

Development and validation of an educational pamphlet on care of mouth for patients with radiation therapy induced oral mucositis, South India

Dr. K. Sathiya^{1*}, Dr.A.Seethalakshmi², Ressay Rachel John³, Josna Steffi. J³, Surya. E³

^{1*}Lecturer, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, India

² Reader, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, India

³ Nursing students, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Chennai, India

*sathiyasrmc@gmail.com

ABSTRACT

Cancer is one of the most frequent causes of death and receiving a diagnosis and treatment of cancer is an extremely physically and mentally stressful experience. So, the patient and the family members should be given adequate knowledge on overcoming the complications of treatment modalities. The objectives of the study to develop a pamphlet on care of mouth for patients with radiation therapy induced oral mucositis and validate the pamphlet on care of mouth for patients with radiation therapy induced oral mucositis by health care professionals Quantitative design were used and 15 health care professionals were selected using purposive sampling technique. Tool used for this study was Structured questionnaire with ten-items rated in a 3-point Likert scale. Results: The fifteen responses were collected and analysed. Item level content validity index (I-CVI) was calculated for individual items which ranged from 0.7 - 1 and Scale level content validity (S-CVI) was calculated for complete ten items and it was found to be 0.96. SCVI should be minimum 0.80 to be acceptable as content valid S-CVI was found to be 0.80 thus the content of educational pamphlet is acceptable. The results presented in this study give an insight into the effects of educational pamphlet in improving knowledge for patients with radiation therapy induced oral mucositis and it is validated scientifically for clinical use.

Keywords: pamphlet, care of mouth, radiation therapy, oral mucositis, cancer therapy

Introduction

Cancer is a cell disease that affects the body's function with abnormal and uncontrolled growth of the cell which invades the surrounding tissues causing further damage by spreading

to other parts of the body (World Health Organization, 2018). 8.2 million people died because of cancer worldwide and in India about 4.77 lakh men, and 5.37 lakh women were diagnosed with cancer. Cancer ranks sixth leading cause of death and a total of 1.1 million new cases of cancer are newly diagnosed each year, of which breast and cervical cancers rank among the top two cancers in terms of both incidence as well as mortality.

The treatment for cancer including chemotherapy, radiotherapy, surgery, immunotherapy, targeted therapy, stem cell therapy, genetic therapy and hormone therapy which can either be taken individually or as a combination of two or more treatment options (Clark, 2017). Chemotherapy works by stopping or slowing the growth of cancer cells. The commonly used chemotherapeutic drugs in practice are cyclophosphamide, cytosar-U, cisplatin, vincristine sulphate, vectibix, gemcitabineoxaliplatinetc (National Cancer Institute, 2017). The side effects of radiation therapy are anaemia, loss of appetite, fatigue, headache, infection, nausea and vomiting, dyspnea, insomnia, weight gain or loss, anxiety, depression, diarrhoea, dry mouth, mouth sores, fever, hair loss, pain from nerve damage, neuropathy, lymphedema, memory problems, concentration problems, skin changes, nail changes, sexual changes, fertility changes, easy bruising and excessive bleeding (Chen, 2016).

A descriptive study on the quality of life for 58 outpatients during and after a course of radiation treatment for cancers of the head and neck and the results revealed that the patients had severe depression even after a month of treatment. (Rose, Pauline MN, RN 2001). A study was conducted among 33 individuals who had received radiotherapy for head and neck cancers. These individuals described their treatment experiences and identified the most troublesome and debilitating side effects of radiotherapy are lethargy and weakness, dry mouth, mouth sores and pain, taste changes, and sore throat. (Alison M. Rose-Ped 2002).

According to the National Cancer Registry Programme of the Indian Council of Medical Research (ICMR), more than 1300 Indians die every day due to cancer. Between 2012 and 2014, the mortality rate due to cancer increased by approximately 6% in 2012 there were 478,180 deaths out of 2,934,314 cases reported. In 2014, 491,598 people died in out of 2,820,179 cases. The incidence and mortality rate of cancer is highest in the north-eastern

region of the country. The journal of lasers medical science conducted a study on Effect of Low-Level Laser Therapy in Treatment of Chemotherapy Induced Oral Mucositis and concluded that the use of GaAs LLLT in treating COM in patients with various malignancies is well tolerated by patients, it results in improvement of mucositis, however; mechanism of

action does not seem to be completely linked to the change of pro or anti-inflammatory cytokines.

Literature review

Igor Figueiredo Pereira et al. (2019) conducted study on Radiation induced oral mucositis in Brazilian patients among 413 patients were analyzed by using a cross sectional retrospective study was performed. The prevalence of OM in the overall sample was 41.9% (n=173) and higher among males (78.2%). The mean age was 55 years. squamous cell carcinoma was the most frequent type of tumour (76.3%, n=174). The frequencies of osteoradionecrosis and oral candidiasis were 9.7% and 17.9%, respectively.(21)

Shadman Nemati et al. (2019) conducted study on frequency of radiation therapy induced mucositis and related risk factors in patients with the head and neck cancer: A survey in the north of Iran among 43 patients analysed by using cross-sectional prospective Design. The findings show patients enrolled in the study were 34 men and 20 women (40-72-year-old) of which 43 cases (79.6%) showed signs and symptoms of CIM/RIM mostly aged 60-69-year-old. Grade 2 mucositis was the most frequent type (18 cases :34.9%) and mouth floor was the most common site of chemotherapy induced mucositis/radiation therapy induced mucositis(15 patients :34.9%) age ($p=0.023$),gender ($p=0.012$), and the severity of pain ($p=0.018$)were significantly related to mucositis in patients with HNCs who underwent radiotherapy.(22)

Anne Margarete gunsgard et al. (2014) conducted study to assess the assessment of cancer therapy induced oral mucositis using a patient -reported oral mucositis among 50 patient by using tool oral mucositis assessment scale (OMAS) .Thirty-three participants completed all stages 7th week after commencing cancer treatment, the Spearman's Rho varied between 0.19 and 0.70 ($p<0.001$).923)

Ahmad Ameri et al. (2015) conducted study on Efficiency of Benzydamine oral rinse in prevention and management of radiation induced oral mucositis among 51 patients with head and neck carcinoma received external radiotherapy for 5day/week to total planned cumulative radiotherapy doses of at least 5000 cGY. The patients were analysed by using A double blind placebo-controlled randomized clinical trial. the degree of mucositis assed by using 4-point rating scale and mean mucositis score was calculated. The findings shows at the end of 4 week score of placebo group was more than treatment group (1.81 vs

1.27, $p=0.001$). This trend continued to end of week 7 (1.98 vs 1.43, $p=0.001$). It can be effective and prevention of oral mucositis.(24)

Ajay prashad et al. (2015) conducted study low level laser therapy against radiation induced oral mucositis in elderly head and neck cancer patients -a randomized placebo controlled trial among 46 patients were analysed by using double blind study was conducted. OM grades (RTOG/EORTC SCALE) & RT break were recorded by a blind assessor. descriptive statistics and repeated measures ANOVA were for analysis keeping $p,0.05$. The findings shows significant reduction in the incidence and duration of severe OM ($p=0.016$) and severe pain ($p=0.023$) and weight loss($p=0.004$) was observed in laser than placebo group. No difference found in enteral feeding use ($p=0.667$) between 2 groups(25)

Methods

2.1 study design and setting

A qualitative method is adopted for this study to validate a pamphlet on care of mouth for patients with radiation therapy induced oral mucositis. The study participants consisted of group of Health care professionals such as doctors, dentists, faculties from nursing and nurses working in radiation oncology OPD were included and those who were not willing were excluded. The study took place at Sri Ramachandra Institute of Higher Education and Research (Deemed to be University) and hospital Chennai.

2.2 Preliminary Collection of Content of Educational handout:

An initial content of the pamphlet was generated through in-depth literature review. The literature review focused on exploring the already available pamphlet for patients on care of mouth for radiation therapy induced oral mucositis and need for more contribution in this context. Input from the experts were taken into account for generating the material, on the basis of their day-to-day clinical experience and patient's ability to read and practice in their day-to-day life.

Handout content: Literature review revealed a necessity of pamphlet for patients to create the awareness on care of mouth. Information was regarding care of mouth for oral mucositis patients and how to promote optimum life. Based on the literature review the Framework was divided into three headings which includes introduction, main text with pictorial representation and disclaimer.

Discussions were carried out with the experts and a thorough analysis of each and every point were done to identify what is expected for a pictorial representation. The best photograph for the educational pamphlet was selected after reviewing several photographs for inclusion in the pamphlet. The criteria for sorting the photographs were kept in such a way that it should be a best match with the content and should give minimum distraction to the patients. It underwent several revisions and resulted in the pre-final draft. This section constitutes 10 interventions with pictorial representation for care of mouth for patients with radiation therapy induced oral mucositis. It underwent several revisions and resulted in the pre-final draft with following sections:

- **Introduction:** This section clearly explains the patients about the purpose and utility of pamphlet.
- **Main text:** This section constitutes ten interventions with pictorial representation and written instructions on care of mouth
 - Brush your teeth after a meal and before going to bed with soft tooth brush / 4 times a day
 - Remove the dentures when you are at rest
 - Rinse your mouth with Sodium bicarbonate water or with salt water after meal and before going to bed / twice a day.
 - Apply coconut oil to lips if dry or cracked.
 - Avoid smoking cigarettes and consumption of alcohol.
 - Avoid taking drinks and foods when it is hot
 - Avoid spicy foods.
 - Don't floss in case of bleeding.
 - Drink at least 8 - 10 glasses of water / fruit juices daily.
 - Avoid caffeinated beverages as caffeine induce oral dryness.

Assessment of Content Validity: This pre-final draft was sent for content validity. The tool used for the study were validated by experts in the field of Nursing and radiation oncology. It was a two-stage process requiring validation in the developmental and judgment-quantification stages. During the developmental stage, a panel of four validated the accuracy of information presented and ability to comprehend according to patients' point of view.

Judgment-quantification stage of content validation involved validation of both the content of the items and the pictures.). Rating scale (structured questionnaires') were sent to 15 health care professionals. The panel of experts were having the relevant training,

experience and qualification for this validation. Experts were selected from different fields to make the pamphlet more user friendly. The panel received specific instructions to determine the content relevance of specific items and of the pamphlet as a whole. Validation was done through a questionnaire consisting of 10 items pertaining to appropriateness, relevant, comprehensive, easily understandable and applicable of pamphlet for patients. Questionnaire was sent through WhatsApp to 15 health care professionals (doctors -5, dentists -5, nursing (3 nurses and 2 faculties), along with a covering letter stating the purpose of this pamphlet, the reason why they have been chosen for validation and the importance of their participation in validating the pamphlet. Scoring was based on 3-point Likert scale. Results were quantified by applying the scale Content Validity Index (CVI).

The standard procedure for Translation & parallel back translation was followed for translation into local language to enhance its utility and acceptability by local population. After completing the content validity, this pamphlet was translated into local language (Tamil) by two independent persons with fluency in both the languages i.e., Tamil and English. Both the versions were discussed with the involvement of third person with bilingual expertise to resolve any identified discrepancies or ambiguity of words. After reaching the final consensus, one single version was prepared. This final copy was sent to another person who was completely blinded for the study to translate it back to English (original language.)

Data Analysis

The descriptive statistics and scale cumulative validity index was used to validate pamphlet and interpret the data.

Results

Table-1 Frequency and percentage distribution of background variables among experts

s.no.	Demographic variables	Frequency (N)	Percentage(%)
1.	Age		
	21-30	1	6.67
	31-40	6	40
	41-50	6	40
	>50	2	13.3
2.	Gender		
	Male	4	26.67
	Female	11	73.3

3.	Educational status Under Graduate	3	20
	Post Graduate	7	46.67
	Ph.D. and above	5	33.3
4.	Speciality Nursing	5	33.3
	Dentistry	5	33.3
	Physician	5	33.3
5.	Years of experiences 1-5	0	0
	5-10	6	40
	>10	9	60

Table 1 reveals that 1 (6.67) belonged to 21-30 years, 6(40%) belonged to 31-40 years, 6(40%) belonged to 41-50years and 2(13.3%) belonged to >50 years. With regard to gender 4(26.67%) were male and 11(73.3%) were female. With regard to educational status 3(20%) were UG's ,7(46.67%) were PG's, 5(33.3%) were Ph.D. With regard to speciality 5(33.3%) were from nursing, 5(33.3%) were from dentistry, 5(33.3%) were physicians and in relation to years of experience 6(40%) had 5-10years, 9(60%) had >10 years.

Fifteen responses were collected and analysed. The number of experts required to validate were arbitrary, depending upon the requirement of the educational content, its scope and area of utility and convenience to get a response. Five physicians, five dentists and five nurses studied the pamphlet and rated the items in the questionnaire. Experts included for validation had a minimum experience of 6 years. With regard to gender maximum were females. With regard to educational status maximum were PG's. With regard to speciality it was equally distributed [table-1].

Table-2 Scale cumulative validity index(S-CVI) of the pamphlet

S.NO	Questions	Cumulative validity index (S-cvi)
1.	The pamphlet was easy to read for patients	1
2.	The pamphlet was appropriate in size	1
3.	The content covered presents relevant information on care of mouth	1

4.	Texts seem clear and comprehensive	0.93
5.	Texts motivate the patients to understand care of mouth	1
6.	The pamphlet was appropriate for the target audience	1
7.	The pamphlet can be given to the patients	0.93
8.	The pamphlet was easy to understand	0.93
9.	This pamphlet can be used in everyday clinical practice	0.93
10.	The information in the pamphlet would answer patient's questions about care of mouth	0.93
	Scale content validity index (s- ccvi) = average of I- ci	9.65/10 = 0.96

Table 2 shows that fifteen responses were collected and analysed. The number of experts required to validate were by arbitrary, depending upon the requirement of the educational content, its scope and area of utility and convenience to get a response. Five physicians, five dentists and five nurses studied the pamphlet and rated the items in the questionnaire. Experts included for validation had a minimum experience of 3 years with a maximum ranging to 15-20 years in oncology. Five items were completely agreed by all validators (Q1, Q2, Q3, Q5, Q6), whereas remaining five questions were agreed by about 93% of them (Q4, Q7, Q8, Q9, Q10). Five questions (Q4, Q7, Q8, Q9, Q10) showed a mild disagreement 7% among the validators. Item level content validity index (I-CVI) was calculated for individual items which ranged from 0.7 - 1 and Scale level content validity (S-CVI) was calculated for complete ten items and it was found to be 0.96. SCVI should be minimum 0.80 to be acceptable as content valid [12,13]. S-CVI was found to be >0.80 thus the content of educational pamphlet is acceptable.

Validators expressed their views in reducing brushing frequency to twice a day and to eliminate sodium bicarbonate usage in oral care as it can irritate oral mucosa even more when more concentrated. These suggestions were incorporated to highlight in the consensus with the subject experts in the final version of the educational pamphlet.

Discussions

The objective of the present study was to develop and validate an educational pamphlet for oral care. Literature has reported that educating patients and providing them with structured written information pamphlet can enhance the probability that important information will be better attended to, understood, accepted and recalled. Thus, the present study was designed

with the purpose to educate the caregivers about home program for early intervention services and encourage their active participation in promoting better development of their child.

The present study involved validators from different specialties and while selecting the panel of experts their qualification, training, experience, publication, presentations and research interests were taken into consideration. This was done in consensus with American Psychological Association guidelines which emphasize that these aspects should be considered to make the material more authenticated and operational for target population . Content validity score shows >0.80 . 6 items scored 100%, only 4 items scored 0.96%. 93% of validators said content is valid & 7% expressed few suggestions to modify the final version of pamphlet. The validation of pamphlet shows that in this stage, a panel of experts validated the accuracy of information presented and ability to comprehend according to patients' point of view. Instrument (structured questionnaires') were sent to 15 health care professionals. Validation was done through a questionnaire consisting of 10 items pertaining to appropriateness, relevant, comprehensive, easily understandable and applicable of pamphlet for patients. Scoring was based on 3-point Likert scale. Results were quantified by applying the scale Content Validity Index (CVI).

Validators expressed their views in reducing brushing frequency to twice a day and to eliminate sodium bicarbonate usage in oral care as it can irritate oral mucosa even more when more concentrated. These suggestions were incorporated to highlight in the consensus with the subject experts in the final version of the educational pamphlet. The present study involved validators from different specialties (Doctors, Dentists, Nursing (3 nurses and 2 faculties) and while selecting the panel of experts their qualification, training, experience, publication, presentations and research interests were taken into consideration. This was done in consensus

with American Psychological Association guidelines which emphasize that these aspects should be considered to make the material more authenticated and operational for target population. The SCVI should 1 for 5 items out of 10 item and remaining 5 items showed that >9 . This item interviewed the validators regarding care of mouth for patients with radiation therapy induced oral mucositis. Mucositis lesions can be painful, affect nutrition and quality of life, and have a significant economic impact. The pathogenesis of oral mucositis is multifactorial and complex. Current clinical management of oral mucositis is largely focused

on palliative measures such as pain management, nutritional support and maintenance of good oral hygiene. However, several promising therapeutic agents are in various stages of clinical development for the management of oral mucositis.

Evidence-based management of oral mucositis can significantly improve the patient's quality of life and facilitate adherence to recommended cancer therapy regimens. Complications arising from chemotherapy must be managed in the most effective fashion. The patient should be regularly checked by their dentist, especially in the first few months. Extractions and other invasive procedures should be avoided for at least 1 year. Maximum number of validators found that it was adequate and expressed their views to add a section on the expected information regarding care of mouth for patients with radiation therapy induced oral mucositis. The pamphlet conveys information in a simple language regarding the importance of care of mouth for patients with radiation therapy induced oral mucositis. The above results supported Conducted preliminary survey conducted among 158 staff nurses showed that 81 (51.3%) of the staff nurses had poor knowledge regarding oral care of cancer patients and majority 128 (81.0%) of them suggested for training in the specific area of oral care of cancer patients. Mucositis lesions can be painful, affect nutrition and quality of life, and have a significant economic impact. The pathogenesis of oral mucositis is multifactorial and complex. Current clinical management of oral mucositis is largely focused on palliative measures such as pain management, nutritional support and maintenance of good oral hygiene. However, several promising therapeutic agents are in various stages of clinical development for the management of oral mucositis.

Majority of the previous studies which have shown that providing patients with well-designed information pamphlet improves patients' acceptance and satisfaction. The educational pamphlet we made it very clear to the patients care of mouth that handout is an adjunct which contains simplified information. 7% of validators expressed their suggestions that were included in the final version of pamphlet. Written information with pictorial representation improves the comprehension, recall and adherence of health education information, especially patients with low literacy skills, as it helps them to understand the abstract information in a much easier way. Thus, considering the above recommendations we have developed this educational pamphlet, it will be a good tool to improve quality of life of radiation induced cancer therapy. Moreover, the availability of pamphlet in local language will further enhance its opportunity to reach to grass root level. Development of pamphlet shows that an initial content of the pamphlet was generated through in-depth literature

review. Literature review revealed a necessity of pamphlet for patients to enhance the Information regarding care of mouth and how to promote optimum life. (24)

Discussions were carried out with the experts and a thorough analysis of each and every point were done to identify what is expected for a pictorial representation. It underwent several revisions and resulted in the pre-final draft. This section constitutes 10 interventions with pictorial representation for care of mouth for patients with radiation therapy induced oral mucositis. This is in line with the previous studies which have shown that providing patients with well-designed information pamphlet improves patients' acceptance and satisfaction. In our educational pamphlet we made it very clear to the patients that educational handout is an adjunct which contains simplified information. Pamphlet is not a substitute for treatment should not pass it on to others by themselves. This is in consensus with the previous studies which states that pamphlet is not all inclusive, they are supplement guides and should be properly discussed with patients to ensure that they have understood its complete purpose. Present study is a part of ongoing study. Future research will be done to assess the efficacy of this educational handout on improving the adherence on creating awareness of care of mouth for radiation induced chemotherapy patients.

Conclusion

The results presented in this study give an insight into the effects of educational pamphlet in improving knowledge for patients with radiation therapy induced oral mucositis and it is validated scientifically for clinical use. This study results confirm that educational initiatives have proven to improve awareness and enhance beliefs for appropriate practice towards care of mouth . Therefore, in addition to providing clear, precise and tailored information regarding care of mouth for patients with radiation therapy induced oral mucositis will reduces the incidence of complications and recommendations for further research is that same study can be done involving target population and intervention study could be conducted using laptop assisted teaching.

Limitations and Future Studies

Pamphlet was validated from Indian experts only. In future intervention study could be conducted using this pamphlet

Acknowledgement: We thank our research team members and experts for validating pamphlets

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