

CHAPTER 7

SUMMARY

7. Summary

7.1 Introduction & Method

Oral cancer is the most common cancer in males in India. With an overall incidence rate of 11%, it ranks second most common cancer in our population. Oro-dental disease burden is very high in our population. Structural oral supportive care is nonexistent in the majority of cancer centers for head and neck cancer patients including oral carcinoma. The recommendation for fluoride use in this section of patients is not clear and is based on extrapolated data from healthy individuals. The present study was conducted to provide recommendations for topical fluoride use in these patients. A randomized controlled trial evaluated the effect of fluoride on dental decay by observing changes in DMFT scores over a period of one-year post chemo-radiotherapy. OHIP-14 scores were also evaluated to see the effect of supportive oral care protocol on oral health-related quality of life scores.

The trial was conducted as per the CONSORT 2010 statement, a total of 145 participants were randomly allocated into four intervention groups. These groups were Monthly fluoride varnish application group (AV), Monthly fluoride gel application group (AG), Quarterly fluoride varnish application group (BV), and Quarterly fluoride gel application group (BG).

7.2 Baseline data

A total of 111 participants completed the study in all parameters and were analyzed. The baseline characteristic of the participants was assessed. The Mean \pm S.D for Age was 49.11 ± 11.36 years with a range from 20-70 years. 86.4% of the population were males and the majority of participants were in the 4-5th decade of their life. 40.5% of participants earned between five and ten thousand INR monthly.

54.9% of participants smoked, 55% consumed tobacco and 28% consumed more than 250 ml of alcohol. 79.2 % of participants use a toothbrush with 93.1% brushing at least once a day.

Among the site of cancer, 30.6% of participants had tongue carcinoma, 26.1% had buccal carcinoma and 15.5 % had carcinoma of the alveolus and gingiva-buccal sulcus. 73.8% of participants had moderately differentiated squamous cell carcinoma; with the majority receiving 60 Gy of radiation. All patients received radiotherapy while 72% received concurrent chemotherapy.

The most common surgery was composite resection (27.9 .1 %) followed by tongue resection (25.2 %). 80 % of patients had Grade II mucositis while 20 % reported Grade III. The mean score and standard deviation for trismus were 30.33 ± 9.68 mm with a range from 5-40 mm trismus.

44% of participants received an extraction, 18% root canal treatment and 80 % received restoration during the study period. The annual expense on SOCP for the majority of participants ranged from ten to twenty thousand.

7.3 DMFT Scores

The median and Interquartile range of DMFT scores for the AV group was 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 four recall points. For group BV it was 3(1-4), 3(1-4), 3(2-6), and 4(2-6) respectively for four recall points. For group BG 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 $P < 0.001$.

While the Mean \pm Standard deviation scores for the same parameters for the AV group were 3.79 ± 4.281 , 3.89 ± 4.193 , 4.71 ± 4.673 , 5.18 ± 4.845 respectively. AG group reported Mean \pm Standard deviation scores as 3.93 ± 4.287 , 4.07 ± 4.305 , 5.52 ± 4.902 , and 5.74 ± 4.981 respectively. For BV Group it was 4.04 ± 5.474 , 4.07 ± 5.449 , 5.15 ± 5.586 , and 5.59 ± 6.034 respectively. While for the BG group it was 2.31 ± 2.422 , 2.38 ± 2.382 , 3.31 ± 2.647 , and 3.69 ± 2.661 respectively.

DMFT scores were taken at recall visits at baseline, one month, six months, and one year for each group. While comparing these scores at four intervals there was no statistically significant difference between the groups. These results show that fluoride the type and the frequency of application did not affect DMFT score amongst the four intervention groups.

The results were significant but the increase in average DMFT scores at one year recall was limited to 1.5 - 2.5 average points and the standard deviation was nearly similar in all groups. This minimal increase in average DMFT scores shows the effectiveness of fluoride in controlling DMFT score despite radiation-induced xerostomia.

7.4 OHIP scores

OHIP-14 score's Median and Interquartile range at baseline, one month, six months, and one-year recall for the AV group was 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. For BG it was 11(5-18.5) 29(23.5-40),3(0-11) and 0(0-6.5) respectively at all four time intervals. These values were highly significant with $P < 0.001$.

OHIP-14 score's Mean and Standard deviation at baseline, one month, six months, and one year recall for the AV group were 16.79 ± 10.27 , 34.96 ± 7.92 , 7.57 ± 7.88 , 3.36 ± 4.86 ; for AG group it was 13.89 ± 12.11 , 31 ± 7.80 , 6.89 ± 6.45 , 2.63 ± 3.80 respectively; for BV was 15.96 ± 8.75 , 35.19 ± 10.45 , 7.33 ± 9.77 , 4.48 ± 7.78 respectively while for BG group it was 12.52 ± 9.92 , 31.48 ± 9.82 , 6.62 ± 8.71 , 3.72 ± 5.79 respectively.

Intergroup comparison was not significant for OHIP-14 scores for four intervention groups. It was observed that patients enrolled in fluoride intervention as part of SOCP reported a highly significant reduction in OHIP-14 scores at one-year recall. SOCP was considered effective in improving oral health-related quality of life scores in these patients.

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 $p < 0.001$. This finding suggested that a mouth opening of less than 20 mm is not sufficient for oral care and results in poor OHIP-14 scores as compared to participants who had a mouth opening of more than 20 mm.

Overall despite the trismus, all groups reported improvement in OHIP-14 scores over a period of one year. There was a doubling of OHIP-14 Scores at one month recall, due to the accumulation of acute side effects of CT-RT. This subsided soon after drastically at six-month recall and reduced to a minimal value at one-year recall. This shows the effectiveness of SOCP on oral health-related quality of life (OHRQOL) in these patients.

7.5 SOCP

As a secondary objective SOCP was validated in a cross-sectional survey across India involving the dental oncology experts working in cancer centers across various states of India. 15 dental experts analyzed the 41-point SOCP protocol and the protocol was approved at an agreement on 99.4% of the content, with some minor modifications. The inter-rater agreement (IVC) of 0.9 to 1 was achieved which was significantly higher than the 0.78 required to validate a protocol.

This protocol was followed for all patients and just the fluoride intervention was different in the four groups studied. It was observed that despite patients receiving 3DCRT radiotherapy along with a high load of oral disease burden at baseline and limited mouth opening the OHRQOL parameters in terms of OHIP-14 scores improved drastically in all patients across all four groups.

These findings suggest that SOCP is an effective protocol that significantly improves the quality of life in head and neck cancer patients including oral carcinoma.

7.6 Conclusion

Topical fluoride application was effective in controlling the increase in DMFT scores. Fluoride varnish and gel, applied either monthly or quarterly provided a similar effect in controlling DMFT scores and significantly reducing OHIP-14

scores. It can be concluded that any combination of the type and frequency of fluoride application is considered effective in the care of these patients. Insufficient mouth opening drastically reduces oral health-related quality of life in these patients and hence they need more care. Supportive oral care protocol (SOCP) is a valid and effective tool in the care of these patients.

7.7 Clinical Recommendation:

Fluoride application as per supportive oral care protocol (SOCP) is recommended as an integral part of the supportive oral care needs of head and neck cancer patients including oral carcinoma. 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.