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Oral Care Protocol for Chemotherapy and Radiation therapy included oral complications in Cancer Patients.

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ABSTRACT

A research study titled “Oral care protocol for chemotherapy and radiation therapy induced oral complications in cancer patients” was carried out at Manipal College of Nursing, MAHE, Manipal by Ms. Radhika R Pai for the award of PhD Nursing degree.

The study was carried out in two phases. The primary objective of the first phase of the study was to training the staff nurses working in oncology related wards in the area of oral care of cancer patients and, the second phase aimed to find out the effectiveness of oral care protocol intervention on oral health and oral complications This phase allocation of cancer patients in experimental and control group. These patients were observed every week up to 6 weeks until the completion of radiation therapy/chemo radiation as well as up to 1-year follow up of oral health was collected from hospital records.

The conceptual framework for the study was based on Iowa model of evidence-based practice to promote quality care (2015). One group pretest posttest design was used for conducting the phase I as it aimed at preparing the staff nurses for oral care of cancer patients and experimental design using Randomized Controlled Trial was adopted for phase II, as the study sought to evaluate the effectiveness of oral care protocol intervention on oral health and oral complications among cancer patients.

The tools used for phase I of Staff nurses training were, Tool 1 Demographic proforma of Staff nurses, Tool 2 Knowledge questionnaire on oral care of cancer patients, Tool 3 checklist on new oral care protocol acceptability, Tool 4 Checklist on Documentation audit. For Phase II of Intervention phase tools used were, Tool 1 Demographic proforma: Patients, Tool 2 Scale on oral health & activities assessment,

Tool 3 Scale on WHO oral mucositis grading, Tool 4 Scale on Oral complications and cost analysis tool, Tool 5 Form on Adverse reaction reporting and Tool 6 Checklist on audit of patient record on follow up of oral health. Validity and reliability of the tools were established using appropriate methods and all the tools were pretested. A pilot study was carried out and the methodology was found feasible.

Administrative permission was obtained for the study. Ethical clearance was obtained from the institutional ethics committee of KMC Mangalore (IEC KMC MLR 03-18/65). The clinical trials registry of India (CTRI) registration number obtained is CTRI/2015/04/005709. Informed consent was obtained from the participants after explaining about the purpose and usefulness of the study and assuring the confidentiality of information.

The data were collected from 72 staff nurses working in oncology related wards and 80 head and neck cancer patients administered for radiation therapy/chemoradiation. The data for the first phase of main study were collected continuously throughout the study period as when there was staff rotation or staff induction ie from March 2015 to 2017 January. The data collection for the second phase of the study started from June 2015 to November 2017. Follow up data for 1year following the completion of radiation therapy/chemoradiation were collected from December 2017 to November 2018 by auditing the patients records.

The mean age of the staff nurses who underwent oral care training was 32.74 years. A majority i.e., 98.6% were females, 69.4% were with the educational qualification of GNM. In that, 4.3% of staff nurses reported to have completed certificate course in cancer nursing and 1.4% completed diploma in cancer nursing. A majority 66.7% were working as staff nurses by their designation, out of them 52.8% had working experience of 1-5 years and 95.8% of them had cancer ward working

experience of 1-5 years. A vast majority i.e., 76.38% of them received information classes regarding oral care of oncology patients. Paired sample t test was computed to compare the mean knowledge scores in pre and post training showed that the training was effective in improving the knowledge (mean difference 4.153, t = 13.31, p <0.001) inferring significant difference between both pre and post test values.

After the introduction of new protocol for oral care of cancer patients acceptability of the new oral care protocol was assessed among the staff nurses which showed that, there was 100% agreement for the areas in the protocol like well-organized content, covered all aspects and it would serve as a helpful guide to provide oral care of cancer patients etc. Patient records were audited for checking the implementation of the oral care protocol by the staff nurses. Only 21 out of 80 records showed to have all areas of oral assessments recorded.

In Phase 2 of the study, Majority i.e., 51.2% in experimental group and 52.5% were in the age group of 56 years and above. Most of the patients were males 92.5% in experimental group and 87.5% in control group. Utmost of the participants i.e., 40% in experimental and 37.5% in control group have reported to have completed primary education. Maximum number of the patients i.e., 42.5% in experimental group and 32.5% in control group were diagnosed to have tongue cancer.

Regarding the treatment details of the participants, majority of the participants i.e., 57.5% in experimental group and 67.5% in control group received chemoradiation as the treatment plan. Most of the participants i.e., 72.5% in experimental group and 85% in control group completed on an average of 70 Grays of radiation dose. Concerning the report of staging of the cancer among these patients most of patients i.e. 47.5% in experimental group and 42.5% in control group with stage IV of cancer.

Among all the oral complications, the median days to mucositis (p = .015), taste loss (p = .028), swallowing difficulty (p= .004), infection (p = .017), xerostomia (p = .004) and bleeding gums (p = .025) were statistically significant in comparison with control, indicating that the intervention was effective. As treatment progressed severity of these structural changes and functional activities increased in both the groups and over the weeks severity of the oral problems increased in both the groups (p<.001).

The results of the present study showed that, comparison to the control group, improvement in oral health was not statistically significant among participants in the experimental group [F = (.596), p =.442]. The interaction effect (time X group) was significant [F = (1.636), p =.175]. Indicating that the group changed overtime, and the change was different across the groups. Post hoc test using Bonferroni analysis revealed that the oral care intervention resulted in statistically significant improvement in oral health between the time points i.e. week 1 till week 6 (p<.001).

A total of 28 patients out of 80 visited the for the follow up. Patients follow up details with respect to oral health upto 1 year after completion of radiation therapy/chemoradiation from the record were taken into consideration. Majority of the participants came out with the symptoms of restricted mouth, mucositis and trismus. Most of the patients visited the OPD on an average of 2 times after completion of treatment. Around 23 patients had interrupted treatment reasons due to various reasons such as DAMA, alcohol withdrawal, pancytopenia, hyperbilirubinemia, fall injury, neck wound and majority of them with a reason as not tolerating chemotherapy.

Key words: oral care, protocol, head and neck cancer patients, chemotherapy, radiation therapy, cancer patients, cancer nurses, knowledge and practice.