

A Comparative Study to Assess the Effectiveness of Turmeric Mouth Wash versus Saline Mouth Wash on Treatment Induced Oral Mucositis (TIOM) in a Selected Hospital at Mangalore

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Abstract

Oral mucositis is the most common, debilitating complication of cancer treatments. Chemotherapy and/or radiation therapy will interfere with the normal turnover of epithelial cells leading to mucosal injury. The care of these patients includes the regular use of an effective mouth wash periodically. The active ingredient in turmeric is curcumin which protects healthy cells from harmful effects of radiation and chemotherapy. Salt mouthwash can soothe the pain and keep food particles clear so as to avoid infection. The study made use of a two group pre-test post-test time series design to determine the effectiveness of Turmeric and Saline mouth wash on TIOM. A purposive random sampling was used and mouth wash was given three times daily for 5 days. The oral mucosa of the patients was assessed using an Oral Mucositis assessment checklist and pain using pain scale every morning before the intervention and evening after the intervention. There was a significant difference in the score of TIOM between pre-intervention on Day 1 morning and post intervention score on day 5 evening in turmeric and saline group but on comparison it was found that turmeric mouth wash was effective than saline mouth in all the days except in Day 3 where there was no significant difference found. Both the mouth wash were individually effective but on comparison turmeric mouth wash was better than saline mouth wash.

Keywords: Effectiveness; Turmeric; Normal saline; Oral mucositis; Mouth wash; Salt

Introduction

Mucositis is the painful inflammation and ulceration of the mucous membrane, usually as an adverse effect of chemotherapy and radiotherapy treatment for cancer. Chemotherapy-induced oral mucositis causes the mucosal lining of the mouth to atrophy and break down forming ulcers and affects almost all patients undergoing high-dose chemotherapy. Radiotherapy to the head and neck or to the pelvis or abdomen is associated with the occurrence of oral mucositis, often exceeding 50% of patients. Among patients undergoing head and neck radiotherapy, pain and decreased oral function may persist long after the conclusion of therapy. Fractionated radiation dosage increases the risk of mucositis to >70% of patients in most trials [1-20].

A study was conducted in the department of Dental Medicine, Winthrop university hospital New York, and it stated that, the oral mucosa is a common site for collateral damage of cancer therapies, including radiation, cytotoxic medication, and newer targeted therapies. Ulcerative oral mucositis is typically painful and affects oral functions including speech, and oral intake of food and medications, thus impacting the quality of life. Prevention of oral mucositis is an ongoing quest currently with relatively few answers. Oral mucositis not only has a dramatic impact on the patient's quality of life, but it also can adversely influence the administration of an optimal anti-neoplastic treatment.

Turmeric is one of nature's most powerful healers. Turmeric has been used for over 2500 years in India. Research conducted at the University of Michigan, by Ayyalusamy Ramamurthy in 2009, showed that curcumin in turmeric helps regulate cells by inserting itself into the cell membranes and interfering with molecular pathways that lead to cancer development and spread. This causes the cells to become less susceptible to infection and even to cancer. Salt mouthwash can soothe the pain and keep food particles clear so as to avoid infection [3]. Normal saline (0.9%) is a not irritant and is believed to help in formation of granulation tissue and to promote healing. It's safe, economical and readily available mouthwash. Salt water mouthwash rinses are considered an excellent treatment when we have wounds in the mouth. The reason is that salt water is not only a natural disinfectant but it also removes any swelling from the tissue. Giving a mouth wash to the patients with a medicinal property like those of turmeric or normal saline can prove very economical and beneficial for the patient in terms of cure and relieve from symptoms and also in regards to its use in the future and preventing complications [21-28].

Materials and Methods

Prior permission was obtained from the ethical committee of the Institutional Research Board (IRB). In order to accomplish the main objectives of determining the effectiveness of turmeric or saline mouth wash on treatment induced oral mucositis among patients with cancer undergoing treatment an evaluative research approach was adopted. The research design used in this study was Repeated Measures two group Pre-test Post-test time series design. This study was conducted at Father Muller Medical College Hospital, which is a super speciality

hospital with 1250 beds with 100 beds for oncology patients. The present study was conducted in oncology wards of this hospital. A purposive sampling technique was used. The subjects for this study consisted of 40 patients, 20 in experimental group I receiving Turmeric mouth wash (Mouth wash solution prepared by mixing 1.5 gms of turmeric powder with 50 ml of water. Each time a 50ml of freshly prepared turmeric mouth wash solution will be administered) and 20 in Group II receiving saline mouth wash (It refers to 0.9 gm of salt in 100 ml of water which contains sodium 150 mmol/litre and chloride 150 mmol/litre. It is a readily available normal saline concentration which is available for IV therapy in hospital use). In this study baseline proforma was used to collect the baseline data from the sample. A self-prepared tool for assessing the oral mucositis among cancer patient was developed according to their clinical signs and symptoms for gathering maximum data and according to the scores the patient was classified from Grade I to Grade IV. The level of pain in the patient was assessed using a standardized pain rating scale according to which the pain was classified as mild, moderate and severe. The tools were sent for validation to the experts and the necessary corrections were made. Inter rater reliability was used to find out the reliability of the tool. The correlation was computed using the inter-class correlation co-efficient. The inter rater reliability was found to be 0.89 which indicated the tool was reliable [29-33].

Results

The data was tabulated, analyzed and interpreted using the descriptive and inferential statistics. The data was analyzed using SPSS 16th version.

The mean pre-test TIOM score of group I is $X_1=25.35$ whereas in post-test it is $X_2=18.85$. The mean of pre-test TIOM score of group II is $X_1=25.05$ whereas in post-test it is $X_2=20.15$. The standard deviation of pretest TIOM score of group I and group II in pretest is 4.97 and 6.62 respectively whereas the standard deviation of post-test TIOM score of group I and group II is 4.23 and 5.86 respectively. The mean post-interventional scores in group I (post Day₅=18.85), (post Day₄=20), (post D₃=21.50), (post D₂=22.75), (post D₁=24.15) of TIOM is significantly lower than the mean pre-interventional scores (pre Day₁ =25.35). The computed value of $F(5,95)=268.05$ is significantly greater than the tabled value $F(5,95)=2.31$ which shows that Turmeric mouth wash is effective on the grade of TIOM. The mean post-interventional scores in group II (post Day₅=20.15), (post Day₄=21.10), (post D₃=21.80), (post D₂=23.25), (post D₁=24.30) of TIOM is significantly lower than the mean pre-interventional scores (pre Day₁=25.05). The computed value of $F(5,95)=144.06$ is significantly greater than the tabled value $F(5,95)=2.31$ which shows that Saline mouth wash is effective on the grade of TIOM (Tables 1-8).

Variables	Group I (Turmeric)		Group II (Saline)	
	Frequency	Percentage (%)	Frequency	Percentage (%)
1.Age in Years				
b.31-50	6	30	10	50
c.51-75	14	70	10	50
2.Gender				
a. Male	16	80	16	80

b. Female	4	20	4	20
3.Diagnosis on Admission				
a. Ca head and Neck	18	90	16	80
b. Others	2	10	4	20
4.Any Associated Disease				
a. Yes	0	0	3	15
b. No	20	100	17	85
5.Treatment Modality				
a. Chemotherapy	1	5	3	15
b. Radiation therapy	3	15	1	5
c. Chemotherapy and Radiation therapy	16	80	16	80

Table 1: Frequency and Percentage Distribution of Subjects According to their Baseline Characteristics.

	Group I(Turmeric)				Group II(Saline)			
	Pre test		Post test		Pre test		Post test	
TIOM	f	%	f	%	f	%	f	%
Score								
11-15	2	10	4	20	2	10	5	25
16-20	2	10	12	60	2	10	4	20
21-25	4	20	3	15	4	20	9	45
26-30	10	50	1	5	10	50	2	10
31-35	2	10	0	0	2	10	0	0

Table 2: Distribution of Subjects According to the TIOM Scores Obtained in Group I and Group II.

		Group I(Turmeric)		Group II(Saline)					
		Pre test	Post test	Pre test	Post test				
TIOM Scores	Grades	f	%	f	%	f	%	f	%
15-Jan	Grade I	2	10	4	20	4	20	5	25
16-30	Grade II	15	75	16	80	13	65	15	75
31-45	Grade III	3	15	0	0	3	15	0	0

Table 3: Distribution of Subjects According to the Grade of TIOM in Group I and Group II.

Groups	Range		Mean		Standard Deviation	
	Pre test	Post test	Pre test	Post test	Pre test	Post test

Group I	19	16	25.35	18.85	4.97	4.23
Group II	21	19	25.05	20.15	6.62	5.86
Maximum scores: 60						

Table 4: Range, Mean and Standard Deviation of pre-test and post-test TIOM Score.

Group	Minimum Score	Maximum Score	Mean	Standard deviation	t-value	p-value
Turmeric	14	33	25.35	4.97	0.16	0.87
Normal saline	13	34	25.05	6.62		
t (38)=2.02, p<0.05						

Table 5: Significant difference between the Pre-interventional TIOM score in Group I and Group II.

Day	Mean	Standard Deviation	Anova value	F-	p-value
Pre D ₁	25.35	4.97	268.05*		p <0.001
Post D ₁	24.15	4.68			
Post D ₂	22.75	4.71			
Post D ₃	21.5	4.36			
Post D ₄	20	4.46			
Post D ₅	18.85	4.23			
F (5,95)=2.31, p<0.05, *=significant					

Table 6: Effectiveness of Turmeric Mouth Wash on the Grade of TIOM on Day 1 Morning and Day 1 to Day 5 Evening.

Turmeric group(Group I)					
Day	Mean Difference	Standard Deviation	t-value		p-value
Post D ₁ -Post D ₂	1.4	0.75	8.30*		p<0.001
Post D ₁ -Post D ₃	2.65	0.93	12.70*		p<0.001
Post D ₁ - Post D ₄	4.15	0.93	19.89*		p<0.001
Post D ₁ - Post D ₅	5.3	1.08	21.93*		p<0.001
Post D ₂ - Post D ₃	1.25	0.55	10.16*		p<0.001
Post D ₂ - Post D ₄	2.75	0.71	17.17*		p<0.001
Post D ₂ -Post D ₅	3.9	0.97	18.02*		p<0.001
Post D ₃ - Post D ₄	1.5	0.61	11.05*		p<0.001
Post D ₃ - Post D ₅	2.65	0.81	14.58*		p<0.001

Post D ₄ - Post D ₅	1.15	0.67	7.67*	p<0.001
t ₁₉ =2.093, p<0.05, *=significant				

Table 7: Significant Difference in the Mean Post-interventional TIOM scores from Day 1 to Day 5 in group I.

Day	Time of the day	Mean	t' value	p value	Inference
1	Morning pre-intervention	25.35	20.31	p<0.001	Significant
5	Evening post-intervention	18.85			
t ₁₉ =2.093, p>0.05					

Table 8: Significant difference between the mean pre-interventional TIOM score on Day 1 and the mean post interventional TIOM score on Day 5.

Discussion

In the present study, majority of the subjects 18 (90%) in group I and 16 (80%) in group II had cancer of head and neck whereas 2 (10%) in group I and 4 (20%) in group II had cancer of other origin. The study findings are in accordance with the findings of a study conducted in USA to characterize the risks and clinical consequences of oral mucositis (OM) in patients with Head and Neck Carcinoma (HNC) which showed that primary tumor locations included the oropharynx (26.4%), larynx (26.4%), oral cavity including the lip (24.4%), hypo pharynx (13.6%), and nasopharynx (9.1%). In the present study, turmeric mouth wash was given to 20 subjects in group I three times a day and pre and post assessment was done on all the 5 days of intervention it was found to be significantly effective on all the 5 days with the reduction in mean (\bar{X} =25.35) on Day 1 to (\bar{X} =18.85) post day 5 and the calculated F value (268.05) was significantly greater than the tabled value (2.305) indicating its effectiveness at all time points. These findings are in accordance with the findings of an investigational study which was conducted to evaluate the efficacy of turmeric in preventing radiation induced oral mucositis in patients receiving head and neck cancer which showed that when compared with the cohorts using povidone-iodine gargle, the group using turmeric as a mouth wash had delayed and reduced the levels of radiation-induced oral mucositis and was statistically significant at all time points (:<0.001 to :<0.0001). Additionally, the cohorts using turmeric had decreased intolerable mucositis (:<0.001) and lesser incidence of treatment breaks in the first half of the treatment schedule before 4 weeks (:<0.01) and reduced change in body weight (:<0.001). Gargling with turmeric by head and neck cancer patients undergoing radiation therapy provided significant benefit by delaying and reducing the severity of mucositis. In the present study paired t-test was computed at a level of 0.05 significance between pre-intervention on day 1 and post-intervention day 5 and found that the calculated t value (t=17.81) was significantly greater than the tabled value (t=2.093) indicating turmeric mouth wash is effective on TIOM. These findings were in accordance with the finding of a study conducted in the department of Dermatology at University of Rochester, USA where t test showed that curcumin reduced RDS at end of treatment compared to placebo (mean RDS=2.6 vs. 3.4; P=0.008) (Tables 9-12).

Day	Mean	Standard Deviation	Anova F	p value
Pre D1	25.05	6.62	144.06*	p <0.001
Post D1	24.3	6.36		
Post D2	23.25	6.31		
Post D3	21.8	6.21		
Post D4	21.1	6.04		
Post D5	20.15	5.86		

F (5,95)=2.31, p>0.05, *=significant

Table 9: Effectiveness of Saline Mouth Wash on the Grade of TIOM on Day 1 Morning and Day 1 to Day 5 Evening.

Saline group (Group II)				
Day	Mean difference	Standard Deviation Difference	't' value	'p' value
Post D1- Post D2	1.05	1.05	4.47*	p<0.001
Post D1- Post D3	2.5	1	11.18*	p<0.001
Post D1- Post D4	3.2	1.056	13.55*	p<0.001
Post D1- Post D5	4.15	1.186	15.70*	p<0.001
Post D2- Post D3	1.45	0.686	9.45*	p<0.001
Post D2- Post D4	2.15	0.875	10.99*	p<0.001
Post D2- Post D5	3.1	0.912	15.20*	p<0.001
Post D3- Post D4	0.7	0.571	5.48*	p<0.001
Post D3- Post D5	1.65	0.671	11.00*	p<0.001
Post D4- Post D5	0.95	0.394	10.78*	p<0.001

t₁₉=2.093, p>0.05, *=significant

Table 10: Significant Difference in the Mean Post-interventional TIOM scores from Day 1 to Day 5 in group II.

Day	Time of the day	Mean	't' value	p-value	Inference
1	Morning pre-intervention	25.05	17.81	p<0.001	Significant
5	Evening post-intervention	20.15			

t₁₉= 2.093, p<0.05

Table 11: Significant difference between the mean pre-intervention Day 1 TIOM score and the mean post intervention Day 5 TIOM score.

Day	Group	Mean difference	Standard Deviation Difference	Mean %	't' value	p-value
Pre D1 -post D1	Turmeric	1.2	0.616	4.73	2.27*	0.029

Pre D1 -post D1	Normal saline	0.75	0.639	2.99		
Pre D1 -post D2	Turmeric	2.6	1.142	10.26	2.05*	0.048
Pre D1 -post D2	Normal saline	1.8	1.322	7.19		
Pre D1 -post D3	Turmeric	3.85	1.309	15.19	1.46	0.153
Pre D1 -post D3	Normal saline	3.25	1.293	12.97		
Pre D1 -post D4	Turmeric	5.35	1.226	21.1	3.54*	0.001
Pre D1 -post D4	Normal Saline	3.95	1.276	15.77		
Pre D1 -post D5	Turmeric	6.5	1.433	25.64	3.51*	0.001
Pre D1 -post D5	Normal saline	4.9	1.447	19.56		

t₃₈ =2.02, p<0.05, *=Significant

Table 12: Comparison of the Effectiveness of Turmeric Mouth Wash and Normal Saline Mouth Wash on the Grade of TIOM among the patient with cancer.

Nursing Implications

The curriculum of nursing can incorporate the planning, development and implementation of complimentary therapies so that the students become aware of these therapies and help the patients for their speedy recovery and prevent chances of life threatening complications.

Recommendations

Keeping in view the findings of the study the following recommendations were made:

The study can be replicated on a larger sample to have generalization.

A similar study can be conducted in different settings and results can be compared.

The effectiveness of turmeric mouth wash can be compared with other complimentary treatment modality.

A similar study could be done with a control group.

The effectiveness of turmeric or saline mouth wash could be compared with either Soda bicarbonate or Betadine mouth wash which is the protocol followed in most of the hospitals for treating TIOM. The effectiveness of turmeric could be found out on other oral conditions [34-45].

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