International Journal of Scientific Engineering and Research (IJSER)
ISSN (Online): 2347-3878
Index Copernicus Value (2015): 62.86 | Impact Factor (2015): 3.791

The Effectiveness of Baking Soda as Mouth Wash in Reducing Oral Mucositis among Pemphigus Vulgaris Patients

Jacob A. R.[1], George R. E.[2], Venkataraman .M[3], George L.[4], Kumar .A .S[5]

[1]Professor, College of Nursing, CMC, Vellore, India

[2]Professor, Dermatology Department, CMC, Vellore, India

[3]Asst. Professor, Dermatology Department, CMC, Vellore, India

[4]Asst. Professor, Dermatology Department, CMC, Vellore, India

[5]Professor, College of Nursing, CMC, Vellore, India

Abstract: ***Pemphigus Vulgaris is a chronic autoimmune intraepithelial blistering disease. Usually affects the oral mucous in 80% of cases leading to significant decrease in patient's daily functioning of oral cavity and quality of life. This is because of the bad odour, tastelessness, difficulty or inability to eat, drink or speak. Objectives of the study is to assess the pre-interventional level of oral mucositis, to assess the effectiveness of baking soda as mouth wash in reducing oral mucositis and to find out the association between the post-interventional level of oral mucositis with the selected demographic variables among pemphigus vulgaris patients. Methods: This study adopted a Randomized control trial and was conducted in the Dermatology OPD and the Dermatology ward of Christian Medical College, Vellore. A sample of sixty four subjects were selected for the study using purposive sampling technique. Effectiveness of Baking soda as mouth was in reducing oral mucositis was assessed using Saraswat's oral Pemphigus score, by the research assistant blinded to group assignment on 1st and 7th day. Descriptive and inferential statistics was used for data analysis. Results:No evidence to conclude that baking soda mouth wash is effective than normal saline in reducing oral mucositis among pemphigus vulgaris. There is no association (p=0.68) between the post interventional oral mucositis and the selected demographic variables. Conclusion: Dermatology nurses should recognize the need for assessment of oral mucositis on a daily basis and provide the most appropriate and cost effective interventions. These interventions could be prepared in simple way at home for their long term use, in alleviating the pain and discomfort, by providing meticulous mouth wash for patients with Pemphigus Vulgaris.***

Keywords: Pemphigus vulgaris, Oral mucositis, Baking soda mouth wash, Normal saline mouth wash,sodium bicarbonate

1. Introduction

Pemphigus is a group of autoimmune blistering disorders. Pemphigus affects 0.1-0.5 patients per 1,00,000 population per year. Pemphigus vulgaris (PV) is the most common and main variant among pemphigus that affects the mouth.50-90% of patients has oral lesions as the first manifestation in this disease(Ruoco, Dagistan, Ariyawardana, Shamim, Camacho, Ben Lagha, Mihai). The highest incidence in 5th and 6th decade of life with the ratio of 1:2 for male to female. Increase of cases from 0.5 to 3.2 cases of every year per 100,000 population.(Shamim).

However there is a major difference in the prevalence of oral lesions in the areas like 66% in Bulgaria, 83% in Italia and 92% in Israel(Black).The response of cutaneous lesions are much higher in comparison with the oral lesion which is now a great challenge(Bystryn). The clinical consequence of oral mucositis is multifaceted. This is the most serious painful and detrimental condition leading to significant decrease in their daily oral functioning and quality of life because of the bad odour, tastelessness, difficulty or inability to eat, drink, swallow or speak. Poor oral care result in oropharyngeal colonization . Mouthwashes can control the oral lesions in patients with low titres of circulating antibodies. The chemical name of baking soda is "sodium bicarbonate". It is a natural buffer that maintains a healthy pH in mouth to promote a clean and fresh oral environment also neutralizes the production of acid in the mouth by acting as an antiseptic to help prevent infections.

Objectives of the study

1) To assess the pre-interventional level of oral mucositis among pemphigus vulgaris patients in the experimental group and control group.
2) To assess the effectiveness of baking soda as mouthwash in reducing oral mucositis among pemphigus patients.
3) To find out the association between the post interventional level of mucositis with the selected demographic variables among pemphigus vulgaris patients.

2. Materials and Methods

The present study was a double blind, randomized control trial. After the approval of the study protocol by the institutional Review Board and Ethical committee, Christian Medical College (CMC), Vellore. Official permission to conduct the study was obtained from the department of Dermatology, Christian Medical College, Vellore. The study was carried out according to the Declaration of Helsinki for biomedical research involving human rights.

Sixty four Pemphigus vulgaris patients with oral mucositis were enrolled in the present study and randomly assigned to the experimental and control groups. The inclusion criteria were as follows:eighteen years and above, can read and comprehend tamil, english and hindi, admitted in the ward after pretest and education for further management and give consent to participate in the study. The exclusion criteria were as follows: subjects who are with cognitive, hearing and speech disabilities, are with serious illness and unable to follow the instructions and are unwilling to comply with the study protocol, mode of administration and duration of treatment. The mouthwash assessed were experimental group-baking soda mouthwash and control group –normal saline mouthwash.

Identical colour with an acceptable taste and alcohol free mouthwashes were prepared at CMC pharmacy, Vellore.The mouthwashes were numbered randomly from 1-64 by the mouthwash manufacturer (dispensing wing, CMC, pharmacy, vellore, India). Computer generated permuted block randomization was done by biostatistian and the coding was done by the manufacturer and was known only to him. It was revealed to the investigator only at the end of the study. The dermatologists and patients were unaware of the treatment modality during the course of the study.

Mouthwashes were dispended in identical 500 ml coded plastic bottles with 350 ml of respective mouthwash solution and a measuring cup was given to take 100 ml of solution at a time after the meals. A patient assigned a particular number was given the mouthwash bottles with the same number. Each patient was given 7 bottles with the same numbered mouthwash on the first visit to OPD, to use it at home for 7 days. The patients were instructed to rinse their mouth and throat with 100 ml of the given mouthwash, thrice a day for a period of 7 days. They were asked to swish the mouth for about 1 minute and to expectorate. They were asked to do after each meals and to abstain from eating for half-an-hour after mouthwash.

Patient compliance was assessed on the 7th day of their visit to dermatology OPD by checking the level of mouthwash left in the bottles. Oral mucositis was assessed at baseline on 1st day and reassessed on the 7th day by research assistant (dermatology OPD staff nurse trained by the investigator) using Saraswat's oral pemphigus score. A single research assistant had carried out the assessments to reduce inter-rater variability.

3. Statistical Analysis

The results were analyzed using SPSS for windows version 17. The primary endpoint of the study was at the end of the 7th day. The present study was designed to have a power of 80% and alpha level of significance was fixed to 0.05. Chi square test was not used because there was no normal distribution of sample. So Mann-Whitney test was used.

4. Results

Of the total 80 patients who reported to Dermatology OPD, CMC, vellore, India during July 2016 to July 2017 for Pemphigus vulgaris, 64 patients who fulfilled the inclusion/exclusion criteria, participated in this study and were randomly allocated into one of this groups. Among them four patients dropped out during the study and all the other 60 patients who completed the study complied with the instructions given to them.

Table 1: Shows the distribution of subjects according to the demographic variables

S. No.	Demographic variables	Normal Saline(control)		Sodium Bicarbanate – Baking soda(experimental)		Total	
		F	%	F	%	F	%
1	**Age**						
	G-1 (18-40)	13	40.6	16	50	29	45.30
	G-2 (41 - 63)	14	43.8	13	40.6	27	42.20
	G-3 (>63)	5	15.6	3	9.4	8	12.50
2	**Gender**						
	Male	12	18.75	14	21.88	32	50.00
	Female	20	31.25	18	28.13	32	50.00
3	**Religion**						
	Hindu	23	35.94	26	40.63	77	49.00
	Christian	4	6.25	2	3.13	9	6.00
	Muslim	5	15.6	4	12.5	14	9.00
4	**Marital Status**						
	Unmarried	5	7.81	3	4.69	8	12.50
	Married	27	42.19	28	43.75	55	85.90
	Widow/Widower	0	0	1	1.56	1	1.60
5	**Education**						
	Illiterate	3	4.69	2	3.13	5	7.80
	Elementary	2	3.13	6	9.38	8	12.50
	Primary	9	14.06	11	17.19	20	31.20
	Secondary	11	17.19	6	9.38	17	26.60
	Collegiate	7	10.94	7	10.94	14	21.90
6	**Occupation**						
	Employed	8	25	9	28.1	17	26.60
	Uenemployed	24	75	23	71.9	47	73.40
7	**Monthly Income**						
	<5000	16	50	18	56.2	34	53.10

	5001-10000	6	18.8	6	18.8	12	18.80
	10001-20000	5	15.6	3	9.4	8	12.50
	20001-30000	5	15.6	3	9.4	8	12.50
	>30001	0	0	2	6.2	2	3.10
8	**Location**						
	Urban	7	10.94	5	7.81	12	18.80
	Rural	25	39.06	27	42.19	52	81.20
9	**Family**						
	Joint	15	49.9	16	50	31	48.40
	Nuclear	17	53.1	16	50	33	51.60

Table I:

Distribution of subjects according to the demographic variables N=64

With regard to the age, majority of the participants 16 (50%) in the experimental group are in the age group of 18-40 years. In the control group female were 20 (31.25%). Regarding religion most of the participants were Hindus 26 (40.63%)in the experimental group. In the aspect of marital status, majority of the participants in the experimental group was married 28 (43.75%). In the control group 11 (17.19%) studied secondary level. In the control group 24 (75%) were unemployed. In the control group 16 (50%) were having the family income less than 5000.

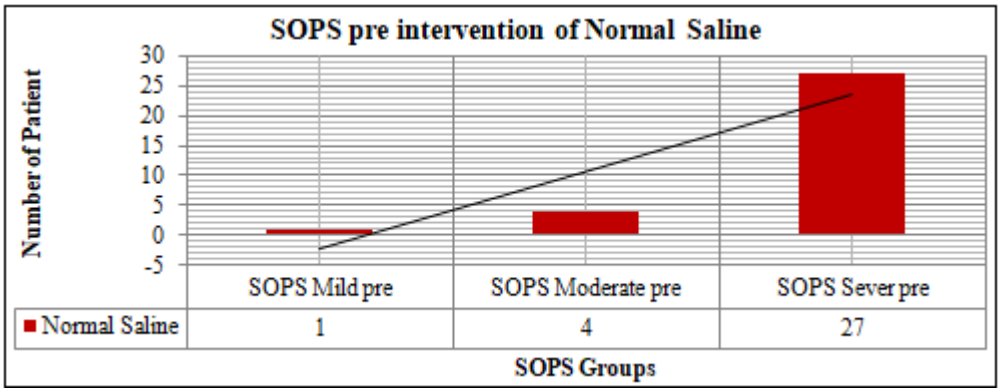

Figure 1: shows the distribution of subjects according to the pre interventional level of oral mucositis in the control group (Normal saline)

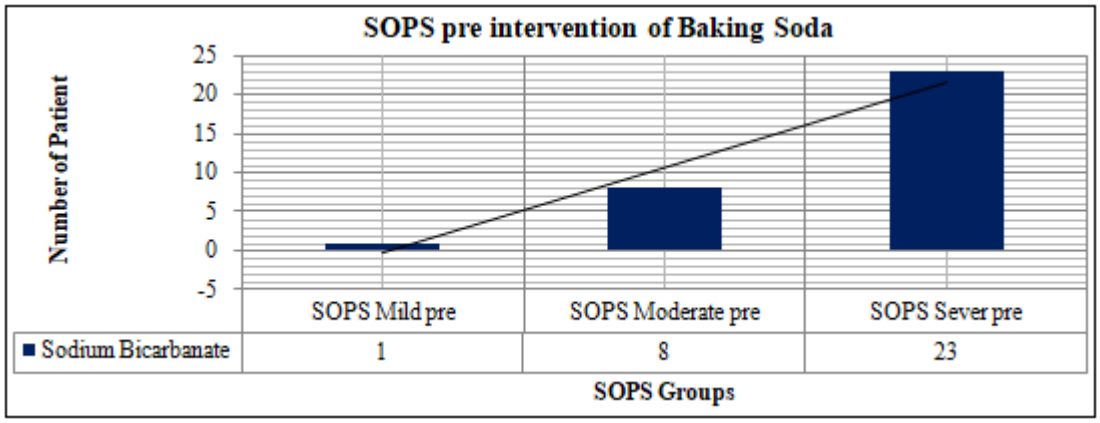

Figure 2: Shows the distribution of subjects according to the pre-interventional level of oral mucositis in the experimental group (baking soda)

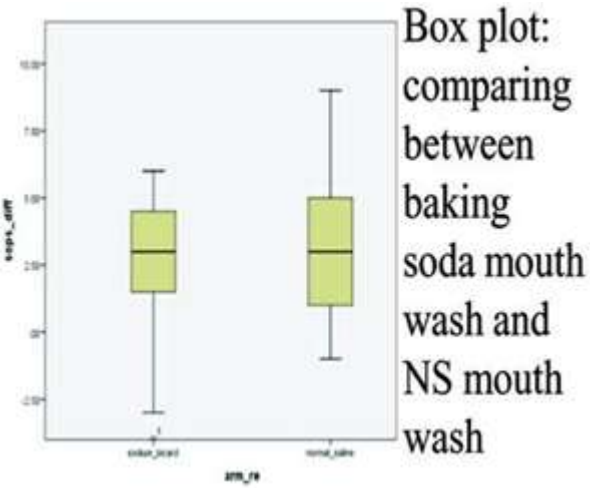

Figure 3: Shows the effectiveness of baking soda in reducing oral mucositis among pemphigus patients

No evidence to conclude that baking soda mouth wash is effective than normal saline in reducing oral mucositis among pemphigus vulgaris.

There is no association between the post-interventional level of oral mucositis and the selected demographic variables.

5. Discussion

The management of oral mucositis is with oral hygiene, adequate hydration and controlling pain. Using proper mouth wash oral mucositis can be prevented. Adherence to soft diet till the lesions heal. Teeth should be checked after the mouth washes. Pharmacists modify the compound preparations for patient better compliance. Thus the investigator was intended to study the effectiveness of baking soda with normal saline. Sodium bicarbonate (baking soda) provides deodoring, buffering activities, clean and refreshing effect and neutralizes the production of acid in the mouth. It also has an antiseptic to prevent infections. This mouth wash can be prepared at home. Recommendations is to dissolve ½ teaspoon of sodium bicarbonate or baking soda in 250 ml of water . No side effects were recorded in either of the groups. To our knowledge the comparison of use of baking soda and normal saline in pemphigus vulgaris patients with oral mucositis has not been reported much in the literature.

6. Conclusion

Based on the findings appropriate recommendations were made. Dermatology nurses will be able to recognize the need for assessment of oral mucositis on a daily basis and provide most appropriate and cost effective interventions that could be prepared in simple way at home for their long term use in alleviating the pain and discomfort by providing alcohol free mouth wash for patients with pemphigus vulgaris.

7. Acknowledgement

The authors acknowledge the financial help received from the Christian Medical College, Vellore for this study. The authors also remember with gratitude the help rendered by the department of Dermatology during the study. The authors thank all the patients who participated in this study, without them this study would not have been possible. My thanks to Dr. Renu E. George for her support, generous help, cooperation, guidance and good wishes. The explicit and timely guidance by my mentor Mrs. Anbu S Kumar and Dr. Venkatramani.M. has been a great help in the preparation of this manuscript. CTRI/2017/09/009775

References

[1] Ruocco E Baroni, A, Wolf R, Rucocco V (2005) Life threatening bullous dermatoses: Pemphigus vulgaris.Clin Dermatology 23: 223-226.
[2] Dagistan S, Goregen M, Miloglu O, Cakur B (2008) Oral Pemphigus Vulgaris: a case report with review of the literature. J Oral Sci 50 359-362
[3] Ariyawardana A, Tilakaratne WM, Dissanayake M, Vitanaarachchi N, BasnayakeLk,Sitheequee MA, et al (2005) Oral Pemphigus Vulgaris in children and adolescents: a review of the literature and a case report. Int J Paediatric Dent 15:287-293.
[4] Shamim T, Varghese VI, Shameena PM, Sudha S (2008) Pemphigus Vulgaris in oral cavity : clinical analysis of 71 cases. Med Oral Patol Oral Cir Bucal 13: 2622-2626.
[5] Camacho-Alonso F, Lopez-Jornet P Bermejo-Fenoll A (2005) a presentation of 14 cases and review of the literature. Med Oral Patol Oral Cir Bucal 10: 282-288.
[6] Ben Lagha N, Poulesquen V, RoujeauJc, Alantar A, Maman L (2005) Pemphigus Vulgaris: a case-based update. J Can Dent Assoc 71: 667-672.
[7] Bystryn JC, Rudolph Jl (2005) Pemphigus Lancet 366: 61-73.
[8] Mihai S, Sitaru C (2007) Immunopathology and molecular diagnosis of autoimmune bullous diseases. J Cell Mol Med 11:462-481.
[9] Black M, Mignogna MD, Scully C (2005) Number II. Pemphigus Vulgaris. Oral Dis 11: 119-130