International Research Journal of Ayurveda & Yoga
Vol. 6 (4),01-05, April,2023
ISSN: 2581-785X : https://irjay.com/
DOI: **10.47223/IRJAY.2023.6401**

Effect of *Triphaladi Choornam* Mouthwash and Chlorhexidine Gluconate Mouthwash in Radio-Chemotherapy Induced Oral Mucositis in Non-Metastatic Squamous Cell Carcinoma of Head and Neck: A Comparative Study

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Article Info

Article history:
Received on: 01-03-2023
Accepted on: 22-04-2023
Available online: 30-04-2023

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ABSTRACT:

Background: The cases of lung and mouth cancer have boomed in the last decade due to various reasons, the major one being tobacco consumption. In non-metastatic squamous cell cancer of the head and neck, oral mucositis becomes prominent, especially during chemo or radiotherapy. Such patients also often suffer from stomatitis, xerostomia and pharyngitis.

Materials and methods: This comparative study comprises of 36 patients undergoing chemo and radiotherapy. Here, 18 patients each are randomly allocated in two groups. One group receiving the existing prophylactic treatment i.e., chlorhexidine gluconate mouthwash and the other group received, *Triphaladi choornam* for gargling. Both the groups were asked to perform gargling, from the first day of radiation therapy to 21 days thereafter.

Analytical tools: The effectiveness of both mouthwashes was compared for their healing potential and quality of life by WHO oral mucositis scale and Patient Reported Oral Mucositis Symptoms (PROMS)scale respectively.

Conclusion: The reduction in mucositis and betterment of quality of life was significant in the group which received ayurvedic mouthwash compared to the prophylactic treatment group.

Keywords: Head and neck cancer, Oral mucositis, Radiotherapy, *Triphaladi choornam.*

INTRODUCTION

About 562,328 people in the world were diagnosed with head and neck cancer in 2020. Out of which an estimated 277,597 people succumbed to the disease.[1] Radiotherapy is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.[2] At high doses, radiation kills cancer cells or slows their growth by damaging their DNA. The delivery of radiotherapy to different cancer sites has changed dramatically, from using IMRT to various types of CRT.[3] A study showed that CRT techniques had more complications compared to IMRT, which included

stomatitis, xerostomia and oral mucositis where patients' quality of life decreases and they are unable to oral feed after 10 days of radiation therapy leading to malnourishment and wastage of muscle further decreasing life expectancy.[4] In most of the cases oral mucositis becomes so prominent that patient require oral feeding tube. There's no approved treatment or prophylaxis protocol for oral side effects of RT. The currently recommended measures include, the use of various mouthwashes, local anaesthetics such as lidocaine, sucking ice, growth factors, non-steroidal and steroidal anti-inflammatory agents, etc.[5]

MATERIALS AND METHODS

This project was initiated after submitting the protocol and receiving approval from the institutional ethics committee with registration number ECR/319/Inst/TN/2013/RR-19. And prior to this the patients were randomized into the chlorhexidine gluconate 2% w/v mouthwash (Group A) and *Triphaladi choornam* (Group B) mouthwash groups by random table numbers. The 'A' group used a mouthwash containing a mixture of 2% chlorhexidine gluconate(w/v), zinc chloride, and sodium fluoride, 3-4 times a day. 'B'group used *Triphaladi choornam* mouthwash (120g of powder was dissolved in 1200ml water (1:10), mixture was boiled to a certain time period until reduced to 300ml, then the mixture was cooled and filtered using a cotton/muslin cloth. It was then dispensed to the patients in a 100ml bottle, three to four times a day. The *Triphaladi choornam* mouthwash was prepared by the pharmacy PG students under the supervision of Nandha Ayurveda College teaching faculties. Patients were instructed not to swallow decoction but to swirl it for at least three minutes. Total treatment period was 21 days where both the groups received verbal instructions on oral hygiene and dietary guidelines. All patients received the same professional oral care if needed but they did not receive steroids and/or antimicrobials before inclusion in the study. Table.1 Components In *Triphaladi Choornam* And Their Uses

RESULTS

Among the study population, 36 patients were selected according to inclusion and exclusion criteria which consist of 23 male patient (64%) and 13 female patient (36%). The primary site of tumor was identified in tongue in about 13 patients (36.11%), buccal mucosa in 6 patients (16.66%), hypopharynx in 5 patients (13.88%), supraglottis in 4 patients (11.11%), and retromolar trigone in another 4 patient (11.11%). In our study, HNSCC patients undergoing concurrent chemo radiotherapy were randomly allocated in two groups. Group A consisted of patients who used chlorhexidine mouthwash, which consisted of a total of 18 patients, among which 13 patients (72.22%) had grade 1 oral mucositis and 5 patients (27.77%) had grade 2 oral mucositis**.** Group B consisted of patients who used *Triphaladi choornam* mouthwash, which consisted of 18 patients, among which 10 patients (55.55%) had grade 1 oral mucositis, 7 patients (38.88%) had grade 2 oral mucositis and 1 patient (5.55%) had grade 3 oral mucositis**.** This was determined by using WHO oral mucositis scale. To evaluate the efficacy of drugs in comparison based on quality of life, Patient oriented oral mucositis (PROMS) scale was chosen, which is a 10-item scaled questionnaire to determine the quality of life of patients with oral mucositis in head and neck cancer.

Patients were evaluated on day before giving mouthwash, drug, 7^{th}, 14^{th} and 21^{st} day. Out of the 10 items mentioned in the PROMS scale, 4 major conditions are discussed (mouth pain, difficulty in talking, difficulty eating solid food, difficulty swallowing) to compare the QoL in patients.

Fig.1 Comparison Of Mouth Pain Between Group A And Group B

Fig.2 Comparison Of Difficulty In Talking Between Group A And Group B

Fig.3 Comparison Of Difficulty In Eating Between Group A And Group B

Fig.4 Comparison Of Difficulty In Swallowing Between Group A And Group B

DISCUSSION

Oral mucositis is maybe the foremost common, debilitating complication of cancer treatments, particularly chemotherapy and radiation.[6] It can lead to several problems like pain, nutritional problems as a result of inability to eat. There's also increased risk of infection due to open sores in the mouth thereby having a significant effect on patient's quality of life and can be dose limiting where the dose would have to be tapered.[7] When caused by chemotherapy, mucositis is usually due to low white blood cell count and when caused by radiation, mucositis is usually due to the necrotic and inflammatory effect of radiation energy on oral mucosa.[8] It can lead to pain,

restricted oral intake, act as portal of entry for organisms, contribute to interruption of therapy, increase the use of antibiotics and narcotics, increase the length of hospitalization and increase the overall cost of treatment.[9] Since there are ample of devastating side effects/complications of RT on cancer patients, evident by dwindling general health, unwanted halts on procedures, there is need for emphasizing the utilization of Ayurvedic *Triphaladi choornam*. Each component of the mentioned drug has been successfully tested for its anti-oxidant, anti-inflammatory and antimicrobial properties.[10] In general, the RT patients are unable to open their mouth because of pain and muscle stiffness which leads to decreased oral hygiene activity, swirling of the solution in oral cavity allows cleansing which thereby reduces fungal or bacterial infection Patients were able to open their mouth with lesser difficulties and eat/drink properly. Patients who adhered to *Triphaladi choornam* had considerable improvement in their quality of life. At the same time, the patients who adopted the chlorhexidine gluconate mouthwash showed relatively less progress in reduction of the oral side effects especially mucositis.[11]

CONCLUSION

This small comparative study indicates that *Triphaladi choornam* have potential beneficial effect on reducing mucositis and enhancing quality of life of patients compared to the chlorhexidine gluconate mouthwash. At present, cancer treatment has a multidisciplinary approach and a more well-designed randomised trial with larger sample size are warranted in this aspect.

Acknowledgments- Nil
Conflicts Of Interest- Nil
Source of finance & support – Nil

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How to cite this article: Nair S, Gokul R, Hameed T, Madhumida, Saravanan G "Effect of *Triphaladi Choornam* Mouthwash and Chlorhexidine Gluconate Mouthwash in Radio-Chemotherapy Induced Oral Mucositis in Non-Metastatic Squamous Cell Carcinoma of Head and Neck: A Comparative Study" IRJAY. [online]2023;6(4);
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DOI link- https://doi.org/**10.47223/IRJAY.2023.6401**

Table.1 Components In *Triphaladi Choornam* And Their Uses

COMPONENTS	USES
Terminalia chebula – Fruit rind	anti-inflammatory, antioxidant, anti-cancerous, anti-ulcerative and antimicrobial
Terminalia bellerica – Fruit rind	
Emblica officinalis – Fruit	
Glycyrrhiza glabra - Root	Anti-inflammatory, wound healing property

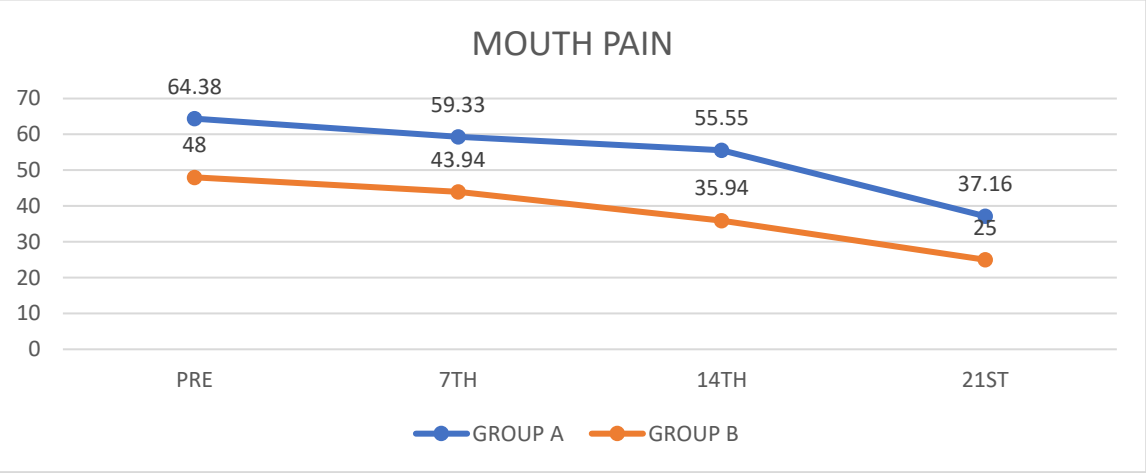

Fig.1 COMPARISION OF MOUTH PAIN BETWEEN GROUP A AND GROUP B

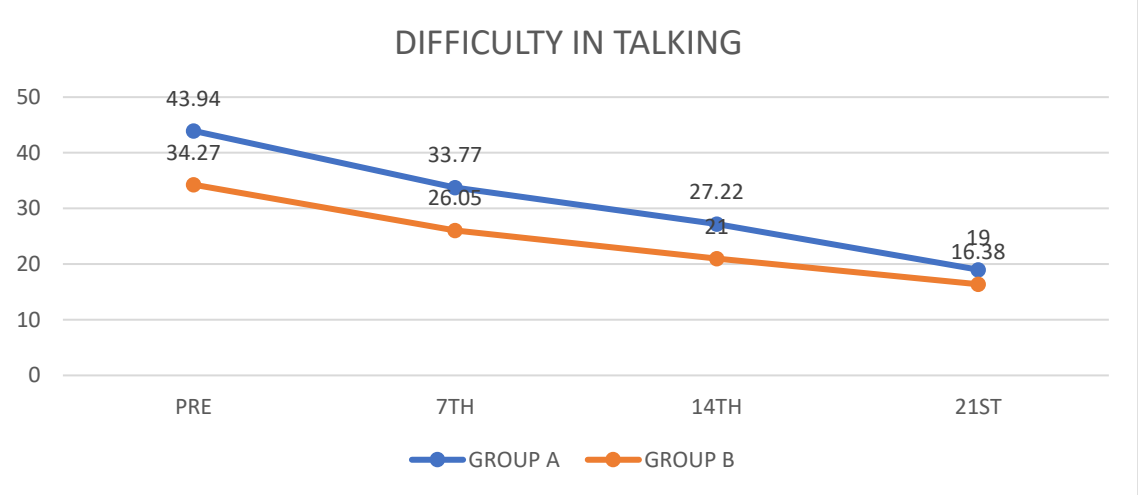

Fig.2 COMPARISION OF DIFFICULTY IN TALKING BETWEEN GROUP A AND GROUP B

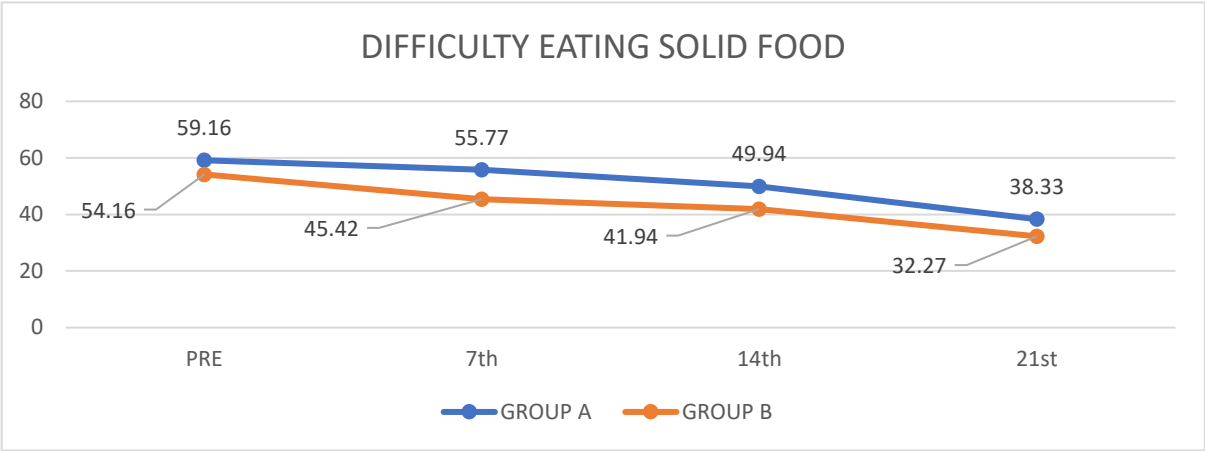

Fig.3 COMPARISION OF DIFFICULTY IN EATING BETWEEN GROUP A AND GROUP B

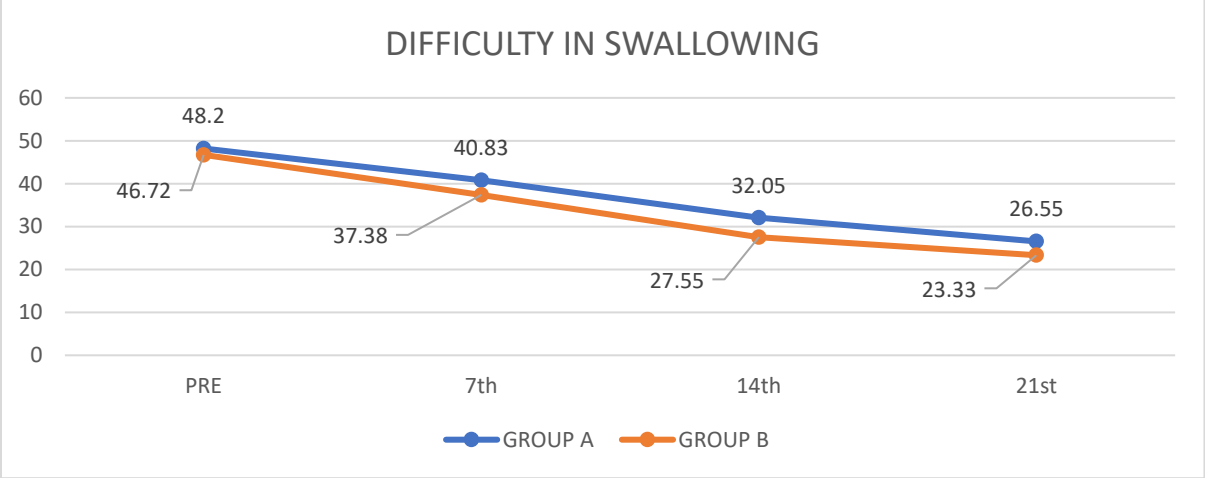

Fig.4 COMPARISION OF DIFFICULTY IN SWALLOWING BETWEEN GROUP A AND GROUP B