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Clinical efficacy of a medical device in the treatment of chemotherapy-induced oral microsites in children

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Introduction: Oral mucositis (OM) is a severe side effect of anti-cancer therapy, especially in children. It causes a painful inflammatory process, which may have a detrimental effect on quality of life and on therapeutic protocols.

Objectives: The aim was to assess the efficacy of a medical device (Mucosyte®), respect of placebo, in the treatment of chemotherapy-induced OM in childhood.

Methods: Patients between 5 and 18 years of age undergoing chemotherapy for malignancies diseases with OM grade 1 or 2 were enrolled in this study. They were randomized in group A (treated with Mucosyte®, 3 mouthwashes/day per 8 days) and group B (treated with placebo, that is an inert water based solution, same dosage). The OM scoring was performed at day 1 (diagnosis of OM-T0), after three days of treatment (T1), and at day 8 (T2). Pain was evaluated through the Visual Analogue Scale (VAS) with the same timing of OM measurement. A statistical analysis was performed.

Results: A total of 59 patients were included (28 patients per group). Group A experienced a statistically significant decline of OM just at T2 ($p=0.0038$) while a statistically significant difference in pain reduction between two groups both at T1 and at T2 ($p<0.005$) was observed.

Conclusions: The present trial demonstrated the efficacy of this medical device (Mucosyte®) on the treatment of chemotherapy-induced OM in children; in fact, thanks to its barrier effect, it is useful in reducing pain, OM score, burning and erythema.

Biography

Alessandra Majorana is the Professor of Dentistry in Medicine Degree Course of University of Brescia and a Counselor of Italian Society of Pediatric Dentistry (SIOI) from 1998 to 2007. He is the President of Italian Society of Pediatric Dentistry (SIOI) from 2007 to 2010 and also Counselor of Italian Society of Oral Medicine (SIPMO) from 2000. He is a Member of European Academy of Oral Medicine (EAOM) and Mucosite Study Group MASCC and also Member of the National Observatory for the Prevention of Oral Health WHO Collaborator of the Italian Ministry of Health (expert in the National Guide Lines for Oral Health in childhood)

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