RESEARCH ARTICLE

COMPARISON EFFECTIVENESS OF HIORA SG GEL AND TRIAMCINOLONE ACETOMIDE GEL IN RECURRENT APTHOUS STOMATITIS IN AZAMGARH POPULATION

Satya Prakash Shukla[1] , Aruna Das.H[2], Rana Praween Kumar[3,] Md.Suleman Tarique khan[4], Shalu Singh[5] Sudheer Patel[6]

1. Post graduate student, Department of Oral Medicine and Radiology,Azamgarh Dental College, Azamgarh, U.P, India
2. Professor, Head & Principal, Dept Of Oral Medicine & Radiology, Dental College Azamgarh, Azamgarh,U.P.
3. Reader, Department of periodontology and Implantology, Awadh Dental College and hospital, Jamshedpur, Jharkhand.
4. Post graduate student, Department of Oral Medicine and Radiology,Azamgarh Dental College, Azamgarh, U.P, India
5. B.D.S. , City Dental Care, Gorakhpur, U.P, India
6. B.D.S., Patel dental clinic, Narsinghpur ,Madhya Pradesh, India.

ABSTRACT

This study aimed tocompare the efficacy of HiOra SG gel with triamcinolone acetonide gel in recurrent aphthous stomatitis.Objectives of this study was to assess ulcer severity on 1st, 5th and 10th day using ulcer severity score in individuals using HiOra SG gel &To assess ulcer severity on 1st, 5th and 10th day using ulcer severity score in individuals using triamcinolone acetonide gel & further compare the efficacy of HiOra SG gel and triamcinolone acetonide gel using ulcer severity scores.

Methodlogy: The patients were included in the study based on the diagnostic and inclusion criteria. Examination is done using diagnostic instruments like mouth mirror, straight probe, explorer, tweezers.The clinical findings of the patient were recorded on 1st, 5th and 10th day after examination in the specialized proforma for this study by the first observer. The medications given were wrapped to look similar and were given to the patients by a second observer for double blinding. HiOra SG gel was coded as DRUG-A and Triamcinolone acetonide gel was coded as DRUG-B.

Results: Thus the present study showed that HiOra SG gel which is a poly herbal formulation can be used effectively in the management of recurrent oral ulcers. Hence the side effects of currently available medications like topical corticosteroids can be avoided. Similar study with increased sample size can be done to validate the efficacy of HiOra SG gel.

Keywords: Recurrent Aphthous Ulcer,Triamcinolone Acetonide , HiOra SG gel

INTRODUCTION:

Recurrent Aphthous Ulcer (RAU) or Recurrent Aphthous Stomatitis (RAS) is one of the common oral disease seen among the general population.[1] According to Scully et al Stomatitis is defined as the inflammation of the oral cavity which occurs due to mechanical, chemical, thermal, bacterial, viral or radiation injury or as a secondary manifestation of any systemic disease.[2,3] Hippocrates who is known as the Father of Medicine (460 to 370 BC) was the first person to use the term “aphthai”. It can occur in all ages, races and geographic regions without gender prevalence.[4] Majority of the patients presented with recurrent aphthous stomatitis are healthy without any systemic

Corresponding Author: Dr Satya Prakash Shukla Email: **drspshukla2000@yahoo.com**

disease. Since definitive diagnosis is not possible with these patients, management of the lesion is to control the active disease locally to reduce pain and maintain function, thus reducing the frequency and severity of remissions[5]. Various treatment modalities are available which is useful in the management of recurrent aphthous stomatitis that includes topical anesthetic preparations such as benzocaine, Diclonine hydrochloride, Lidocaine with Diphenhydramine, topical as well as systemic corticosteroids, silver nitrate cauterization, antibiotics and laser therapy. Topical corticosteroids may cause side effects like cutaneous atrophy, oral candidiasis etc.[6,7] Since herbal medicines are gaining importance nowadays due to their decreased side effects, the present study was done by comparing the topical application of polyherbal formulation (HiOra SG gel) with triamcinolone acetonide 0.1% (Oraways) in managing recurrent aphthous stomatitis. The ingredients of HiOra SG gel include Glycyrrhiza glabra, Jasminum grandiflorum, Azadirachta indica, Ocimum basilicum, Boerhaavia diffusa, Syzygium aromaticum and Triphala. A very few studies have been conducted to prove the efficacy of herbal medicines in recurrent aphthous stomatitis and therefore more studies are needed to substantiate its effects. Thus the purpose of this study was to compare the effectiveness of polyherbal formulation (HiOra SG gel) with Triamcinolone acetonide 0.1% in recurrent aphthous stomatitis.

MATERIALS AND METHODS:

The present study was a randomized controlled clinical trial to compare the effectiveness of HiOra SG gel with Triamcinolone acetonide gel in recurrent aphthous stomatitis. The study was conducted in Dental College Azamgarh, Azamgarh , Uttar Pradesh. The study was carried out only after obtaining ethical clearance. The study was on 60 patients from the outpatient department section of Dental College Azamgarh. The sample size was estimated and the study consisted of 2 groups. a) Group I (HiOra SG gel Group) ,b) Group II (Triamcinolone acetonide group) each having 30 subjects .Inclusion criteria were Individuals of either gender, aged 18 years and above, Diagnosed with Recurrent aphthous stomatitis, Exclusion criteria were Allergic to any topical pharmaceutical products , With any other systemic diseases, With chronic ulcerative conditions. The patients were included in the study based on the diagnostic and inclusion criteria. Examination is done using diagnostic instruments like mouth mirror, straight probe, explorer, tweezers and William’s periodontal probe. The demographic details, detailed medical

history and dental history is taken and documented in the Patient proforma. Patient proforma is enclosed in the annexure. The clinical findings of the patient were recorded on 1st, 5th and 10th day after examination in the specialized proforma for this study by the first observer. The medications given were wrapped to look similar and were given to the patients by a second observer for double blinding. HiOra SG gel was coded as DRUG-A and Triamcinolone acetonide gel was coded as DRUG-B. Once the study was over the drug details were decoded to the first observer and investigator to prepare the master chart. Individuals were advised to take HiOra SG gel or 0.1% triamcinolone acetonide gel at the tip of the index finger and apply it over mouth ulcers 4-5 times daily after meals for a period of 10 days. The clinical findings were evaluated as per Ulcer Severity Score and were recorded in patient proforma. No other topical or systemic medications were administered during the period of the study. Skin examination was also done locally during each visit. Patients were permitted to withdraw from the study at any point when they needed. Ulcer severity score was calculated According to Tappuni et al ulcer severity score .[9.] Pain duration: Score = Total No of days of pain reported by the patient on 1st follow up and 2nd follow up , Pain duration score= 1 for each day; with Max Score=5. The severity of the ulcers was examined on 5th and 10th days and assessments were documented on the patient proforma. Also the pain duration during each follow up is also recorded.

RESULTS:

Group I – 4(13%) were less than 20 years, 15(50%) were between 21-30 years, 9(30%) were between 31-40 years, 2(7%) were between 41-50 years and none of them were there in 51-60 years. Group II – 7(23%) were less than 20 years, 16(53%) were between 21-30 years, 4(13%) were between 31-40 years, none of them between 41-50 years and 3 (10%) were between 51-60 years of age. The distribution of patients with RAS in the present study was more within the age range of 21- 30 years in both study groups.

TABLE 1: AGE DISTRIBUTION

	STUDY GROUP		
AGE GROUP	**HIORA N (%)**	**TRIAMCINOLONE**	**TOTAL**
<20	4(13%)	7(23%)	11
		16(53%)	31

21 - 30	15(50%)		
31 - 40	9(30%)	4(13%)	13
41 - 50	2(7%)	0	2
51 - 60	0	3(10%)	3
Total	30	30	60

n = number of subjects

Group I – 5 (17%) were males and 25 (83%) were females. Group II – 10(33%) were males and 20 (67%) were females. The gender distribution in the two groups showed increased number of females with RAS. But p value was >0.05 which showed that distribution of aphthous ulcer among males and females were not statistically significant.

TABLE 2: GENDER DISTRIBUTION

GENDER DISTRIBUTION		
	STUDY GROUP	
GENDER	**HIORA GEL**	**TRIAMCINOLONE ACETONIDE**
MALE	5(17%)	10(33%)
FEMALE	25(83%)	20(67%)

TABLE 3: COMPARISON BETWEEN PAIN SCORES ON 1ST, 5TH AND 10TH DAYS IN HIORA GROUP

				95% CI for Mean				
PERIOD	Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	6.63	1.752	0.32	5.98	7.29	3	10	
DAY 5	2.77	1.977	0.361	2.03	3.5	0	7	p <0.001*
DAY 10	0.57	1.04	0.19	0.18	0.96	0	3	
TOTAL	3.32	2.997	0.316	2.69	3.95	0	10	

The mean pain scores in HiOra group were given as mean ± SD. On day 1 mean VAS score was 6.63± 1.752 and on day 5 and day 10 the VAS pain scores reduced to 2.77± 1.977 and 0.57± 1.04 respectively. Thus the total mean pain score was 3.32± 2.997. ANOVA test was used to compare the Pain scores. The p value was <0.001 which showed significant reduction in the pain intensity.

TABLE 4: COMPARISON BETWEEN PAIN SCORES ON 1ST, 5TH AND 10TH DAYS IN TRIAMCINOLONE ACETONIDE GROUP.

				95% CI for Mean				
PERIOD	Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	6.6	1.993	0.364	5.86	7.34	3	10	
DAY 5	2.7	1.643	0.3	2.09	3.31	0	7	p <0.001*
DAY 10	0.37	.0928	0.169	0.02	0.71	0	4	
TOTAL	3.22	3.023	0.319	2.59	3.86	0	10	

SD = Standard Deviation * = statistically significant p-value =<0.001

The mean pain scores in Triamcinolone group was given as mean + or – SD. On day 1 mean VAS score was 6.6± 1.993 and on day 5 and day 10 the VAS pain scores reduced to 2.7±1.643 and 0.37± 0.928 respectively. Thus the total mean VAS score calculated was 3.22±3.023. And the p value was <0.001 which shows significant decrease in the pain intensity during the follow up period.

TABLE 5: COMPARISON BETWEEN TOTAL ULCER SEVERITY SCORES ON DAY1, DAY 5 AND DAY 10 IN HIORA GROUP.

				95% CI for Mean				
PERIOD	Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	16.43	11.855	2.164	12.01	20.86	6	68	
DAY 5	9.23	9.946	1.816	5.52	12.95	0	54	p <0.001*
DAY 10	2.43	3.342	0.61	1.19	3.68	0	10	
TOTAL	9.37	10.71	1.129	7.12	11.61	0	68	

The mean total ulcer severity scores in HiOra group on day 1, day 5 and day 10 were compared in table 5. The result showed that the mean Total USS on day 1 was 16.43±11.855 which reduced to 9.23±9.946 and 2.43±3.342 on day 5 and day 10 respectively. The p value was found to be < 0. 001 and this showed that the Total USS was statistically significant in HiOra group.

TABLE 6: COMPARISON BETWEEN TOTAL ULCER SEVERITY SCORES ON DAY1, DAY 5 AND DAY 10 IN TRIAMCINOLONE ACETONIDE GROUP.

				95% CI for Mean				
PERIOD	Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	13.97	5.249	0.958	12.01	15.93	7	33	
DAY 5	7	4.871	0.889	5.18	8.82	0	26	p <0.001*
DAY 10	1.97	4.013	0.745	0.44	3.49	0	18	
TOTAL	7.71	6.813	0.722	6.27	9.14	0	33	

TABLE 7: COMPARISON OF PAIN SCORES BETWEEN THE TWO STUDY GROUPS

					95% CI for Mean				
PERIOD		Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	HIORA	6.63	1.752	0.32	5.98	7.29	3	10	
	TRIAM	6.6	1.993	0.364	5.86	7.34	3	10	0.945
DAY 5	HIORA	2.77	1.977	0.361	2.03	3.5	0	7	
	TRIAM	2.7	1.643	0.3	2.09	3.31	0	7	0.888
DAY 10	HIORA	0.57	1.04	0.19	0.18	0.96	0	3	
	TRIAM	0.37	0.928	0.169	0.02	0.71	0	4	0.435

SD = Standard Deviation

Table 7 shows the comparison of pain scores between the two study groups on day 1, day 5 and day10. The p value on day 1 was 0.945 and on day 5 was 0.888 and on day 10 it was 0.435. As the p values were >0.05, the comparison of pain scores between the study groups were not statistically significant. This showed that there was no significant difference between the two groups in alleviating the pain caused by RAS.

TABLE 8: COMPARISON OF TOTAL ULCER SEVERITY SCORES BETWEEN THE STUDY GROUPS

					95% CI for Mean				
PERIOD		Mean	SD	Std. Error	Lower Bound	Upper Bound	Minimum	Maximum	P-value
DAY 1	HIORA	16.43	11.855	2.164	12.01	20.86	6	68	

	TRIAM	13.97	5.249	0.958	12.01	15.93	7	33	0.302
DAY 5	HIORA	9.23	9.946	1.816	5.52	12.95	0	54	
	TRIAM	7	4.871	0.889	5.18	8.82	0	26	0.274
DAY 10	HIORA	2.43	3.342	0.61	1.19	3.68	0	10	
	TRIAM	1.97	4.013	0.745	0.44	3.49	0	18	0.628

SD = Standard Deviation

Table 8 shows comparison between Total Ulcer Severity Scores on day 1, day 5 and day 10 among the study groups. On day 1 the p value was 0.302 and on day 5 p value was 0.274 and on day 10 p value was 0.628. p values were >0.05 and showed that Ulcer Severity Scores between the study groups were not statistically significant. Thus the results demonstrated that there was no significant difference in the USS between the two groups after the treatment.

DISCUSSION:

Recurrent aphthous stomatitis is one of the common diseases of the oral cavity that we confront in our daily practice. This painful ulcerative condition restricts the normal activities like eating, swallowing and sometimes speech too becomes difficult. [8] Hence the management of this condition is considered to be important and the main aim of the treatment includes decreasing the symptoms and reducing the number and size of the ulcers. [1]According to Tappuni et al[9], the ulcer severity was estimated by considering six ulcer characteristics like number, site, size, duration, ulcer-free period and pain. The total ulcer severity score was calculated which indicated the disease severity. In our study the ulcer severity was calculated using four ulcer characteristics which include number, site, and size and pain intensity. The pain duration was also calculated after using both the topical medications. Patil et al[8] did a study to find the prevalence of recurrent oral ulcers in Indian population and he found that more number of patients affected with RAS were seen among 31-40 years of age group followed by 21-30 years of age group. In present study, higher number of patients with RAS was seen between 21-30 years of age in both the study groups.

According to Preethi et al [10]the mean pain score in HiOra SG gel group was7.67±0.90 on day 0, followed by 4.87±0.99 on day 4

and 1.67±0.73 on day 7. Thus the results showed a significant reduction in the pain intensity during follow up period after using HiOra gel. These results were in accordance with our study. Tappuni et al[9] did the clinical assessment of RAS by calculating the Ulcer Severity Score which decreased significantly after topical corticosteroid treatment from 34.6 ±7.1 to 27.4± 11 with a P value < 0.001. These results were similar to the present study. Unur et al[11] did a comparative study in 2014 to determine and compare the efficacy of a new medicinal plant extract and Triamcinolone acetonide in the management of RAS. The extracts of medicinal plants used in the study were Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpinia officinarum and Urtica dioica. There was no significant difference noted between the two groups on comparing the mean ulcer size, Effectiveness index and pain scores on day 3 and day 7. Thus the study showed similar results to our study. Thus the present study showed that HiOra SG gel which is a poly herbal formulation can be used effectively in the management of recurrent oral ulcers. Hence the side effects of currently available medications like topical corticosteroids can be avoided. Similar study with increased sample size can be done to validate the efficacy of HiOra SG gel

CONCLUSION:

Study was done to assess and compare the effectiveness of HiOra SG gel with Triamcinolone acetonide gel in the treatment of Recurrent Aphthous Stomatitis. The results suggest that there was no significant difference between HiOra SG gel and Triamcinolone acetonide gel in reducing the ulcer severity, pain duration and pain intensity. No adverse effects were reported by any of the patients after using HiOra SG gel in this study. Hence the results of the present research show that this polyherbal formulation can be used as a safer and effective alternative medication to topical corticosteroids, which is being used as an extensive medication for the management of this condition.

REFERENCES:

1. VG Sukumaran, Amutha, P Vivekananda, D Palaniyamma. A randomized placebo- controlled comparative study to evaluate the efficacy of HiOra-SG gel in stomatitis. Indian J Clinical Practice. 2010 Nov;21(6):307–11.
2. C. Scully and D. H. Felix. Oral medicine — Update for the dental practitioner Aphthous and other

common ulcers. Br Dent J. 2005 Sep;199(5):259–64.
3. Sircus W, Church R, Kelleher J. Recurrent aphthous ulceration of the mouth: a study of the natural history, aetiology, and treatment. Quart J Med. 1957;26:239–45.
4. Embil JA, Stephens RG, Manuel FR. Prevalence of recurrent herpes labialis and aphthous ulcersamong young adults on six continents. Can Med Assoc J. 1975;113:627–30.
5. Woo S-B, Sonis ST. Recurrent aphthous ulcers: a review of diagnosis and treatment. J Am Dent Assoc. 1996 Aug;127(8):1202–13.
6. Fisher DA. Adverse effects of topical corticosteroid use. West J Med. 1995;162(2):123.
7. Preeti Chawla, Kawar Randhawa, Navkiran,Ramandeep S Narang. 5% Ameloxonox and Hiora SG gel in the treatment of recurrent aphthous stomatitis. Indian J of Comprehensive Dental Care. 2012 Jun;2(1):109–13.
8. Patil S, Reddy SN, Maheshwari S, Khandelwal S, Shruthi D, Doni B. Prevalence of recurrent aphthous ulceration in the Indian Population. Clin Exp Dent. 2014;6(1):36–40.
9. Tappuni AR, Kovacevic T, Shirlaw PJ, Challacombe SJ. Clinical assessment of disease severity in recurrent aphthous stomatitis. J Oral Pathol Med. 2013 Sep;42(8):635–41.
10. Preeti Chawla, Kawar Randhawa, Navkiran,Ramandeep S Narang. 5% Ameloxonox and Hiora SG gel in the treatment of recurrent aphthous stomatitis. Indian J of Comprehensive Dental Care. 2012 Jun;2(1):109–13.
11. Unur M, Ofluoglu D, Koray M, Mumcu G, Onal AE, Tanyeri H. Comparison of a New Medicinal Plant Extract and Triamcinolone Acetonide in Treatment of Recurrent Aphthous Stomatitis. Balk J Dent Med [Internet]. 2014 Jan 1 [cited 2018 Jan 11];18(1).