

Title: “Comparison of two fluoride application regime in oral cancer patients; A Randomized controlled trial. ”

ABSTRACT

Introduction: Oral cancer ranks first among males and second overall in the Indian population as per GLOBOCAN 2020. In these patients Supportive oral care lack as an integrated part of cancer care. The most prevalent side effect of chemo-radiotherapy (CT-RT) is Radiation caries and their sequel. This results in increased dental disease burden and poor oral health-related quality of life scores (OHRQOL).

Aim: Present Randomized controlled trial was conducted to evaluate the effect of fluoride on dental disease burden in terms of DMFT scores in patients who have received CT-RT in the region of the oral cavity. Oral health-related quality of life in terms of OHIP-14 scores was also assessed.

Materials& Methods: 111 patients participated in the randomized controlled trial as per the CONSORT statement. Two regimens, Monthly, and quarterly application were further divided into varnish and gel subgroups. This resulted in a total of four groups including monthly varnish application (AV), monthly gel application (AG), quarterly varnish application (BV), and quarterly gel application (BG). These were analyzed for DMFT and OHIP-14 scores at baseline, one month, six months, and one-year recall post chemo-radiotherapy (CT-RT).

Results: Median and Interquartile range of DMFT scores for the AV group were 2(0.25-6), 2(1-6), 3(1-7.7), and 4(1-9) at baseline, one month, six months and one

year recall respectively. For the AG group, it was 2(1-5), 2(1-5), 4(1-8), and 5(1-8) respectively. For BV Group it was 3(1-4), 3(1-4), 3(2-6), and 4(2-6) respectively, while for BG Group it was 2(0-4), 2(0-4), 3(1.5-4.5) and 4(2-5) respectively for four recall points. These values were highly significant $P < 0.001$.

OHIP-14 score's Median and Interquartile range at baseline, one month, six months, and one year recall were 14(11-25.7), 35(28.2-40), 5.5(0-6) respectively. For AG group it was 13(2-24), 29(26-36), 6(0-12) and 0(0-6) respectively. For BV group it was 15(10-24), 34(27-46), 3(0-14) and 0(0-7) respectively. While For BG it was 11(5-18.5) 29(23.5-40), 3(0-11) and 0(0-6.5) respectively. These values were highly significant with $P < 0.001$.

Intergroup comparison was not significant for DMFT and OHIP-14 scores for four intervention groups. OHIP-14 score's Mean and standard deviation values for sufficient mouth opening and insufficient mouth opening were 20.6 ± 9.5 and 12.8 ± 9.8 respectively, which was highly significant with $p < 0.001$.

Conclusion: DMFT scores reported a significant and minimal constant increase in patients at one-year recall from baseline. Fluoride application was effective in controlling the DMFT scores at one-year recall in these patients. OHIP-14 scores significantly improved at recall visits from baseline by use of fluoride as part of the Supportive Oral Care Protocol (SOCP). Fluoride varnish and gel applied either monthly or quarterly provided similar changes in DMFT and OHIP-14 scores. Hence any combination of these can be considered effective in the care of these patients. Insufficient mouth opening drastically reduces oral health-related quality of life scores in these patients and hence they required more care.

Clinical Recommendation: Fluoride application as per supportive oral care protocol (SOCP) is recommended as an integral part of the oral care needs of head and neck cancer patients including oral carcinoma. Monthly topical fluoride application during the first year post CT-RT and thereafter-quarterly application lifelong is advised. Involvement of a Dental supportive care expert from the point of diagnosis of cancer is needed. A Dental expert as a part of the multidisciplinary team for cancer care of head and neck cancer patients is recommended.

Keywords: Oral Carcinoma, Head and Neck Cancer, Fluoride Gel, Fluoride Varnish, Supportive Oral Care Protocol, Dental Supportive Care Expert, Oral Health-Related Quality Of Life, DMFT, OHIP-14.