

The Potency of Kuldon® Solution in The Healing Process of Aphthous Stomatitis

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Abstract

Objectives: This study aimed to assess the efficacy of Kuldon® solution in the healing process of aphthous stomatitis. **Methods:** A double-blind randomized controlled trial was conducted involving 60 subjects (27 males, 33 females), randomly assigned to receive either Kuldon® solution (Drug A) or hyaluronic acid rinse (Drug B). Pain was evaluated using the Visual Analogue Scale (VAS), and lesion diameter was measured on days 2, 5, and 7. Data were analyzed using the Mann-Whitney test ($p < 0.05$). **Results:** Drug A showed a greater reduction in pain and lesion size compared to Drug B. By day 5, 100% of Drug A users reported no pain, with 90% showing lesion reduction. **Conclusion:** Kuldon® solution demonstrates significant therapeutic potential in managing aphthous stomatitis.

Keywords: Aphthous Stomatitis; Kuldon® solution; Healing Potency.

INTRODUCTION

Recurrent aphthous stomatitis (RAS), is one of the most common oral disease and called "canker sores." RAS is a perplexing oral condition characterized by the recurrent development of painful aphthous ulcers on non-keratinized oral mucous membranes. This condition poses a significant challenge to patients and healthcare professionals due to its uncertain etiology. RAS is a reserve in the oral mucosa with a worldwide prevalence of 5-25%. RAS mostly occurs at the age of 10-40 years and many occur in women (Sánchez-Bernal J, et. al, 2020).

RAS One or several discrete, shallow, painful ulcers are visible on the unattached oral mucous membranes. RAS is a *self-limited disease* and a typical minor aphthous ulcer can spontaneously heal within 4-14 days (Ginat W Mirowski, et. al, 2020). Individual ulcers typically last 7-10 days and heal without scarring. Larger ulcers may last several weeks to months and can scar when healing (Mahmoud K, et al 2015). The basic principle of treatment is to reduce pain, shorten the course of the lesion by extending the interval for the lesion to appear (Marco Manfredini, et. al, 2021).

Treatment can use patent medicines or traditional medicines but still safe and the price of the medicines is relatively cheap. During the latter part of the 20th century herbalism has become mainstream worldwide. This is due in part to the recognition of the value of traditional and indigenous pharmacopoeias, the incorporation of some derived from these sources into pharmaceuticals), the need to make health care affordable for all, and the perception that natural remedies are somehow safer and more efficacious than remedies that are pharmaceutically derive (Elvin-Lewis M, 2001). The discovery of herbal medicinal ingredients is not only based on experiences from generation to generation, but also based on experimental or scientific study (Waode Munaeni, et.al, 2022).

Kuldon® solution as a. Standardized commercial herbal syrup consists of *Rizhoma of Imperata*, *Abrus precatorius*, Herbal Thyme (*Thymus vulgaris*), *Centella asiatica*, *Curcuma xanthorrhiza* Roxb, *Piper battle*, *Chrysanthemiflos*, and *Glycyrrhiza glabra*. The rhizome of Imperata could be used either alone or in combination with other herbal medicines to cure hematuria, jaundice and reducing fever, to treat inflammation (Wei Zou, et. al, 2021). (Figure 1A)



Figure 1. A. rhizome of *Impeata*; B. *abrus precatorius*; C. *Thymus*; D. *Centella asiatica*; E. *Curcuma*; F. piper betle leaf; G. *Chrysanthemum*; H. *Glycyrrhiza xanthorrhiza* R.

The *Abrus precatorius* is having medicinal potential to cure various diseases. The roots, leaves and seeds of this plant are used for different medicinal purpose. *Abrus precatorius* are *laxative, expectorant and aphrodisiac medicines* and are used in urticaria, eczema, stomatitis, conjunctivitis (Garaniya, N et.al, 2014). (Figure. 1B). The *Thymus vulgaris* is generally known as thyme. The plant is useful as infusion to treat cough, diabetes, and cold and chest infections. It is also soothing for sore throat, as thyme has antiseptic, antibiotic, and antifungal properties. *Thymus vulgaris* has been thought of to be astringent, anthelmintic, carminative, disinfectant, and tonic (Nasrun,MF. et.al, 2023). (Figure. 1C)

Centella asiatica is an important medicinal herb. Triterpenoid, saponins, the primary constituents of *Centella asiatica* are mainly believed to be responsible for its wide therapeutic actions. Apart from wound healing, the herb is recommended for the treatment of various skin conditions such as leprosy, lupus, varicose ulcers, eczema, psoriasis, diarrhoea, fever, amenorrhea, diseases of the female genitourinary tract and also for relieving anxiety and improving cognition (Gohil KJ. et. al, 2010). (Figure. 1D)

The *Curcuma xanthorrhiza* Roxb., locally famed as Temulawak, has been extensively utilized in Indonesia as medicinal and nutritional plants since immemorial time. The rhizome of this plant is an important ingredient for *jamu* formulation (Indonesian traditional medicine). *C. xanthorrhiza* is traditionally used to treat several ailments such as lack of appetite, stomach disorder, liver illness, constipation, bloody diarrhea, dysentery, arthritis,

children's fevers, hypotriglyceridaemia, hemorrhoids, vaginal discharge, rheumatism, and skin eruptions (Rahmat Endang, et.al,2021). (Figure. 1E).

Piper betle (L) is a popular medicinal plant in Asia. Plant leaves have been used as a traditional medicine to treat various health conditions. This current review showed that betel leaves extract, essential oil, preparations, and isolates could inhibit microbial growth and kill various Gram-negative and Gram-positive bacteria as well as fungal species, including those that are multidrug-resistant and cause serious infectious diseases. Some studies also showed that the combination of betel leaves extract and essential oil with antibiotics (streptomycin, chloramphenicol and gentamicin) could provide potentiating antibacterial properties Mara NM (Nayaka,et.al, 2021). (Figure. 1F)

The *Chrysanthemum* contains chemicals called flavonoids, which have antioxidant and anti-inflammatory effects. It also contains chemicals that may increase blood flow to the heart. *Chrysanthemum* flowers are rich in phenolic compounds and exhibit strong properties including antioxidant, antimicrobial, anti-inflammatory, anticancer, anti-allergic, anti-obesity, immune regulation, hepatoprotective, and nephroprotective activities (Niharika Sharma, et. al, 2023) (Figure. 1G). The *Glycyrrhiza glabra* is an herbal plant which has lots of medicinal properties, there are various beneficial effects of *Glycyrrhiza glabra* (licorice) root extracts, such as treating throat infections, tuberculosis, respiratory, liver diseases, antibacterial,

anti-inflammatory, and immunodeficiency (Siracusa L, et. al, 2011). (Figure. 1H).

Findings of the current review indicated medicinal plants and phytochemicals as effective and safe agents that for the treatment of recurrent aphthous stomatitis (Shavakhi M, et. al, 2021). There is some evidence of the efficacy of topically applied natural herbal medicines with regards to improved recurrent aphthous stomatitis outcome measures and fewer side effects (Li CL, et. al, 2016). Based on this, we conducted research is there any effectiveness and how long of herbal syrup in healing process of aphthous stomatitis?

The research gap is that it takes time to provide kuldon syrup processed in factories, well-designed and high-quality randomized controlled trials are required for further exploration

This study aimed to evaluate the efficacy of Kuldon® solution in the healing process of aphthous stomatitis

MATERIALS AND METHODS

A double-blind, randomized controlled trial (RCT) was conducted with 60 subjects (27 males and 33 females), who were randomly assigned to receive either Drug A (Kuldon® solution) or Drug B (Hyaluronic Acid rinse) under consent. Pain levels were assessed using a Visual Analogue Scale (VAS), and the diameter of the lesions was measured on days 2, 5, and 7. Research was carried out at Dental Hospital Faculty of Dentistry Universitas Trisakti.

Data analysis

Data were analyzed using the Mann-Whitney test. The significance level was determined at $p < 0.05$.

RESULTS AND DISCUSSION

Result

The demographic characteristics of the 60 participants are summarized in the following table. As shown in table 1, the majority of the participants were female (55%) and Male 27 (45%), with the most size of lesion are minor 57(95%) and Mayor 3 (3%).

Table 1. The demographic characteristics.

Variables	n	%
Gender		
Female	33	55
Male	27	45
Size of lesion		
minor	57	95
mayor	3	3

Measurement of pain was using VAS in 60 patients with aphthous stomatitis before being given treatment, where the majority felt moderate pain 87% (52 patients), followed by severe pain of 13% (8 patients) and 0% (0 patients) mild pain. On the second day, 73.3% of the subjects using Drug A reported no pain, compared to 60% of those using Drug B. By the fifth day, all subjects (100%) using Drug A experienced no pain, while 90% of those using Drug B reported the same. Lesion diameter reduction was 40% for both treatments by day 2. By day 5, 90% of subjects using Drug A showed a reduction in lesion diameter, compared to 16.6% of those using Drug B.

Table 2. Normality Test Shapiro-Wilk.

			Kolmogorov-Smirnov			Shapiro-Wilk		
			Statistic	dF	Sig.	Statistic	dF	Sig.
Lesion Size	Day 0	Drug A	.276	30	.000	.724	30	.000
		Drug B	.413	30	.000	.588	30	.000
	Day-2	Drug A	.179	30	.016	.881	30	.003
		Drug B	.208	30	.002	.753	30	.000
	Day 3	Drug A	.487	30	.000	.452	30	.000
		Drug B	.470	30	.000	.497	30	.000
Pain Intensity	Day-7	Drug B	.539	30	.000	.180	30	.000
	Day 0	Drug A	.292	30	.000	.789	30	.000
		Drug B	.340	30	.000	.708	30	.000
	Day 2	Drug A	.441	30	.000	.608	30	.000
		Drug B	.353	30	.000	.712	30	.000
	Day 5	Drug B	.526	30	.000	.360	30	.000

Table 3. Statistics Analysis.

	Lesion Size				Pain Intensity (VAS)			
	Day 0	Day 2	Day 5	Day 7	Day 0	Day 2	Day 5	Day 7
Man-Whitney U Test	281.000	423.500	430.000	435.000	446.500	380.500	405.000	450.000
Wilcoxon W	746.000	888.500	895.000	900.000	911.500	845.500	870.000	915.000
Z - Test	-2.602	-.404	-.438	-1.000	-.055	-1.227	-1.762	.000
Asymp. Sig. (2-tailed)	.009	.686	.661	.317	.956	.220	.078	1.000

Discussion

On Day 2 there was an equivalence between drug A (Kuldon® solution) and drug B (Hyaluronic Acid rinse®) in reducing the diameter of the lesion, which was 40% each because it had a potent anti-inflammatory of each of these drugs. The VAS showed that as many as 22 patients (73.33%) on drug A experienced no pain. Not painful was also admitted by 18 patients (60.00%) using drug B. Drug A showed more anti inflammation and analgesics compared to drug B.

Drug A, which is a standardized commercial herbal syrup known as Kuldon® syrup, contains a vine *saga* (*Abrus precatorius*) has roots, stems, and leaves. Saga contains *glycyrrhizine A* which has activity as an anti-inflammatory, antitubercular, antiplasmodial, platelet anti-aggregation and antiallergic activity (Yuli W, M. Bakti, 2011). Abruquinone G is active as an antiviral and has toxic properties (Rahmat Endang, et.al, 2021). Another compound that also has anti-inflammatory activity is the saponin triterpene. Especially the *Glycyrrhiza glabra*, of this plant has therapeutic properties, namely extracts used as tonics, detoxification, expectorants, anti-inflammatory, antimicrobial, antiatherogenic, antiallergic, antiviral against metabolic syndrome, obesity and changes in the immune system. *Centella asiatica* has *Asiaticoside* which functions to improve the repair and strengthening of skin cells, stimulation of growth, nails, hair, connective tissue, stimulating blood cells, has good vascularization and immune system and is a type of natural antibiotic. (Steven, E, 2008). Other ingredients in Kuldon® solution play a synergistic role in causing anti-inflammation, such as *Curcuma Xanthorrhiza* has antitoxic, anti-hepatotoxic and antibacterial compounds. *Curcumin* and *xanthorrhizol* are the main active ingredient components of essential oils¹³. In betel leaf (*Piper betle*) there are eugenol as methyl eugenol, *carvacrol*, *chavicol*, *allcatechol*, *cavibetok*, *cineol*, *estagrol*, *thiamine*, *riboflavin*, and *vitamin C*. these are efficacious for antiseptic, astringent, expectorant and hemostatic (Kartasapoetra G, 1992). Reed root (*Imperata rhizoma*), a kind of weed root, is empirically used to lower temperature, help urinate, stop bleeding, and as a remedy for bleeding in the nose, vomiting blood, Gonorrhoea, hepatitis, and kidney infections (Yuli, WM, 2011). Meanwhile, thyme herb (*Thymus vulgaris*) has antimicrobial, ant stimulant, antioxidant, and anti-inflammatory properties (Yuli W, M. Bakti, 2011).

Drug B as positive control is a patent mouthwash consisting of aloe vera (*Aloe vera*), sodium hyaluronate has a hyaluronic acid content, which is an additional therapy after mechanical therapy, namely, to accelerate wound healing, anti-inflammatory, cell proliferation, and migration, angiogenesis and reepithelialization through keratin basal cell proliferation. Hyaluronic acid molecules reduce the proliferation of epithelial cells,

such as fibroblasts and lymphocytes, that play an active role in chronic inflammatory states, thereby accelerating the regeneration of new healthy tissue cells (Schroeder HE, et. al, 1983). *Glycyrrhetic acid* has pharmacological properties, namely anti-inflammatory and anti-ulcer, anti-tumour, anti-viral, anti-hepatotoxic, and *Polyvinylpyrrolidone* (PVP) (Sibbald R, et. al, 2011; Ricky, et. al, 2016, Lewis MAO, 2012).

Furthermore, on the 5th day with drug A, as many as 90.00% of patients had no visible lesions, and with drug B, only 3.44%. Drug A has good vascularization (Ehrlich Steven, 2008, Dewi Rizna Triana, et.al, 2015) and other ingredients that play a synergistic role in causing anti-inflammatory effects so that it has a better healing effect. Drug B has PVP as a binder and thickener (Ricky, et. al, 2016; Lewis MAO, 2012), so patients feel uncomfortable when using the drug. This affects subjective assessments using VAS.

In the last control (day 7), there were still 10% of patients who had healed oral lesions using drug A while 16.67% of patients were using drug B. There was a balance in the healing process based on the diameter of the lesions of the two drugs. Patients using drug A no longer felt pain on day 7, but in group drug B user, there were still 3 patients. Drug A showed better effectiveness in curing aphthous stomatitis based on a subjective assessment of the level of comfort (pain).

In the normality test, the data used for each variable is less than 50. Therefore, a normality test is carried out using the Shapiro-Wilk method. Then it was tested again using the Mann-Whitney method with a Sig or P ($p < 0.05$). The test showed a p-value of $0.000 < 0.05$, which was significant. This shows the significant effective of standardized commercial herbal syrups in the healing process of minor and major aphthous stomatitis. (Table 2; Table 3)

CONCLUSIONS

The Kuldon® solution demonstrates significant potency in the healing of aphthous stomatitis lesions.

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Conflicts of Interest: AP is on the editorial board of the *Biology, Medicine, & Natural Product Chemistry*, and

was recused from this article's review and decision. The authors declare that there are no conflicts of interest.

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