

A CLINICAL EVALUATION OF PATOLYADI LEPA IN THE MANAGEMENT OF MADHUMEHAJA VRANA

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ABSTRACT

The concept of *Vraṇa* (wound) has been around the beginning of time. The word „*Vraṇa*’ appears in Vedic literature for the first time in the context of injuries. The basics of wound cleaning, closure and splinting have been stated by several medical systems. Ayurveda is a science of life and it contains a thorough explanation of *Vraṇa*, its classification and treatment along with various local and systemic interventions. *Caraka Samhita*, *Suśruta Samhita* and *Aṣṭāṅga Hṛdaya* are the three important treatise (*Brhatrayi*) that gave detailed descriptions of *Vraṇa*. *Suśruta* (1000 B.C.), Father of Indian Surgery” had elucidated the concept of *Vraṇa*, its aetio pathogenesis, types and therapeutic options. He devised sixty protocols dealing with *Vraṇa* using numerous drugs. The wound-care principles and treatments developed by *Suśruta* are still in use today. Various researchers have studied on the wound, with encouraging results.^[1] All Ācāryas in Ayurveda classify *Prameha* as a *Mahāvvyādhi* and 20 *Prakāra* of *Prameha* are mentioned. According to

Vṛiddha Vāgbhaṭa, *Prameha* is a horrible disease since it involves all three *doṣas*, is localized in the most vital organs, lasts a long time and is accompanied with many complications. *Vraṇa* could be regarded a *Prameha Upadrava*. *Madhumehajanya Vraṇa* are typically classified as *Duṣṭa Vraṇa* and is considered *Kricchra Sādhya* or *Yāpya*. Current medicines have a low success rate and do not address the microvascular pathology that diabetics experience.^[2] The conditions for diabetic lower extremity preservation have never been great earlier several researches have been carried out. The task at hand is to get these patients back

on their feet. According to International Diabetes Federation (IDF) 540 million people across the globe are estimated to be living with diabetes.^[3] India is deemed to be the Diabetic Capital of the world and in most households, it is known as “sugar” or “The Sugar Disease”. Out of this, 25% develops Diabetic Foot Ulcers (DFU), of which 50% become infected requiring Hospitalization while 20% need amputation. DFUs contribute to approximately 80% of all non-traumatic amputations in India annually. Diabetic foot ulcer is a major complication of Diabetes Mellitus. It becomes one of the medical, social and economic problems worldwide. India being termed as capital of DM. AYUSH department of India also declared theme “Mission Madhumeha through Ayurveda”. In diabetes, 85% of leg amputations are preceded by a seemingly insignificant leg ulcer. Lower extremities issues are common in diabetic patients, afflicting one out of four people. In individuals with Diabetes, poor healing is a serious clinical issue which even lead to lower-limb amputation.^[3]

AIMS AND OBJECTIVES

Aim

- i. To study the efficacy of Patolyadi Lepa in the management of Madhumehaja Vrana.

Objectives

- i. To understand diabetic ulcer in the purview of Madhumehaja Vrana.
- ii. To study the efficacy of Patolyadi Lepa in converting Madhumehaja Vrana into Shuddha vrana.

Inclusive and exclusive criteria

Inclusive criteria

- Patients suffering from Diabetes.
- Patients suffering from Madhumehaja vrana with minimum history of 2 months
- Patients of irrespective gender.
- Patients age ranging from 30-55 years.
- Madhumehaja vrana of irrespective size.

Exclusive criteria

- Chronic systemic diseases like SLE, Multiple sclerosis, R.Arthritis
- Malignancy.
- Tuberculosis.
- Cardiac ailments like congestive heart failure, C.A.D

- Renal ailments like chronic kidney disease.
- Osteomyelitis.
- Signs of gangrene.
- Other vascular ulcers.

Assessment Criteria^[4]

The patient's response was assessed on the basis of subjective and objective criteria by assigning the suitable Grade to each parameter. The method adopted for grading. in order to assess the efficacy of procedures was as follows

SHOWING ASSESSMENT CRITERIA OF PRESENT STUDY

Subjective criteria	Objective criteria
1. Vedana (pain)	Size of the ulcer Wagner ulcer grade classification system
2. Daha (burning sensation)	
3. Kandu (itching)	
4. Srava (discharge)	

Parameters with grading

Subjective parameter grading

1. VEDANA (PAIN)

SHOWING VEDANA (PAIN) GRADING

Vedana	Grading
No pain	0
Mild (localized feeling of pain during movement, no pain at rest)	1
Moderate (localized pain at rest, sleep not disturbed)	2
Severe (continuous localized feeling of pain that disturbs sleep)	3

2. DAHA (BURNING SENSATION)

SHOWING DAHA (BURNING SENSATION) GRADING

Daha	Grading
No burning sensation	1
Mild (intermittent burning sensation)	2
Moderate (continuous burning sensation, no disturbing sleep)	3
Severe (continuous burning sensation, disturbing sleep)	4

3. KANDU (ITCHING)

SHOWING KANDU (ITCHING) GRADING

Kandu	Garding
No itching	1
Mild (slight localized itching sensation)	2

Moderate (more localized itching sensation, no disturbing sleep)	3
Severe (continuous itching, disturbed sleep)	4

4. SRAVA (DISCHARGE)

SHOWING SRAVA (DISCHARGE) GRADING

Srava (discharge)	Grading
No discharge	0
Mild (scanty, occasional discharge with little wet dressing)	1
Moderate (often discharge with blood on dressing)	2
Severe (profuse continuous discharge which needs frequent dressing)	3

b) Objective parameter grading

1. SIZE OF THE ULCER

SHOWING SIZE OF THE ULCER GRADING

Size of the ulcer	Grading
Normal (completely healed with acceptable scar)	0
Wound size 2-3 cm (reduced to 3/4 th of the initial size)	1
Wound size 4-6 cm (reduced to 1/2 th of the initial size)	2
Wound size greater than 6 cm (reduced to 1/4 th of the initial size)	3

2. WAGNER ULCER GRADE CLASSIFICATION SYSTEM

SHOWING WAGNER ULCER GRADE CLASSIFICATION SYSTEM

Wagner ulcer grade classification system	Grading
No ulcer but, high-risk foot	0
Superficial ulcer	1
Deep ulcer, no bony involvement or abscess	2
Abscess with bony involvement	3
Localized gangrene	4
Extensive gangrene involving the whole foot	5

Criteria for assessment of overall effect- it is assessed in terms of healing of ulcer (complete), marked improvement, moderate improvement, mild improvement and unchanged by adopting the following criteria

- 1. Complete healing:** No recurrence during follow up are considered to be 100% relief in chief complaint.
- 2. b. Marked improvement:** 70-99 % of improvement in chief complaint is considered as marked improvement.
- 3. c. Moderate improvement:** 50-75 % in improvement in chief complaint is considered as moderate improvement.
- 4. d. Mild improvement:** 25-49 % of improvement in chief complaint is considered as mild improvement.

5. **e. No healing:** less than 24 % reduction in chief complaint or recurrence in the chief complaint / severity of the symptoms remains unchanged is considered to be non-healing.

OBSERVATION AND RESULTS

In the assessment of subjective parameters, it was found that the percentage of benefits is significantly high in Group-A; 87.50% (*Vedanā*/ Pain) to 84.16% (*Srāva* /Discharge). It indicates the efficacy of the drug used in the trial. In Group-B, it also has shown significant percentage of benefits as the overall reduction from 81.66% (*Vedanā*/ Pain) to 84.16% (*Srāva* /Discharge) of benefit across the subjective parameters.

As per Objective parameters of the study, it was observed that the percentage of benefit in Group A is slightly high i.e. from 85.00% (Wagner's grade) to 74.16% (size of ulcer) before and after treatment. In Group-B it is slightly higher across all objective parameters i.e. from 82.50%(Wagner's grade) to 70.33% (size of ulcer). Therefore, it can be said that the method of application of *Patolyadi Lepa* is more effective in change of grade of ulcer and size of ulcer when compared to *Jatyadi Taila* application.

The progress of the therapies and their effect is also depicted as photographs of the ulcers under the trial at various stages showing the difference in features during the therapies.

Therefore, it can be said completely with evaluation and results along with the statistical analysis that Group A i.e. treated with *patolyadi lepa* has shown the maximum relief in symptoms and healing of ulcers with less wound dehiscence.

PATOLYADI LEPA^[9,10]: The probable effects of *patolyadi lepa* produced by its various properties are summarized below

- *Tikta Rasa*: *Tikta Rasa* is mainly *Dīpana*, *Pācana*, *Lekhana*, *Upaśoṣaṇa*, *Srotośodhana* and *Sthirīkaraṇa* in nature. *Tikta* is the most *Laghu* amongst the six *Rasa* there by relieving the symptom *Gaurava*. It is also *Rukṣa* and *Śīta* in nature.
- *patolyadi lepa* is mainly having *Laghu and Rukṣa Guṇa* which helps to reduce the secretion or pus formation that helps in the healing of *Vraṇa*.
- *Laghu*: *Laghu Guṇa* is known for its action of *Lāghavakara* (lightness), *Kaphaghna* (alleviating *Kapha* Doṣa) and *Śīghrapākitva* (quickly digestible). *Laghu Guṇa* also causes *Lekhana* (removes corpulence) and *Ropaṇa* (heals wound).
- *Rukṣa*: *Rukṣa Guṇa* is the opposite to *Snigdha Guṇa*. It causes absorption of excess

Kapha Doṣa, *Rasādi Dhātus* and *Malās*. It is known to be dominant in *Vāyu* and *Agni Mahābhūta* which results in the clearance the *Kledata* and *Snigdhata* from the *Vraṇa*.

- *Doṣa* involved in *DuṣṭaVraṇa* is *tridoṣa* and the ingredients of *patolyadi* together possess *Tridoṣahara* property. Combined effect of these eight drugs along with *saindva lavana* helps to alleviate the *Samprāptighaṭaka* (pathogenesis), thus helps in healing of the ulcer or *vraṇa*.
- Analysis of phytochemical profile of *patola* leaves churna have proven its antimicrobial and anti-oxidant activity.
- Presence of active compounds in *patola* such as nicotinic acid, riboflavin, Vitamin-c, 5-hydroxytryptamine, cucurbita-5 and 24-dienol plays major role in exhibiting these properties.
- Topical application of *patola patra* churna was found to be effective which seems to be responsible for wound contraction and increased rate of epithelization.
- *Tila* which is known to have *lekana* property helps in scrapping of the debris and helps in re epithelisation of the tissue and also have the property of *srotovishodanam*. It also relieves pain,
- Ethanoic extracts *yastimadhu* was found to have phytochemicals that contain several active compounds including glycyrrizin, glycyrrhithinic acid, isoflavonoids, chalcones, triterpenoids, coumarins, sterols, lignans, amino acids, amines, gums, and volatile oils are known to inhibit anti-inflammatory antioxidant, antiviral, and wound healing-tissue repair property.
- *Danti* has *shodana* property along with *krumihara* and *kanduhara*. When applied on wound it exhibits analgesic, anti-inflammatory, anti-histamine property.
- *Trivrit*, root along with *haridra* churna made into paste, when applied externally shows anti proliferative, antimicrobial, anti-inflammatory property which enhances wound healing.
- *Nimba*, another *tikta rasa pradana* drug which is *vrana-hara*, *krumihara*, *kruminut* heals wound quickly. It is anti-microbial, wound cleansing, antipruritic in action and also reduces burning sensation in wounds.

Overall effect of *Patolyadi Lepa* can be attributed to the synergistic effect of the ingredients resulting in anti-bacterial and anti-inflammatory action. Because of the presence of tannins and several other phyto-constituents it promotes the production of collagen. When used externally for *Lepa* it also shows *Lekhana* property, which removes the dead skin, and in

turns encourages the formation of epithelium and also stops the production of pus and debris, hence helps in the quick and complete healing of the wound.

CONCLUSION

The present study entitled with “*A Clinical Evaluation of Patolyadi Lepa in The Management of Madhumehaja Vrana (Diabetic Foot Ulcer)*” was carried out with 40 patients divided into 2 Groups.

- GROUP A – Application of *Patolyadi Lepa*
- GROUP B – Application of *Jatyadi taila*.

This treatment protocol was conducted for 30 days with three months of follow up. At the end of the clinical trial the following Conclusions are drawn

- Application of *Patolydi Lepa* is done for Group A for 30 days on the ulcer. The reference of *Lepa* has been taken from Chakradatta (chikitsasangraha) chapter XLIV under the context of Treatment of *Vranasotha*. As it is easy to prepare and apply and has become a handy and effective remedy to patients suffering from Diabetic ulcer.
- Application of *Jatyadi taila* has been done for 30 days.
- The application of *Patolyadi Lepa* is found to be as effective as *Jatyadi taila* in the management of Diabetic ulcers due to the synergistic effect of the ingredients resulting in anti-inflammatory, anti-Fungal, Anti diabetic, anti-microbial, antihistamine action. The drug that consists of 8 ingredients which shows various activities in wound cleansing and wound healing help in faster and better healing depending on the chronicity of the ulcer.
- *Patolyadi Lepa* contains *Tila*, *Daruharidra* which shows *Lekhana* property, that removes the dead skin, and in turns encourages the formation of epithelium and also stops the production of pus and Debris, *Yastimadhu*, *Haridra*, *Patola*, *Danti*, *Nimba* has *shodana*, *ropana* property, hence helps in the quick and complete healing of the wound.
- After overall assessment of the procedure for *Madhumehaja Vrana* (Diabetic Foot Ulcer), *Patolyadi Lepa* as External Application is more beneficial and economically feasible for the patients suffering from long standing non-healing ulcers.
- There were no complications that occurred during the study and any other adverse reactions reported in the study due to the procedures applied in the clinical trial.
- The status of completely healed ulcers was observed as healthy with light scar without spasm directs us to understand the ‘*Vaikṛtāpaham*’ (good cosmetic value) methods.
- The status of wound healing was recorded as completely healed, healed and static and

Spreading type.

- No single case has been recorded under spreading type of ulcer whereas 6 cases have shown recurrence rate after the follow-up duration.
- Hence both the trials conducted in the study has shown very significant variation in the symptoms and both are simple, cost effective, easily administered and very much safe in any kind of patients as Diabetic ulcer is mostly seen at the old age due to the reason that elderly people are prone to Peripheral neuropathy, foot deformities and Peripheral Arterial Diseases (PAD). The *Nija Vraṇa* may be caused by certain systemic disorders occurring as a complication of *Madhumehajanya Vraṇa*. It generally occurs in the later stage of life, where *Sanga* and *Vimārgagamana* type of *Srotoduṣṭi* is the main factor.
- The present clinical trial is a limited study where both the therapies are administered to only 40 patients and its effectiveness can be completely evaluated when this trial has been done in larger groups to specify the exact mode of action and efficacy.
- However, in most cases in the trial, the healing is in positive mode and it is observed in a few cases complete healing has occurred even before the trial duration. In few cases complete healing has occurred after the follow-up whereas the recurrence rate is far less compared to any other therapies of wound healing in *Madhumehaja Vrana*.

SCOPE FOR FURTHER STUDY

- Further research is needed to do sensitivity study to find specific anti- microbial activity.
- Effect of *Patolyadi Lepa* on *Madhumehaja Vrana* with Histopathological studies before and after treatment can be studied.
- Duration of the study can be extended to get better results.
- Further research in a novel approach for developing a Topical Drug Delivery System in the form of Transdermal patches made from the formulations used in this clinical study.
- Feasibility in external application of *Patolyadi Gana* drugs and *Yastimadu*, *Nimba*, *Trivrit* etc in the form of creams.

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