

A Randomised Control Trial comparing the efficacy of Jati Ghrita and 1% Chlorhexidine Gluconate on Aphthous Stomatitis

Research Article

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Abstract

Background: Aphthous ulcer is seen to be one of the most commonly occurring ailments found among patients that dentists may come across on a daily basis. Taking into consideration the agents that have been used for treatment of aphthous stomatitis, it would seem advisable to apply the agent that is the safest and has the least toxic properties that can bring about symptomatic relief and that can be applied topically. These days, there are few reliable natural remedies that are emerging as a therapy for aphthae. Herbal and polyherbal medicines will alleviate pain, induce healing, prevent infection, and lessen inflammation in aphthous ulcers without any adverse effects. Aim: To evaluate the efficacy of Jati Ghrita and 1% chlorhexidine gluconate and its comparison on aphthous stomatitis patients.Materials and methods: A randomized control trial is carried out in the Department of Oral Medicine and Radiology, Sharad Pawar Dental College and Dattatray Ayurvedic Rasashala. The study population consisting of 30 patients with Aphthous stomatitis is divided randomly into two groups i.e., Jati Ghrita and 1% Chlorhexidine gluconate, each group consisting of 15 patients. The intergroup comparison is done by independent sample t test. Results: Jati Ghrita is found to be effective in faster healing of aphthous stomatitis with reduction in pain. Jati is found to be more effective than 1% chlorhexidine gluconate. Conclusion: Jati has good medicinal properties and ghee accelerates wound healing so combination of this was found to be effective for treating aphthous ulcers. It is advised to use these natural treatments in place of conventional medicine method in the treatment of recurrent aphthous stomatitis due to the affordability, accessibility, and lack of potential side effects of these herbal treatments.

Key Words: Recurrence, Healing, Oral ulcer, Inflammation, Pain, Erythema.

Introduction

The oral mucosa, which is non-keratinized, is affected by tiny, recurring, round to ovoid, painful ulcers that have a crateriform base covered in a grey pseudomembrane and an obvious erythematous halo. (1) The lesions often heal on their own, may last for 1–2 weeks, and may leave scars or not. Numerous etiological variables may be present, including local trauma, microbiological infections, systemic diseases, hereditary factors, dietary deficiencies, and allergy disorders. Despite much investigation, the underlying aetiology is still unknown. Lehner described the recurrent aphthous stomatitis (RAS) lesions from a study of 210 individuals using Cooke's classification of

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the lesions into three types. These include herpetiform ulcers, minor aphthous ulcers, and major aphthous ulcers (2).

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Minor RAS, also known as mild aphthous ulcers, are thought to be the most typical form of recurrent aphthous stomatitis, affecting between 75 and 85% of individuals. (3) They are shallow, round or oval ulcers that are encircled by a zone of peripheral edoema and covered in fibromembranous slough. They normally heal without leaving scars and have a diameter of a little more than 1.0 cm.

Major RAS are thought to be a more severe type of aphthous stomatitis and affect roughly 10–15 percent of people. They are also known as periadenitis mucosa necroticarecurrens or Sutton's ulcers. They can persist for up to 6 weeks and frequently have scars that are larger than 1.0 inch in diameter. Due to a failure in immunoregulation, they are mostly linked to HIV-positive individuals (4,5).

Only 10% of individuals will have herpetiform RAS, the least frequent type of the disease. They initially appear as numerous tiny groups of pinpoint ulcers, distinct 1 to 2 mm papules, and then



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papulovesicles. With time, they develop into bigger plaqueform lesions and can persist anywhere between 7 and 30 days before scarring. (5) The herpetiform lesions, although herpes-like in origin, have nothing to do with the herpes simplex virus.

Despite being a self-limiting condition, RAS causes discomfort, erythema, a high rate of recurrence, and functional impairment, all of which lower quality of life. The three main objectives of treatment are to reduce ulcer discomfort, hasten ulcer healing, and stop recurrence. The use of various drugs in current treatments is risky and could result in negative side effects. Herbal medicines are receiving more attention as a way to reduce the frequency of side effects. (3,6)

Traditional applications of jati (*Jasminum officinale*) include curing odontalgia, mobile teeth, ulcerative stomatitis, skin conditions, otorrhoea, hearing problems, dysmenorrhoea, ulcers, wounds, ringworm, and corns. (7). Ghee and jati extract hasten the healing of wounds. (8). Ghee enhances the percutaneous absorption of substances, as stated in Ayurveda. Since ghee is more lipophilic and has been processed, it aids in the diffusion and percutaneous absorption of medicines and other compounds that are applied topically. (9)

Therefore, the aim of this study was to evaluate and contrast *Jati Ghrita's* efficacy in treating RAS with 1% chlorhexidine gluconate in gel form.

Materials and Methods

The Institutional Ethical Committee has authorised a randomised control study with IEC reference number DMIMS (DU)/IEC/2022/1173. The study was conducted at Sharad Pawar Dental College in the Department of Oral Medicine and Radiology and Dattatray Ayurveda Rasashala of Mahatma Gandhi Ayurved College and Research Center, Salod, a constituent college of the Datta Meghe Institute of Medical Sciences (Deemed University), Wardha Hospital, and Central Research Laboratory Jawaharlal Nehru Medical College and Hospital, Wardha. The three-month research was place between July 2022 and September 2022. Participants in this study include those who have had recurrent aphthous stomatitis within two days of the onset of an ulcer. In addition to receiving written informed permission from each patient, the operation was explained to them all. Only patients who were willing to participate in the trial were taken into consideration

Inclusion criteria

This study included Men and Women of age between 18- 65 years presenting with 1-5 aphthous ulcers of less than 48 hours duration.

Exclusion criteria

Patients who are undergoing any treatment or therapy for aphthous ulcers, individuals with any known systemic disorders, pregnant and lactating women, and clinical conditions including serious kidney, liver and heart dysfunction will be excluded from the study.

Methodology

Preparation of Jati Ghrita

To produce any medicated *Ghruta* or oil, mix together 1 part of *Kalka Dravya* (Fine paste of medicinal herbs should be consumed as *Kalka Dravya*), 4 parts of *MurchhitGhruta*/Oil (*Sneha Dravya*: Mainly types of fat containing media such as *Ghruta*), and 16 parts of *Dravya* (Water, *Kwatha*, *Swarasa*, *Kanji*, *Ksheera*, *Dadhi*, *Takra*, etc.), It is then filtered and examined. (10).

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- 1 part of the paste of the drugs: Juice/paste of *Jati* leaves *Jasminum officinale* air-dried leaves were crushed. An electronic blender was used to turn the dry leaves into powder. An airtight container was used to retain the fine powder.
- 4 parts ghee
- 16 parts water
- Ratio-1:4:16

This mixture is mixed then boiled and reduced till Ghee is left over. Then this mixture is filtered and examined.

Method of collection of data

Detailed case history, extraoral and intraoral examination was performed. A study population comprising of 30 patients that were segregated randomly into two groups i.e., *Jati Ghrita* and 1% chlorhexidine gluconate, each group consisting of 15 patients. This study will include Male and female patients of age between 15-50 years presenting with aphthous ulcers of less than forty-eight hours duration (onset). In order to randomly split these 30 patients into two groups, a computer-controlled lottery procedure was used in which

- Group A- 15 patients (1%chlorhexidine gluconate)
- Group B- 15 patients (*JatiGhrita*)

The period required to treat was 3 days, both to be applied topically by themselves twice a day.

Jati Ghrita will be prepared in Dattatray Ayurvedic Rasashala , Mahatma Gandhi Ayurved College and Research Center , Salod , a constituent college of Datta Meghe Institute of Medical Sciences (Deemed University) Wardha.

On day 0, the patient's ulcer count and size were assessed, and the patient's pain level was recorded. Using a Periodontal Probe calibrated by William's, the size of the ulcer was determined along its longest diameter, and the pain level was recorded on a scale of 0 to 10 using the Visual Analogue Scale (VAS). Efficacy was assessed by patient's response. Hayes and Patterson in 1921 used the first pain rating scale as Visual Analogue Scale (VAS). Scale is based on the scores which shows measures of symptoms that are reported by the patients that are taken down with a single handwritten mark assigned at a point alongside the length of a 10-cm line that denotes two ends of the scale i.e. "no pain" on the left extremity i.e. 0 cm of the scale and the "worst pain" on the right extremity of the scale i.e. 10 cm. (11). Patients were examined on days 0 and 3 to look for any pain or regression in the number or size of the ulcer. Pain score was noted on the first and the third day by the investigator.



Criteria of assessment of patient with scoring

1. Assessment of pain

Pain on VAS Scale

- · 0- No pain
- · 1-3 Mild Pain
- · 4-6 Moderate pain
- · 7-9 Severe pain
- · 10- Worst pain

2. Size of ulcer

A Williams calibrated periodontal probe was used to measure the ulcer's greatest diameter on the first day before treatment that is immediately and on the third day. The ulcer's maximum diameter was measured as well as its length and breadth, and the area of the ulcer was then calculated.

3. Presence of erythema.

- 0- No erythema
- 1-Light red/pink
- 2- Red but not dark in colour
- 3- Very red/dark in colour

4. Functional Disability

This involved the evaluation of effects of oral ulcers on tasting, speaking, and eating/chewing/swallowing. This was evaluated by both Likert- type scale Functional disability was measured 1st day before application, immediately after application and on the 3rd day.

Criteria

- 0- None of the time
- 1- Lasting for few minutes
- 2- Lasting for around 1- 6hours
- 3- Lasting for around 6-12 hours
- 4- All of the time

Statistical analysis

Statistical analysis of evaluation of pain score, ulcer size, erythema level and functional disability on 1st day before application (*Jati Ghrita*/1% Chlorhexidine gluconate gel), immediately after application and their efficacy on 3rd day on patients was carried out to find the significant difference between those values. Analysis of the data was done by using descriptive and inferential statistics both.

The software used in the analysis were SPSS 27.0 and Graph Pad Prism 7.0 version and p<0.05 is considered as level of significance. The statistical tests used for the analysis of the result were -

- 1. Chi square Test
- 2. Student's paired t test
- 3. Student's unpaired t test

Results

The present study was undertaken for comparing the efficacy of *Jati Ghrita* with 1% Chlorhexidine Gluconate gel in management of Aphthous Stomatitis. Considering all the exclusion and inclusion criteria, a total 30 patients were selected for the study. Data was

tabulated and also presented as tabular and graphical representations.

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Table 1 and Graph 1- Demonstrate the distribution of ages.

The mean age in Group A (1% Chlorhexidine Gluconate) was determined to be 29.60±9.29 years. Group B (*Jati Ghrita*) its mean age was calculated as 29.33±8.86 years. The majority of the patients in Group A were between the ages of 31 and 40, whereas those in Group B were mostly between the ages of 21 and 30. The bare minimum of patients in Group A (aged 41–50) and Group B (aged 41–50) were seen. Chi-square analysis was done. For the age of patients in both groups, the x2 - value was 0.82 and the p-value was 0.84, which was not significant. In the current study, RAS prevalence was shown to be higher in the second and third decade.

Table 1: Demonstrate the distribution of ages.

Age Group (yrs)	Group A	Group B	X2-value
11-20 yrs	3 (20%)	3 (20%)	
21-30 yrs	5 (33.33%)	6 (40%)	
31-40 yrs	6 (40%)	4 (26.67%)	0.02
41-50 yrs	1 (6.67%)	2 (13.33%)	0.82 P=0.84, NS
Total	15 (100%)	15 (100%)	1-0.64, NS
Mean±SD	29.60±9.29	29.33±8.86	
Range	17-46 yrs	15-45 yrs	

Graph 1: Distribution of patients in two groups according to their age in years

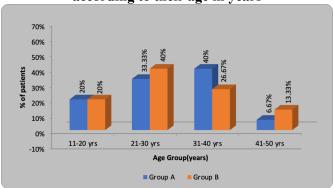


Table 2 and Graph 2 – Demonstrate the distribution of gender.

In the present study, there were 9 (60%) male and 6 (40%) female in Group A and 7 (47%) male and 8 (53%) female in Group B. By using chi-square test, x2 -value 0.53, p value 0.46 which was not significant. Amongst the total number of patients, the most common gender to be affected was female.



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Table 2: Demonstrate the distribution of gender

Gender	Group A	Group B	X2-value	
Male	9 (60%)	7 (46.67%)	0.52	
Female	6 (40%)	8 (53.33%)	0.53 P=0.46, NS	
Total	15 (100%)	15 (100%)	1 -0.40, 113	

Graph 2: Distribution of patients in two groups according to gender

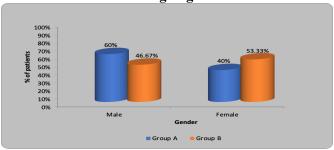


Table 3 and Graph 3 – Comparison of patients in two groups according to pain on VAS after three days of application.

Following observations were recorded after treatment: In Group A, out of 15 patients, 11 (73.33%) patients had complete resolution of pain while 10 (66.67%) patients experienced mild pain. In Group B, out of 15 patients, complete relief of pain was seen in 10 (66.67%) patients while 5 (33.33%) patients experienced mild pain. After performing Chi-square test, the x2 value was 0.15 and p-value was 0.69 which was statistically insignificant. In comparing the VAS score of an aphthous ulcer between Groups A and B after 3 days of application, it was shown that while both groups had pain relief after the third day, Group A experienced a greater degree of relief. These results suggested that 1% chlorhexidine gluconate might work better for pain alleviation after three days of treatment.

Table 3 – Comparison of patients in two groups according to pain on VAS after three days of application

application					
Pain on VAS	Group A	Group B	X2-value		
No Pain	11 (73.33%)	10 (66.67%)			
Mild Pain	4 (26.67%)	5 (33.33%)			
Moderate Pain	0 (0%)	0 (0%)			
Severe Pain	0 (0%)	0 (0%)	0.15		
Worst Pain	0 (0%)	0 (0%)	P=0.69, NS		
Total	15 (100%)	15 (100%)			
Mean±SD	0.40 ± 0.73	0.40 ± 0.630			
Range	0-2	0-2			

Graph 3: Distribution of patients in two groups according to pain on VAS

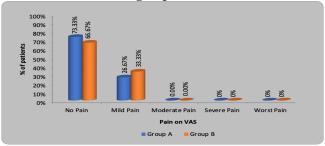


Table 4 and Graph 4 -Comparison of size of ulcer in patients of two groups after 3 days

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The mean ulcer size in mm after 3 days of application in Group A was 0.63 ± 1.04 and in Group B was 0.53 ± 0.91 mm. On application of Student unpaired test, t-value was 0.27 and p-value was found to be 0.18 indicating statistically insignificant difference in both groups. These findings were suggestive of better results of *Jati Ghrita* after three days of application with reference to ulcer size.

Table 4: Comparison of size of ulcer in patients of two groups after 3 days

C	NI	м	Std.	Std. Error	4 1
Group	N	Mean	Deviation	Mean	t-value
Group A	15	0.63	1.04	0.26	0.27
Group B	15	0.53	0.91	0.23	P=0.18, NS

Graph 4: Comparison of size of ulcer in patients of two groups

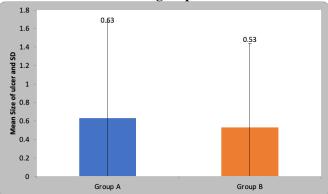


Table 5 and Graph 5 -Comparison of patients in two groups according to Erythema after 3 days

The degree of erythema was evaluated by the four-point scale ranging from 0-3. In Group-A, maximum patients, 8 (53.3%) patients were on the 0-point with light no erythema, while in the Group-B maximum patients, 9 (60%) were in the 0-point with no erythema. Using the chi-square test, there is an insignificant difference in erythema reduction (x2 value 0.13 and p-value 0.71). Observations are suggestive of more efficacy of *Jati Ghrita* in reducing the degree of erythema.

Table 5: Comparison of patients in two groups according to Erythema after 3 days

according to Erythema arter e days					
Erythema	Group A	Group B	X2-value		
No Erythema	8 (53.3%)	9 (60%)			
Light red/pink	7 (46.7%)	6 (40%)			
Red but not dark	0 (0%)	0 (0%)	0.13		
Very red/dark	0 (0%)	0 (0%)	P=0.71, NS		
Total	15 (100%)	15 (100%)			
Mean±SD	0.46 ± 0.51	0.40±0.50			
Range	0-1	0-1			



Graph 5: Distribution of patients in two groups according to Erythema

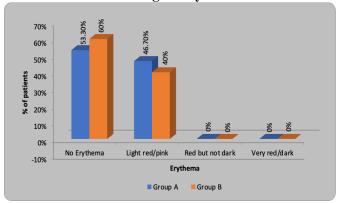


Table 6 and Graph 6- Comparison of patients in two groups according to pain on VAS

In Group A, 11 (73.33%) patients had mild pain immediately when reported and 4 (26.67%) patients reported with mild pain after three days of treatment whereas in Group B, 11 (73.33%) patients reported with mild pain and after three days of treatment 5 (33.33%) patients had mild pain. When chisquare test was applied, the x2 value was 34.61 and p-value was 0.0001. 1% chlorhexidine gluconate gel gives more significant reduction in pain as compared to *Jati Ghrita* with immediate effects.

Table 6: Comparison of patients in two groups according to pain on VAS

Pain on VAS	Group A		Group B		
	Immediate	After 3 days	Immediate	After 3 days	
No Pain	0 (0%)	11 (73.33%)	0 (0%)	10 (66.67%)	
Mild Pain	11 (73.33%)	4 (26.67%)	11 (73.33%)	5 (33.33%)	
Moderate Pain	4 (26.67%)	0 (0%)	4 (26.67%)	0 (0%)	
Severe Pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Worst Pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Total	15 (100%)	15 (100%)	15 (100%)	15 (100%)	
Mean±SD	2.73±1.48	0.40±0.73	2.53±1.30	0.40±0.630	
Range	1-6	0-2	1-5	0-2	
X2-value	34.61, p=0.0001, S				

Graph 6: Distribution of patients in two groups according to pain on VAS

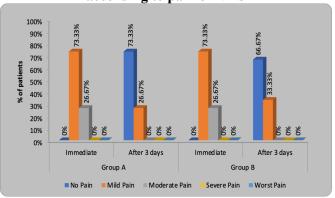


Table 7 and Graph 7 - Comparison of patients in two groups according to Functional Disability

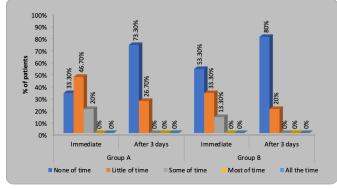
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In Group A, 7 (46.7%) patients show functional disability for little of time immediately when reported and 4 (26.67%) patients reported with functional disability for little of time after three days of treatment whereas in Group B, 5 (33.3%) patients when reported immediately with functional disability for little of time and after three days of treatment 3 (20%) patients had mild pain. When the chi-square test was applied, the x2 value was 10.58 and p-value was 0.10. which was statistically insignificant. These findings were suggestive of better results of *Jati Ghrita* after three days of application with reference to functional disability.

Table 7: Comparison of patients in two groups according to Functional Disability

Functional	Group A		Group B	
Disability	Immediate	After 3 days	Immediate	After 3 days
None of time	5 (33.3%)	11 (73.3%)	8 (53.3%)	12 (80%)
Little of time	7 (46.7%)	4 (26.7%)	5 (33.3%)	3 (20%)
Some of time	3 (20%)	0 (0%)	2 (13.3%)	0 (0%)
Most of time	0 (0%)	0 (0%)	0 (0%)	0 (0%)
All the time	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	15 (100%)	15 (100%)	15 (100%)	15 (100%)
Mean±SD	1.46 ± 0.51	0.26 ± 0.45	1.40±0.50	0.20±0.41
Range	1-2	0-1	1-2	0-1
X2-value	10.58, p=0.10, NS			

Graph 7: Distribution of patients in two groups according to Functional Disability



Discussion

In order to identify the best treatment option for aphthous stomatitis that would lessen the number, size, exudate level, pain, and discomfort of the ulcerations, Renu DA et al. did research in 2018. In this study, they investigated the clinical effectiveness of several topical medications. Five groups of patients, each with ten patients, were created. The following topical therapy options were used: 20:2:1 mixture of normal saline, 5% Amlexanox, 0.1% Triamcinolone Acetonide, 20% Benzocaine Gel, and 100 mg Doxycycline HyclateThe trial employed a 10 gramme placebo gel and was placebo controlled. They found that 0.1% Triamcinolone Acetonide and 5% Amlexanox were statistically significantly more effective than a single



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application of 100 mg Doxycycline Hyclate, 20% Benzocaine gel, and the placebo in reducing the size, number, pain, erythema, and exudate levels at days 8 and 10, respectively (p =.000* and.000*). VAS scale was significant for 20% Benzocaine gel and 100 mg Doxycycline Hyclate. As a result, the authors came to the conclusion that the chosen topical treatment technique can give affordable, efficient, and safe medication therapy that helps the patient by improving their daily activities and events. (12)

Miles DA et al. conducted a study in 1993 in which they analysed the effectiveness of pain control of Chlorhexidine compared with Triamcinolone acetonide used to treat aphthous stomatitis. Their Study involved 30 patients affected with aphthous ulceration. They were segregated randomly into three groups, one of these was a control group. The remaining were experimental groups that were topically given either triamcinolone acetonide or chlorhexidine digluconate. Patients were instructed to note their pain tolerance level on a ten-centimetre Visual Analogue Scale till the ulcer was completely healed. Based on the results, the authors concluded that there are high levels of significant differences in pain severity and perception during different days, and chlorhexidine reduces pain similarly to triamcinolone. Consequently, there was no remarkable difference found between chlorhexidine gluconate and triamcinolone acetonide. (13)

Sathish H.S et al. in the year 2018 evaluated wound healing potential of medicated ghee. In their study, they have formulated the drug named as *Jati Kalpa Ghrita* which was derived from the combination of drugs having wound healing properties. Their Study involved 110 patients divided into two groups A and B with 75 and 35 patients respectively. They found that

there was highly significant wound contraction with the trial drug when compared to the control group. Authors concluded that *Jati Kalpa Ghrita* is highly efficacious in healing of *Shuddha Vrana* and proves to be a potent drug for wound healing.[14]

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In the year 2019, Mangtani KN et al. conducted a study to determine the effectiveness of *Jasminum officinale* leaf extracts in treating ulcers by their antibacterial activity against oral infections. They used an agar well diffusion technique to examine the antibacterial activity against S. aureus, Escherichia coli, Pseudomonas aeruginosa, Bacillus subtilis, and Enterococcus faecalis. They came to the conclusion that Jasminum officinale leaf extract is efficient against oral infections that cause mouth ulcers, therefore in the future, natural remedies can be used instead of antibiotics. [15]

A Study conducted in the year 2022 by Sunita Kumari Bijarniya et al. on An Open-Label Randomized Comparative Clinical Study of *Triphaladivati* and *Jatyadigandusha* on Tobacco Chewing-Induced *Mukhapakaw*.s.r. to Stomatitis in which they involved 30 patients and they were divided into 2 groups in which Group A was given *Triphaladivati* and GroupB was given *Jatyadigandusha*. They concluded that both the groups *Triphaladivati* and *Jatyadigandusha* are effective in the management of *Mukhapaka* (stomatitis) but GroupB (*Jatyadigandusha*) has better results than Group A (*Triphaladivati*) and similarly our study consisted of 30 patients divided in two groups and Group B included *Jati Ghrita* which constituted the common ingredients in Group B of both the studies that were *Jati* (Jati leaves) and *Ghrita* (Ghee). (16)

Fig 1- Immediate (Group A)

Fig 2- After 3 days (Group A)

Fig 3 – Immediate (Group B)

Fig 4- After 3 days (Group B)









Conclusion

Aphthous stomatitis is a frequently occurring oral mucosal condition of undetermined etiopathogenesis for which symptomatic therapy only is available. As a result, treatments are limited to suppressing symptoms rather than addressing susceptibility and prevention. *Jati ghrita* is composed of *Jati* leaves extract and ghee. As Jati has good medicinal properties and ghee accelerates wound healing so combination of this was found to be effective for treating aphthous ulcers. It is advised to use these natural treatments in place of conventional medicine method in the treatment of

recurrent aphthous stomatitis due to the affordability, accessibility, and lack of potential side effects of these herbal treatments

Declaration

The research protocol for this study has already been accepted in the Journal of clinical and Diagnostic Research.

Acknowledgement

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