INCIDENCE OF ORAL MUCOSITIS IN PATIENTS UNDERGOING SYSTEMIC CHEMOTHERAPY FOR HEMATOLOGIC MALIGNANCIES

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INTRODUCTION

Chemotherapy-induced oral mucositis (OM) represents a major complication related to systemic anti-cancer treatment leading to disruptions in the treatment plan, decreased quality of life due to pain, distress and discomfort, as well as local and systemic infections. One in every five patients receiving systemic chemotherapy develops OM (1).

METHODS

A randomized phase I/II clinical trial called Study for the Prevention of Oral Mucositis (SPOM, NCT05338398) was conducted at a single hematology center in Armenia, aiming to compare different methods for the prevention of oral mucositis. Patients with hematologic malignancies undergoing chemotherapy for their primary disease are randomized into one of two types of mouthwash (benzydamine or normal saline) 3-5 times daily for 2 weeks from day 0 of their treatment. Half of patients in each group also received orally inserted medical device to enhance the prevention effects. Based on available preliminary data, the incidence of and severity of chemotherapy-induced OM were calculated for the entire cohort of patients.

Randomization

Block 1
Control group
Saline mouthwash (0.9%, 120mL)

Block 2
Study group
Benzydamine mouthwash (0.15%, 120mL)

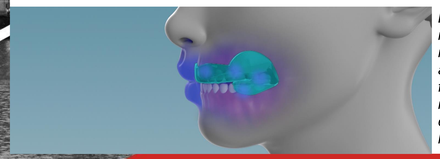


***Fig 1** Bocaliner™ – a silicone-made orally inserted novel medical device used after application of a mouthwash for 5-20 minutes with an intention to enhance the effects of active agents by longer retention in the mouth.*

RESULTS

From a total of 52 patients (26 males and 26 females, mean age of 47 years) with completed data, 9 (17%, 5 female, 4 male) developed OM related to chemotherapy.

Benzydamine was used in 24 patients, 12 of which also received oral device. Saline was used in 28 patients, 13 of which also received oral device. OM developed in 3 patients from benzydamine group and 6 in saline group. Two patients in each group also used oral devices.

Six patients developed OM during the first 7 days since the start of chemotherapy, the other three developed on days 8, 9, 14 of their treatments. Severe OM was seen in four patients (3 females, 1 male) with Grade III, while another five (2 females, 3 males) had mild OM (Grade I). In all patients, OM resolved within one week since the onset of OM without further complications.

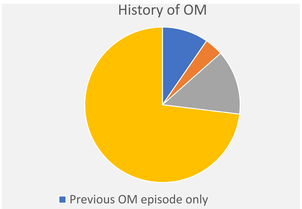


***Fig 2** Previous episode of OM in the cohort*

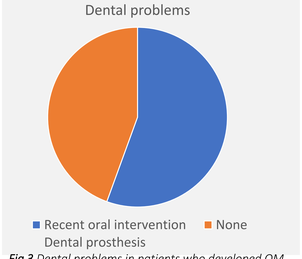


***Fig 3** Dental problems in patients who developed OM*

Cancer type	Total (n)	OM n	Grade	OM Prevention	Treatment
AML	15	1	Grade III	Saline	7+3
nHL	12	3	Grade III Grade I Grade I	Benzydamine Benzydamine + device Saline + device	R-CHOP DA-R-EPOCH GMALL
ALL	10	3	Grade III Grade III Grade I	Benzydamine + device Saline Saline	MTX GMALL GMALL
HL	6	0	–	–	–
MM	5	1	Grade I	Saline + oral device	VCD
BPDCN	2	0	–	–	–
HCL	1	0	–	–	–
MDS	1	1	Grade I	Saline + oral device	low-dose cytarabine + venetoclax

Table 1. Patient Characteristics

CONCLUSIONS

OM remains a serious adverse event of systemic chemotherapy that was seen in every sixth of our patients. Future trial results will provide more data on associated risk factors and the efficacy of preventive strategies, such as benzydamine mouthwash or oral medical device, investigated within the study. Prospective research studies should also evaluate on clinical aspects of OM development, progression, as well as on strategies for better prevention and management



Grade I
Erythema ±soreness
Little change in oral intake

Grade II
Ulcerations ±erythema
Solid food is tolerated

Grade III
Wide ulcers ±exudates
Liquid food only

Grade IV
Deep ulcers ±necrosis
Impossible oral intake

***Fig 1** WHO Oral Toxicity Scale (Courtesy: Dr. Patrick Stiff, Loyola University Medical Center, Maywood, IL, USA)*

REFERENCES

1 Elad S, Cheng KK, Lalla RV, Yarom N, Hong C, Logan RM, Bowen J, Gibson R, Saunders DP, Zadik Y, Ariyawardana A. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. *Cancer. 2020 Oct 1;126(19):4423-31.*

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