THE EFFECTS OF THREE PRODUCTS IN THE PREVENTION AND TREATMENT OF ORAL MUCOSITIS INDUCED BY CHEMOTHERAPY AND RADIATION THERAPY

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BACKGROUND

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Oral mucositis (OM) is a complication of radio and chemotherapy. It's produces considerable pain and morbidity to patients. Research to preventive and management strategies has lagged behind research for other cancer treatment morbidities as nausea, vomiting and cytopenias. This disparity is also related to a complicated risk assessment for variability of patients and treatment factors. There are also different rating scales to evaluate mucositis. So few clinical trials have focused on mucositis as a specific outcome.

Managing OM relies on supportive care and symptom palliation. However, OM is a common problem associated with significant patient morbidity and increased resource use. The magnitude of the problem demands innovative approaches based on expert judgment as evidence accumulates to support specific recommendations. The purpose of this study is to look at outcomes of patients who received radio and chemotherapy for solid tumors and the impact of the three products used on OM.

METHODS

This is an observational, single-center study. From March to June 2018, 60 patients (pts) were randomized by Medical Oncology Unit of Rho - Milan. The pts were divided in 3 arms, balanced for tumor site and treatment, to receive the following medical devices: bio-adhesive zinc and taurine complex oral spray (Group1), oral liquid lipid-based fluid (Group2) and a bio-adherent oral gel (Group3). Primary aim of the study was evaluation of OM onset, severity, reduction or remission and pain relief with the three devices in study.

We analysed data with forms compiled by pts in 2 different steps: T0 (baseline) and follow-up (after 16 w); the clinicians evaluated OM grade in 2 steps: after 4 weeks and after 8 weeks. The patients safety profile form included 10 items concerning difficulty of speaking, feeding, drinking and change of taste.

PRIMARY END POINT: Primary aim of the study is evaluation of Oral Mucositis onset, severity, its reduction or remission during the treatment and pain relief

SECONDARY END POINTS Severity decrease of OM grade after 1 month of treatment and at the end of the treatment; Improvement of the quality of life of patients.

Tumors' characteristics	
Patients	60
Male/female	30/30
Main Age (years)	68
Median (range)	68 (33-84)
Performance status 0 **1**	41 19
Previous mucositis experience **YES Previous chemotherapy** **YES Previous radio/ chemotherapy** **NO**	 13 8 39

Tumors' characteristics	
GI (liver, stomach..)	29
Breast	11
Lung	7
Ovary	5
Oral and nasal	6
Other	2

RESULTS

The data analysis showed a significant difference among the 3 Groups. OM grade of Group 2 after 4 weeks is higher if compared with Group 1 and Group 3.

After 4 weeks two cases of grade 4 mucositis has been achieved in Group 2, none in Group 1 and Group 3. Group 1 demonstrated an overall better efficacy, in every analyzed safety profile items.

Evaluation	Grade	Group 1	Group 2	Group 3
T0	0	12	14	12
	1	4	4	4
	2	2	2	3
	3	2	0	1
After 4 weeks	0	8	5	4
	1	6	7	9
	2	1	5	6
	3	5	1	1
	>3		2	0
After 8 weeks	0	6	2	5
	1	10	10	9
	2	3	5	4
	3	0	1	0
	>3	0	1	0
	n.a	1	1	1
Follow-up	0	11	2	4
	1	7	10	10
	2	1	7	2
	3	0	0	3
	>3	0	0	0
	n.a	1	1	1

CONCLUSION

Even if prevention and treatment of OM are not yet clearly defined and recognized in the clinical practice, the study shows how the correct use of anti-mucositis products (accompanied by an appropriate hygienic and dietetic regimen) seems to be effective in the prevention of this pathology, which is the most frequent side effects on patients undergoing chemotherapy.

gelX® ORAL SPRAY

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