, suffering from oral mucositis lasting for no more than 4 days due to chemotherapy and/or radiotherapy in consequence of acute lymphoid or myeloid leukemia, were observed at the Stomatologic and Oral Surgery Emergency Unit at the Red Cross University Children Hospital of Manizales (Colombia). The children were treated at the onset of the lesions with a *Triticum vulgare* containing mouth gel, spreaded three times in a day as thin layer on the mucosal lesions for 14 days. The mouth was rinsed with bicarbonate solution (5 g in 50 mL of water) every two hours

and a standard oral care (teeth brushing, use of a tooth paste containing fluoride and dental flossing) was adopted also. The informed consent was obtained by the parents or guardians before the therapeutic procedure start. Control visits were conducted at the days 4th, 7th and 14th. During each visit both the capability of ingesting solid food and beverage were evaluated, as well as the pain intensity - judged by VAS (Visual Analog Scale, graded 0-10, where 0 is no pain and 10 is unbearable pain) [21]; a digital image of the lesions was also recorded. Before the treatment, the mean pain intensity was 8.2; at the day 4th the mean VAS value decreased to 4.6 and at the day 7th to 1.3. At the day 14th pain was referred by any patient. The Fig. 1 shows the mean (and SD) VAS score trough the study.



At the day 4th, 4/5 patients were able to ingest liquids and foods. The images recorded before (left) and 7 days after treatment (right) in three patients are shown in the picture 1; a significant improvement of the lesions was observed.

## 3. DISCUSSION

Oral mucositis is a significant problem in cancer patients treated with radiation and/or chemotherapy. Pain is the most distressing symptom, leading to loss of orofacial function and poor quality of life. The control of oral mucositis has been the focus of several studies, which highlighted the fact that its effective management may allow more aggressive therapeutic doses. Moreover, there are currently no conclusive records on the efficacy of the



**Picture 1. Clinical findings before (left) and 7 days after treatment (right) in three patients**

various treatments or established prescription protocols [22]. Evidence exist that the watery extract of *Triticum vulgare* determines a noticeable acceleration of tissutal repairing processes, stimulates chemotaxis and the fibroblastic maturation and significantly increases the fibroblastic index, which are crucial points in the repairing processes. These activities find an experimental confirmation both in the accelerated protein synthesis and in the enhanced ability of captation and incorporation of marked proline from tissues. Furthermore, the presence of 2-phenoxy ethanol in the gel ensures an efficient antiseptical action. Previous clinical studies

showed that the *Triticum vulgare*-containing products are a safe and effective treatment for the oral lesions of various origin [17] and for the oral mucositis [18]. Our case-series show that the *Triticum vulgare*-containing mouth gel may be a safe and effective treatment for the oral mucositis in children with cancer. Moreover, our results refer to a clinical experience not to a clinical trial. A formal clinical study should be planned in the future, on the basis of this experience.

#### 4. CONCLUSION

The *Triticum vulgare*-containing mouth gel may be a safe and effective treatment for the oral mucositis in children with cancer.

#### CONSENT

Not applicable.

#### ETHICAL APPROVAL

Not applicable.

#### COMPETING INTERESTS

Dr Muñoz Lòpez Eliana E. declares that there is no conflict of interest regarding the publication of this paper. ISPharm srl was granted by Damor Farmaceutici (Naples, Italy) for checking data and revising the manuscript.

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