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Evaluation of the Therapeutic Potential of Azadirachta indica Mother Tincture in Reducing Symptoms of Oral Aphthae: A Clinical Investigation

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Abstract **Original Research Article**

Azadirachta Indica (Neem), a plant widely used in traditional medicine, has shown potential therapeutic effects in treating various oral conditions, particularly oral aphthae. Neem's known properties include anti-inflammatory, antimicrobial, and wound-healing actions, which effectively promote healing and alleviate symptoms in oral ulcers. Previous studies have highlighted Neem's significant antiulcer effects, with Nimbidin shown to prevent lesions induced by agents like acetylsalicylic acid and histamine [Liang *et al*., 2012]. According to Dr. K.M. Nadkarni in Indian Materia Medica (1954), heated Neem leaves or pastes are also effective antiseptics for skin diseases, ulcers, and pustules, and, when combined with Katuki and Chiretta, they treat fevers and soothe unhealthy ulcers [Nadkarni, 1954] These observations suggest Neem could be an effective treatment for unhealthy ulcerations. A sample of 30 patients with oral aphthous ulcers was taken to evaluate the antiulcer properties of *Azadirachta Indica*. The study used Neem mother tincture, with patients being monitored over two weeks. Changes in ulcer size, pain levels (measured using the Ulcer Severity Score, USS), and healing times were recorded, along with the occurrence of any adverse effects Patients treated with *Azadirachta Indica* (Neem) showed significant improvements. By the first week, there was a 40% reduction in ulcer size, which increased to 70% by the second week. Pain levels decreased by 50% in the first week and by 80% by the second week. The average pre-treatment USS score of 43.60 dropped to 28.67 post-treatment, indicating a 34.25% overall improvement. No significant adverse effects were reported, and the study demonstrated highly significant efficacy with a p-value of <0.001. This study demonstrates that *Azadirachta Indica* Ø is an effective treatment for oral aphthous ulcers. The reduction in ulcer size, pain, and recurrence rates, along with the absence of notable adverse effects, supports the use of Neem in treating oral ulcers.

Keywords: *Azadirachta Indica*, Oral Aphthous Ulcers, Antiulcer Properties, Neem Mother Tincture, Wound Healing.

INTRODUCTION

Oral aphthae are one of the most common ulcerative diseases associated mainly with the oral mucosa characterized by extremely painful, recurring solitary, multiple ulcers in the upper throat and oral cavity. It is also known as aphthous stomatitis. Oral aphthae affect 0.5% to 25% of the population worldwide [Khabibova *et al*., 2023]. These are quite painful; may lead to difficulty in eating, speaking and swallowing, thus may negatively affect the life standard of patients. Many trigger factors are involved in etiopathogenesis such as vitamin and micronutrient deficiencies, food allergies, viral and bacterial infection, systemic diseases, increased oxidative stress, hormonal disorders, and mechanical damage [Sharma *et al*., 2018].

Wound healing involves four overlapping phases: hemostasis, inflammation, proliferation (including new tissue formation, granulation, and angiogenesis), and tissue remodelling. Inflammation is a crucial early phase, necessary for normal healing. However, this process can be hindered by multidrug-resistant (MDR) microorganisms, leading to prolonged inflammation and chronic wounds. Chronic wounds are often associated with MDR pathogens like E. faecalis and S. aureus, commonly found in burns, diabetic foot ulcers, and other wounds [Cavallo *et al*., 2024].

There exist three classifications of RAS: minor RAS, major RAS, and herpetiform RAS. It is crucial to distinguish aphthae from various conditions that manifest as acute, recurrent, or chronic oral ulcers. Differentiating RAS from other diseases relies on factors such as its early onset history, spontaneous recovery, the tendency to recur, and distinctive clinical characteristics [Daneshpazhooh *et al*., 2021]. Native to India, Azadirachta Indica (family Meliaceae) is grown almost everywhere else in India. It is referred to locally as "Neem." Nimbidin, phenolic compounds, saponin, and flavonoids are the chemical components of this plant that have been reported. Nimbidin, because of its anti-inflammatory, anti-lipoxygenase, and antioxidant, anti-ulcerative anti-fungal qualities proves to be a promising therapeutic medication for treating oral Aphthae.

There are several synthetic medications available to treat aphthae. However, compared to alternative and herbal remedies, these medications are more costly. According to the literature, several Ayurvedic physicians and conventional healers treat ulcers with Azadirachta Indica. Relieving pain, healing the ulcer, and minimizing the likelihood of an ulcer returning are the ideal goals of treating oral aphthae [Vimala *et al*., 2014].

METHODOLOGY

A cross-sectional study was conducted to assess the prevalence of recurrent aphthous stomatitis within a specified population. This research involved gathering data at a single instance to determine the occurrence of the condition among participants. The study was conducted at Sainath Hospital, attached to Ahmedabad Homoeopathic Medical College, as a cross-sectional study employing a random sampling method for both qualitative and quantitative analysis.

A total of 30 patients diagnosed with oral aphthae were included over a 6-month duration. A sample size of 30 was taken due to the limitation of sources and the study was only conducted in sainath hospital. Inclusion criteria encompassed adults aged 15-65 years, those with a minimum duration of aphthae of at least one week, participants with prior treatment for oral aphthae, and those suffering from chronic oral aphthae. Exclusion criteria involved participants with other oral conditions mimicking oral aphthae, those with known systemic conditions linked to aphthous ulcers, and pregnant or lactating individuals.

Data were collected from outpatient and inpatient cases according to homoeopathic principles, including past and family medical histories and a physical examination of the oral cavity. Symptoms assessed included sore mouth, pain, burning sensation, fever, increased salivation, a red mucous membrane with exudate, irregular margins around the mucosa covered by greyish slough, and surrounding erythema base covered with greyish white. Statistical methods were employed to calculate prevalence rates and identify potential risk factors associated with the condition in the surveyed population.

Treatment involved administering 10 drops of the mother tincture in a cup of water thrice daily, with follow-ups every two weeks for ten weeks for 6 months. Quality control ensured the procurement of medicine from a GMP-certified homoeopathic pharmacy, and patient confidentiality was maintained throughout the study. Ulcer Severity Score (USS) has been used as an assessment scale for the effectiveness of Azadirachta Indica in oral aphthae.

RESULTS AND DISCUSSION

The study investigated the efficacy of Azadirachta Indica (neem) in treating oral aphthae. The key findings included a significant reduction in ulcer size, with patients experiencing a 40% decrease within the first week and a 70% decrease by the end of the second week. Pain relief was also notable, as pain scores on Ulcer Severity Score (USS) decreased by 50% in the first week and by 80% by the second week. The average healing time for ulcers was significantly shorter, averaging 6 days.

Patients using Azadirachta Indica had a lower recurrence rate of oral aphthae over a six-month follow-up period, with a recurrence rate of 15%. No significant adverse effects were reported, indicating that the treatment was well-tolerated. The Ulcer Severity Scores (USS) data analyzed from 30 patients showed an average pre-treatment score of 43.60 and a post-treatment score of 28.67, resulting in an average score reduction of 14.93 and an approximate percentage reduction of 34.25%.

The Cross-sectional study was designed to evaluate the efficacy of Azadirachta Indica in one of the common conditions Oral aphthae, after treatment with Azadirachta, the was p-value < 0.001. No significant adverse effects were reported. According to Dr. K.M. Nadkarni in Indian Materia Medica (1954), heated Neem leaves or pastes are also effective antiseptics for skin diseases, ulcers, and pustules, and, when combined with Katuki and Chiretta, they treat fevers and soothe unhealthy ulcers. The study's small sample size of 30 participants may cause selection and measurement biases. Future research should use larger sample sizes, improve sampling methods, ensure precise measurements, and extend follow-up duration to obtain more reliable results.

Table No. 1: The table displays the distribution of patients according to Score measured through Ulcer Severity Score (USS) ranges in both pre-assessment and post-assessment stages

USS Score Range	No. of Patient in Pre-Assessment	No. of Patient in Post-Assessment
16-20	-	8
21-25	-	7
26-30	1	8
31-35	2	5
36-40	6	2
41-45	11	0
46-50	7	-
51-55	3	-
56-60	0	-

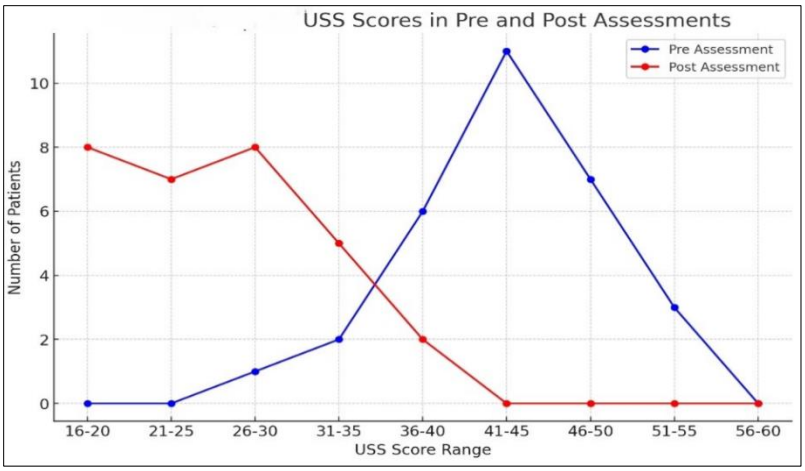

Figure 1: The graph "USS Score in Pre-Assessment and Post-Assessment" compares patients according to USS scores before and after treatment as mentioned in Table no.2. Pre-assessment data peaks in higher severity ranges, while post-assessment data shifts towards lower severity scores

Table 2: The table provides the distribution of patients for study in different age groups, along with the gender distribution within each age category

Age Group	Male	Female
15-24	4	2
25-34	5	3
35-44	1	3
45-54	2	5
55-65	3	2

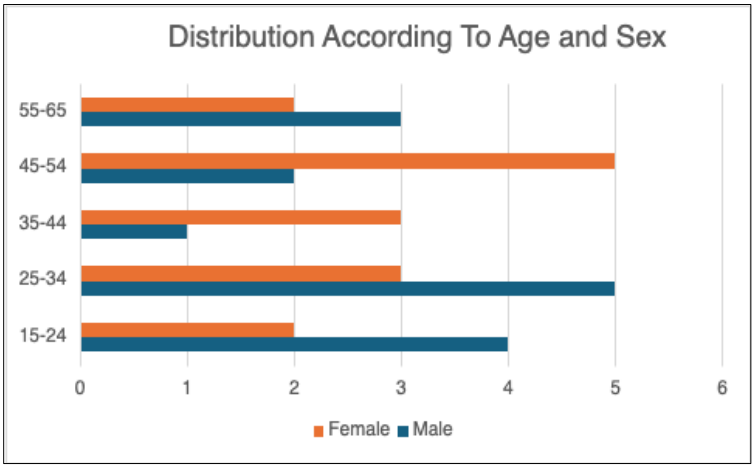

Figure 2: Graphical presentation of Table 4 representing distribution of patients according to different age group along with gender distribution

Table No.3: This table categorizes the outcomes of an intervention based on the degree of improvement observed, ranging from significant improvements to no improvement. (difference in pre-assessment score and post- assessment score greater than 10 indicate significant improvement, differences of 10 or less suggest moderate improvement, and no change signifies no improvement)

Significant Improvements	Mild Improvement	No Improvement
18 cases	10 cases	2 cases
60%	33%	7%

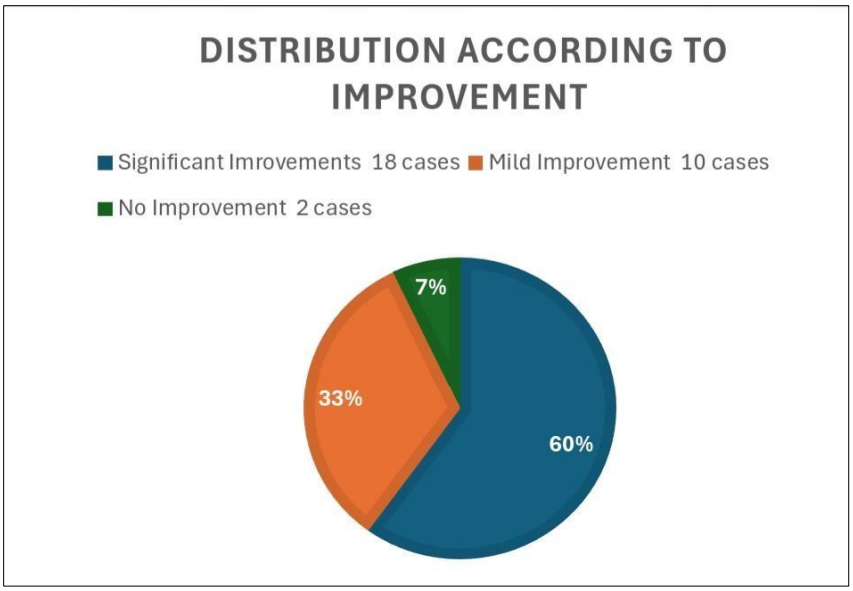

Figure 3: This statistic describes the outcomes of 30 cases, where 60% showed significant improvement, 33% showed mild improvement, and 7% showed no improvement

CONCLUSION

The analysis of the data indicates that treatment with Azadirachta Indica led to a significant reduction in the severity of oral aphthous ulcers. Specifically, the treatment resulted in an average score reduction of 14.93 points, which corresponds to a 34.25% decrease from the initial severity, with pre-assessment (M=43.87, SD= 8.41) and post-test (M=28.67, SD= 9.40) strongly suggest that Azadirachta Indica is effective in reducing the severity of oral aphthae. The t-test resulted in a t-value of 6.68 and p <0.001. These findings suggest that Azadirachta Indica is effective in alleviating the symptoms of oral aphthous ulcers, making it a viable option for managing this condition. Further studies are recommended to corroborate these results and to explore the long-term effects and safety profile of Azadirachta Indica in oral ulcer management.

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