

## Supportive and Palliative Care

# An Ayurveda Gargle Regimen in Management of Radiotherapy-induced Oral Mucositis

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South Asian J Cancer 2021;9:250–252.

## Abstract



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### Keywords

- ▶ oral mucositis
- ▶ Ayurveda gargle regimen
- ▶ saphthachhadadi gandoosham

**Background** Radiotherapy-induced oral mucositis (RIOM) in patients with head and neck cancer may lead to significant morbidity. OM may result in erythema, ulceration, and pseudomembrane formation. The usual time of onset is second or third week of radiotherapy (RT), after the doses of 16 to 18 Gy. OM may cause severe pain, significant weight loss, increased resource use, interruption or discontinuation of the treatment, and added cost of supportive care.

**Materials and Methods** Patients who underwent RT and chemoradiation (CTRT) for head and neck squamous cell carcinoma (HNSCC) from 2015 to 2016 were included. The patients who were treated with the add-on Ayurveda gargle regimen (AGR) of *saphthachhadadi gandoosham* were evaluated against patients treated with standard symptomatic care (SSC).

**Statistical Analysis** Chi-square test was used to compare the difference between the two groups in the present study with SPSS (SPSS version 20 for Windows package SPSS Science, Chicago, IL, USA). software.

**Result** Grade III to IV OM was lower in the AGR group when compared with the SSC group ( $p < 0.001$ ). Onset of OM was significantly delayed in patients from the AGR group ( $p < 0.001$ ).

**Conclusion** The AGR with *saphthachhadadi gandoosham* is effective in delaying the onset and reducing severity of OM in HNSCC, without compromising the rate of locoregional recurrence.

## Introduction

Oral mucositis (OM) is one of the most common acute toxicities in patients with neck squamous cell carcinoma (HNSCC),

undergoing radiation/radiotherapy (RT) or chemoradiation (CTRT).

OM may cause significant morbidity during RT in HNSCC patients, which is one of the most common acute adverse

DOI <https://doi.org/10.1055/s-0041-1726138> ISSN 2278-330X.

**How to cite this article:** Wanjarkhedkar P, Pingley S, Shende S, Kelkar D, Parasnis A, Sambhus M, Phadake G, Hingmire S, Kulkarni P, Deshmukh C. An Ayurveda Gargle Regimen in Management of Radiotherapy-induced Oral Mucositis South Asian J Cancer 2021;9(4):250–252.

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effects of RT. OM may result in erythema, ulceration, pseudomembrane formation. The usual time of onset is second or third week of RT after the doses of 16 to 18 Gy. OM is associated with severe pain, significant weight loss, increased resource use, interruption or discontinuation of the treatment, and added cost of supportive care. Preventive strategies are, therefore, valuable.<sup>1</sup>

Ayurveda, the ancient Indian system of medicine, has traditionally recommended topical gargle termed “*gandoosham*” in Sanskrit for the management of mucositis in general.<sup>2</sup> This low-cost regimen may be an effective intervention to reduce the incidence and severity of OM and, thus, may positively contribute in the management of RT-induced OM in HNSCC.

## Materials and Methods

Patients who received RT and CTRT for HNSCC from 2015 to 2016 were reviewed. Comparative analysis of the patients who were treated with the add-on Ayurveda gargle regimen (AGR) (→ **Table 1**) and patients on chlorhexidine gluconate 0.2% weight/volume gargle as standard symptomatic care (SSC) was done. This analysis included patients of either gender, from the age of 18 years to 70 years, with HNSCC including oral cavity, oropharynx, and nasopharynx undergoing RT or CTRT. Patients with recurrent HNSCC were included if they had not received RT previously.

### Method of Use

Patients in the AGR group were following gargling with *sapthachhadadi gandoosham* 20 mL, diluted in 100 mL water just before use. The median frequency of gargling per day was 6 times (range 4–10). The gargles were advised from week 1 of RT for 7 weeks in the AGR group.

Patients were clinically examined weekly during the period of RT/CTRT and were followed-up for 3 months at regular intervals for post-RT acute toxicity. The electronic Lent Soma Scale was used to assess acute RT toxicity.<sup>15</sup>

**Table 1** Composition of ready to use Indian Food and Drug Administration–approved GMP (good manufacturing practice)-certified Ayurveda gargle

<i>Sapthachhadadi gandoosham</i>	
<i>Alstonia scholaris</i>	Induces cellular immune response <sup>3</sup>
<i>Vertiveria zizanioides</i>	Antifungal <sup>4</sup>
<i>Trichosanthes dioca</i>	Anti-inflammatory, <sup>5</sup> wound healing, antiulcer <sup>6</sup>
<i>Cyperus rotundus</i>	Antimicrobial, antioxidant <sup>7</sup>
<i>Terminalia chebula</i>	Antimicrobial, <sup>3</sup> antiadherent <sup>8</sup>
<i>Solanum xanthocarpum</i>	Analgesic <sup>9</sup>
<i>Picrorrhiza kurroa</i>	Antiulcer <sup>10</sup>
<i>Santalum album</i>	Antiviral, anticancer <sup>11</sup>
<i>Glycyrrhiza glabra</i>	Heals oral mucositis <sup>12–14</sup>
<i>Cassia fistula</i>	Antimicrobial

Patients in both the groups received saline and baking soda gargle as prophylactic treatment. Once mucositis was developed, treatment prescribed in both the groups was NSAIDs (non steroidal anti inflammatory drugs), topical anesthetics, and steroids as per the standard of care.

Patients were followed till completion of 3 years post RT to detect any locoregional/systemic recurrences.

## Results

Out of 62 patients, 32 were treated with add-on AGR and 30 patients were on SSC. Patients received either type of RT—conventional radiotherapy (CRT) or intensity-modulated radiation therapy (IMRT). CRT was received by 46.7% patients in the SSC group and 65.6% patients in the AGR group, while those treated with IMRT were 53.3% patients in the SSC group and 34.4% patients in the AGR group.

The field of irradiation was unilateral for 26.7% patients in the SSC group and 28.1% patients in the AGR group, while it was bilateral for 73.3% patients in the SSC group and 71.9% patients in the AGR group.

The average dose of RT was similar in both the groups (63.66 ± 5.55 Gy in the SSC group and 63.35 ± 4.63 Gy in the AGR group).

Grade III OM was observed in 43.3% patients in the SSC group and in only 6.2% patients in the AGR group ( $p < 0.001$ ). Grade III dysphagia was reported in 56.7% patients in the SSC group as compared with only 15.6% patients in the AGR group ( $p < 0.001$ ). Thus, the need of nasogastric (NG) feeding tube was reduced in AGR group ( $p < 0.05$ ).

The onset of OM in the AGR group with CTRT was week 4 to week 5, and in the SSC group it was toward the end of week 2 ( $p < 0.001$ ).

Weekly cisplatin was administered concurrently in 63.3% and 56.25% patients as standard of care in the SSC and AGR groups, respectively. An average dose of 200 mg cisplatin concurrently was received by 19 patients in the AGR group and 18 in the SSC group.

RT was completed by 32/32 patients in the study group while in the control group 28/30 patients completed the treatment.

The rate of recurrence at the end of 3 years was similar in both the groups (33.3% in the SSC group and 28.1% in the AGR group). OM and dysphagia were significantly reduced in the AGR group ( $p < 0.002$ ).

## Discussion

*Sapthachhadadi gandoosham* has been documented as gargle for mucositis in ancient Indian doctrines of Ayurveda, and is presently known to have antimicrobial, antiviral, anti-inflammatory, antioxidant, anticancer, antiadherent, and antiulcer properties in various published biomedical researches. The wound healing and cellular immune responsive action would have contributed to the observed therapeutic role in radiation-induced OM.

Ayurveda gargle regime (AGR) is cost-effective and easy to use. AGR is observed to be effective in the management of

OM and dysphagia, and in reducing need of NG tube feeding. Thus, it has improved quality of life in HNSCC patients undergoing RT and reduced the possibility of added cost of supportive and symptomatic care.

However, small sample size and nonrandomized study remain as the limitations of the present study. Randomized study with a larger sample is recommended.

## Conclusion

The AGR with *sapthachhadadi gandoosham* is effective in delaying the onset and reducing the severity of OM in HNSCC without compromising the rate of locoregional recurrence.

### Financial Support and Sponsorship

None.

### Conflicts of Interest

None declared.

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