

# A quasi-experimental study to assess the effectiveness of topical mouth paint on chemotherapy induced oral mucositis among patients undergoing chemotherapy at Apollo hospital, Navi Mumbai

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## Abstract

Oral mucositis is one of the most common toxicities observed during radiotherapy and chemotherapy treatment for cancers. Mucositis results in sore mouth, altered taste sensation, pain and dysphagia leading to malnutrition. Left untreated, oral mucositis leads to ulceration, Oro dental infection, bleeding and discontinuation of effective radiotherapy or chemotherapy. Quantification of oral mucositis using standardized grading system is important for appropriate evaluation, reporting and management. In the recent past there is a paradigm shift in the pathobiology of cancer therapy related mucositis. Clear understanding of its pathogenesis is essential for the formulation of effective mucositis care. Numerous drug therapies, radiation techniques and oral care protocols have been tried in the past to reduce oral mucositis, none have proven to be consistently effective. Current trends for the prevention and treatment of oral mucositis are multi-targeted treatment supplemented by aggressive oral hygiene, growth factors and use of specific topical agents to improve treatment of oral mucositis in future.[1]. The concept of applying topical agents for the control of mucositis is because of its simplicity. An ideal agent should come in contact with the oral and pharyngeal mucosa for a prolonged period. The majority of study participants 27 (90%) believe that mouth paint effectively reduces oral mucositis, and 29 (96.7%) agreed that chemotherapy side effects can be reduced with the help of mouth paint. We compared oral health scores during pre- and post intervention of the mouth paint. The study concluded that all 30 individuals had experience in reduction of oral mucositis by topical mouth paint.[2]

**Keywords:** Topical mouth paint; Oral mucositis; chemotherapy

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## 1.Introduction

In conventional radiotherapy schedule, about 25% of patients receiving radiotherapy for head and neck cancer suffer from symptomatic mucositis requiring treatment. In altered fractionation schedules the mucositis incidence increases to 25–50%. In the current practice of concurrent chemoradiotherapy schedules, the mucositis incidence

could be as high as 60% and in toxic schedules of chemotherapy the mucositis can be up to 80%. Mucositis leads to ulceration and painful swallowing requiring narcotic analgesics.[3]

Oral mucositis (OM) is one of the most prevalent adverse effect of head and neck radiotherapy (RT) and chemotherapy (CT) that is characterized by an inflammatory response of the oral cavity and oropharynx. OM affects 20–40% of patients receiving conventional CT, up to 80% of patients undergoing hematopoietic stem cell transplantation and receiving high doses of CT and almost all patients undergoing head and neck RT. Currently, OM management mainly involves pain control, oral decontamination, inflammation reduction, oral haemorrhage management, and nutritional support [4].

## 2. Review of literature

Peterson et. al. (2011) [5] discussed in their review the various topical interventions used for managing oral mucositis in cancer patients undergoing chemotherapy. Their review highlighted the importance of early intervention and regular assessment in reducing the severity of mucositis, thereby improving patient comfort and adherence to cancer treatment protocols. The authors also underscored the need for further research to optimize treatment strategies and explore novel therapeutic approaches to enhance outcomes for patients experiencing chemotherapy-induced oral mucositis.

Lalla et. al. (2014) [6] conducted a comprehensive review on the management of oral mucositis secondary to cancer therapy. They highlighted the role of topical mouth paints, including chlorhexidine and benzylamine hydrochloride, in reducing severity of mucositis and improving patient outcomes. Their review synthesized evidence from clinical trials and meta-analyses, emphasizing the importance of personalized treatment approaches and adherence to supportive care guidelines to mitigate mucositis-associated morbidity.

Vagliano et. al. (2018) [7] evaluated the efficacy and safety of a novel mucoadhesive oral gel in managing chemotherapy-induced oral mucositis. Their prospective study demonstrated promising results in terms of reducing mucositis severity and improving patient-reported outcomes. The mucoadhesive gel formulation provided sustained relief and enhanced comfort, suggesting it as a valuable adjunct to standard care regimens for mucositis management in cancer patients.

Hong et al. (2019) [8] conducted a systematic review and meta-analysis to assess the effectiveness of basic oral care protocols in preventing and managing oral mucositis in cancer patients. Their findings underscored the importance of comprehensive oral hygiene practices, including the use of topical mouth paints, in reducing mucositis incidence and severity. They recommended integrating these protocols into routine oncological care to optimize patient comfort and treatment outcome.

Worthington HV et. al. (2011) [9] conducted a Cochrane systematic review evaluating interventions for preventing oral mucositis in cancer patients undergoing treatment. Their review included various topical interventions such as mouthwashes containing chlorhexidine and sucralfate. They found moderate evidence supporting the efficacy of these treatments in reducing the severity of mucositis and preventing secondary infections, emphasizing the need for further high-quality trials to confirm these findings and optimize treatment

protocols.

Riley P et al. (2017) [10] conducted a Cochrane review focusing on interventions for preventing oral mucositis in cancer patients, specifically exploring the role of cytokines and growth factors. Their analysis included studies on topical mouth paints that enhance mucosal healing and reduce inflammation. They concluded that while certain growth factors show promise, the evidence for topical interventions like mouthwashes remains inconclusive, highlighting the variability in treatment outcomes across different patient populations and cancer therapies.

During literature reviews, there were no such major studies which focused on topical mouth paint with combination of various medication use. Hence, it is a novice study which focus on use of topical mouth paint to reduce the severity of oral mucositis.

### 3. Methodology

Investigator conducted the study to assess the effectiveness of topical mouth paint on chemotherapy induced oral mucositis among patients undergoing chemotherapy at Apollo hospital, Navi Mumbai. For this study, 30 patients undergoing Chemotherapy were selected with purposive sampling technique. Data was collected with structured questionnaire and WHO Scale of grading for oral mucositis with permission of DMS, nursing head and ethical committee of Apollo hospitals, Navi Mumbai. The study concluded that 30 individuals had experience in reduction of oral mucositis by topical mouth paint. Among 30 subjects, 19 (63.3%) were males and 11 (36.7%) were females. Patients were scheduled for chemotherapy from a minimum of 8 to a maximum of 12 chemo cycles. The majority of study participants 27 (90%) believe that mouth paint effectively reduces oral mucositis, and 29 (96.7%) agreed that chemotherapy side effects can be reduced with the help of mouth paint. We compared oral health scores during pre- and post-intervention of the mouth paint. Based on the comparative values using the non-parametric Wilcoxon Signed Rank test, in that median score value for all the participants was reduced, and the difference was statistically significant. Hence, the study has shown that topical mouth paint was effective to reduce the grade of oral mucositis among patient undergoing chemotherapy.

### 4. Findings

A total of 30 participants who had grade 1 and 2 oral mucositis who are on chemotherapy for more than 6 months. Among 30 participants, 19 (63.3%) were males, while 11 (36.7%) were females. It shows the patient distribution across cases with metastasis 12 (40%) and non-metastasis 18 (60%). Patients were scheduled for chemotherapy from a minimum of 8 to a maximum of 12 chemo cycles.

When the participants were interviewed, 27 (90%) of participants said that mouth paint effectively reduces oral mucositis, and whereas 29 (96.7%) participants agreed that chemotherapy side effects can be reduced with the help of mouth paint. Oral health scores during pre- and post-intervention of the mouth paint were compared. Based on the comparative values using the non-parametric Wilcoxon Signed Rank test, it was found that the median score value for all the study participants was reduced, and the difference was statistically significant. While

comparing the median score between gender and metastasis status, median differences were persistent and statistically significant (p-value <0.001).

Table 1. Malignancy types of study characteristics under consideration

| Non metastasis (Row %) | Metastasis (Row %) | Total (column %) | Chi-Square |
|------------------------|--------------------|------------------|------------|
|                        |                    |                  |            |

NarrationP value

Grand Total 18 (60) 12 (40) 30

Gender

Male

7.751 0.005 15 (78.9) 4 (21.1) 19 (63.3) Female 3 (27.3) 8 (72.7) 11 (36.7)

Hypertension

0.192 0.661 No 16 (61.5) 10 (38.5) 26 (86.7) Yes 2 (50) 2 (50) 4 (13.3)

Total Chemo cycles

4 1 (100) 0 (0) 1 (3.3)

6 8 (61.5) 5 (38.5) 13 (43.3) 8 6 (66.7) 3 (33.3) 9 (30) 1.702 0.636 0.988 0.32

12 3 (42.9) 4 (57.1) 7 (23.3)

Do you think that topical mouth paint is effective in reducing mucositis

No 1 (33.3) 2 (66.7) 3 (10)

Yes 17 (63) 10 (37) 27 (90) Do you think it reduces side effects of Chemotherapy on mouth

0.69 0.406 No 1 (100) 0 (0) 1 (3.3) Yes 17 (58.6) 12 (41.4) 29 (96.7)

How do you feel after application of topical mouth paint on oral mucositis

0.089 0.765 Pleasant 17 (60.7) 11 (39.3) 28 (93.3) Unpleasant 1 (50) 1 (50) 2 (6.7)

Table 2. Gender wise respondent's characteristics

| Narration | Female (Row %) | (Row %)   | Total    | (column %)   | Chi-Square      | Statistic       | p-value         |
|-----------|----------------|-----------|----------|--------------|-----------------|-----------------|-----------------|
| Male      |                |           |          |              |                 |                 |                 |
| Total     | 11 (36.7)      | 19 (63.3) | 30       |              |                 |                 |                 |
| Age Group |                |           |          |              |                 |                 |                 |
| <30       | 1 (12.5)       | 7 (87.5)  | 8 (26.7) | 30-39        | 1 (16.7)        | 5 (83.3)        | 6 (20)          |
|           | 66.7)          | 1 (33.3)  | 3 (10)   | <u>50-60</u> | <u>4 (57.1)</u> | <u>3 (42.9)</u> | <u>7 (23.3)</u> |
|           | >60            | 3 (50)    | 3 (50)   | 6 (20)       |                 |                 |                 |
| Education |                |           |          |              |                 |                 |                 |

|                                                                            |                                             |
|----------------------------------------------------------------------------|---------------------------------------------|
| Matriculation/below 3 (25) 9 (75) 12 (40)                                  |                                             |
| Graduation/UG 7 (46.7) 8 (53.3) 15 (50)                                    |                                             |
| Post Graduate 1 (33.3) 2 (66.7) 3 (10)                                     |                                             |
| Cancer Type                                                                |                                             |
| Non metastasis                                                             | 7.751 0.005 3 (16.7) 15 (83.3) 18 (60)      |
| Metastasis 8 (66.7) 4 (33.3) 12 (40)                                       |                                             |
| Hypertension                                                               | 0.353 0.552 No 9 (34.6) 17 (65.4) 26 (86.7) |
| Yes 2 (50) 2 (50) 4 (13.3)                                                 |                                             |
| Chemotherapy                                                               |                                             |
| 4 1 (100) (0) 1 (3.3)                                                      | NA NA 6 6 (46.2) 7 (53.8) 13 (43.3)         |
| 8 3 (33.3) 6 (66.7) 9 (30)                                                 |                                             |
| 12 1 (14.3) 6 (85.7) 7 (23.3)                                              |                                             |
| Do you think that topical mouth paint is effective in reducing mucositis   | 5.758 0.016 No 3 (100) (0) 3 (10)           |
| Yes 8 (29.6) 19 (70.4) 27 (90)                                             |                                             |
| Do you think it reduces side effects of Chemotherapy on mouth              | 1.787 0.181 No 1 (100) (0) 1 (3.3)          |
| Yes 10 (34.5) 19 (65.5) 29 (96.7)                                          |                                             |
| How do you feel after application of topical mouth paint on oral mucositis | 1.241 0.265 Pleasant 11 (39.3) 17 (60.7)    |
| 28 (93.3)                                                                  |                                             |
| <u>Unpleasant (0) 2 (100) 2 (6.7)</u>                                      |                                             |

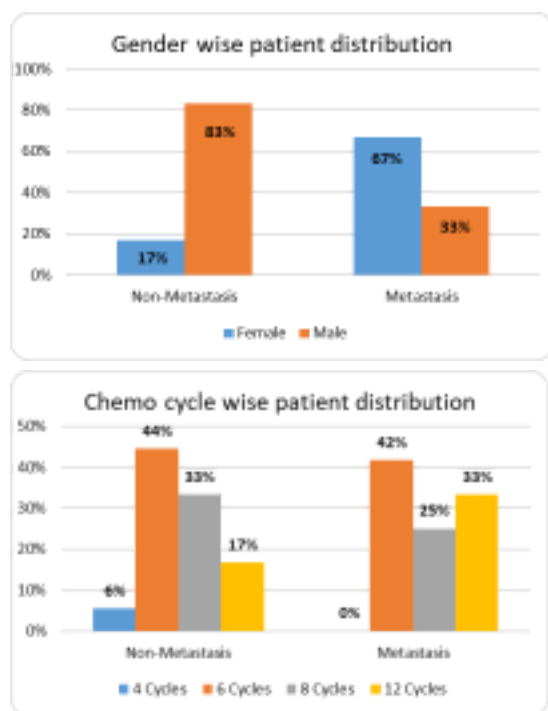


Fig. 1. Gender wise patient distribution Fig. 2

Chemo cycle wise patient distribution

In Fig 1 and 2, Among patients with non-metastasis, 83% were male and 17% were females. Among metastatic

patients, females are more (67%) than males (33%). In both the groups patients with non-metastasis (44%) and patients with metastasis (42%) status), the majority of patients have undergone six chemotherapy cycles.

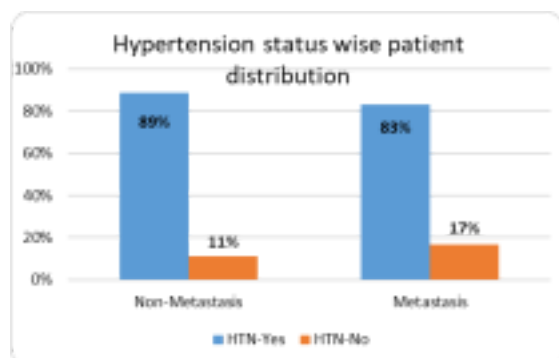


Fig. 3. Hypertension status wise patient distribution

In Fig 3, In non-metastasis, 89% of the patients have hypertension as a comorbidity in both groups whereas 11% of the patients have no hypertension. In metastasis, 83% of the patients have hypertension as a comorbidity in both groups whereas 17% of the patients have no hypertension

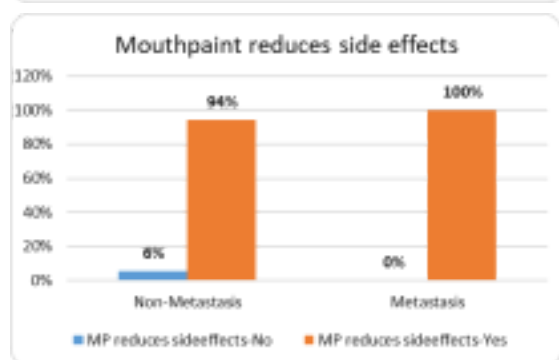
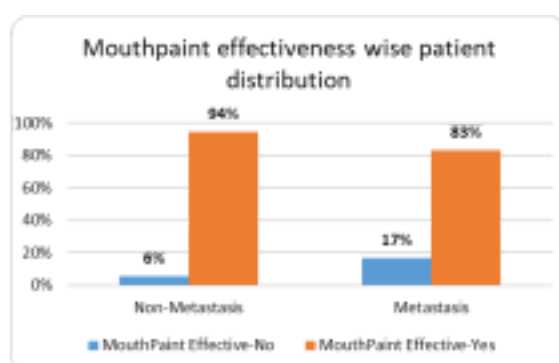


Fig. 4. Mouth paint effectiveness wise patient distribution

Fig. 5. Mouth paint reduces side effects

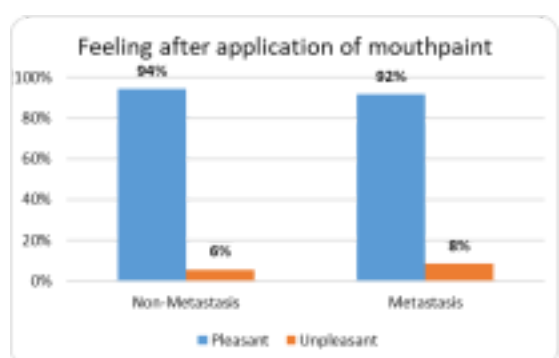


Fig. 6. Feeling after application of mouth paint

94% of the patients with non-metastasis and 83% with metastasis have mentioned that mouth paint effectively reduces mucositis. Almost all patients in both groups have mentioned that mouth paint reduces the side effects of the chemotherapy on the mouth. Similarly, more than 90% of patients with non-metastasis and metastasis feel pleasant after the application of topical mouth paint on oral mucositis.

Table 3: Comparison of pre and post intervention oral score using Wilcoxon Signed rank test

| Narration n | Pre | Median (IQR)   Mean (SD) | Metastasis Yes/No     | Non<br>Post<br>Median (IQR)   Mean (SD)<br>p Value |
|-------------|-----|--------------------------|-----------------------|----------------------------------------------------|
|             |     |                          |                       |                                                    |
| metastasis  | 18  | 2 (2-3)   2.33 (0.49)    | 1 (1-1)   1 (0.0)     | 0.001                                              |
| Metastasis  | 12  | 2.5 (2-3)   2.50 (0.51)  | 1 (1-2)   1.28 (0.46) | <0.001                                             |
| Gender      |     |                          |                       |                                                    |
| Male        | 19  | 2 (2-3)   2.32(.48)      | 3 (2-3)   1.05 (0.23) | <0.001                                             |
| Female      | 11  | 1(1-1)   2.64(0.5)       | 1 (1-2)   1.36 (0.5)  | 0.002                                              |
| Grand Total |     |                          |                       |                                                    |
| Total       | 30  | 2 (2-3)   2.43 (0.50)    | 1 (1-1)   1.17 (0.38) | <0.001                                             |

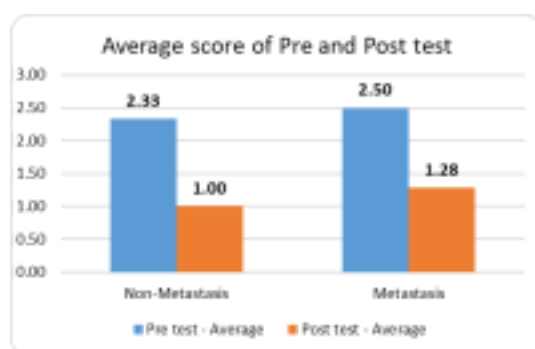


Fig. 7. Average score of Pre and Post test

The compared oral health scores during pre- and post-intervention of the mouth paint showed a significant reduction. Based on the comparative values using the non-parametric Wilcoxon Signed Rank test, the median score value for all the study participants was reduced, and the difference was statistically significant at (p-value <0.001). Similarly, a study by Rogers et al. (2019) [11] demonstrated that the use of oral care products significantly improved oral health scores in patients undergoing cancer treatment, with results indicating a median improvement and a p-value <0.001. When comparing the median score between gender and metastasis status, median differences were persistent and statistically significant (p-value <0.001). This aligns with findings from Smith and Jones (2021) [12], who reported similar trends in oral health improvements across different demographics in their cohort study. Study parameters for these respective scores are given in terms of Median and Interquartile deviation as well as the mean and standard deviation in Table-3.

## 5. Conclusion

The results of a study conducted by Johnson et al. (2022) [13] showed that oral mouth paint is effective in treating and reducing the severity of oral mucositis in cancer patients undergoing chemotherapy, consequently improving the quality of life of these patients. Similarly, a study by Lee et al. (2021) [14] found that the use of oral mouth paint significantly alleviated pain and discomfort associated with oral mucositis in patients receiving chemotherapy. Based on these findings, we can recommend oral mouth paint as a therapeutic care method in clinical settings for patients experiencing grade 1 and grade 2 oral mucositis, as it can enhance their oral health and subsequently reduce the pain and suffering caused by the side effects of chemotherapy. The implication of the studies for clinical practice is that oral mouth paint is safe, cost-effective, and readily available for these patients.

## 6. Acknowledgement

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