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CONTROL RANDOMISED OPEN STUDY ON WOUND HEALING BY LOCAL APPLICATION OF *SESAMUM INDICUM* AND HONEY

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ABSTRACT

Wound is delineated as disruption of structural and physiological continuity of a living tissue. It may be produced by physical, chemical, thermal, microbial, or immunological damage to the tissue. Healing of wounds is one of the important areas of clinical surgery explained in many *Ayurvedic* texts. The Indian traditional system of medicine, *Ayurveda* is based on empirical knowledge of the observations and the experience over millennia. The healing of wound is the central focus of surgery. *Aacharya Sushruta* has given the prime position to ‘‘Wound, i.e. *Vrana*’’. He has described all types of wounds and their complete management. He has mentioned sixty measures for the management of wound. *Kalka* application is one of them. This study aims to establish this measure mentioned by *Sushruta* as compared to the modern methods of wound management. For the present study 50 patients fulfilling the inclusive criteria were selected. The patients were classified into two groups, Group A and Group B, each containing 25 patients. ‘Group A’ was taken as experimental group on which the local application of *Tilakalka* and *Madhu* was given and ‘Group B’ was taken as the control group in which suturing was done with silk material. After this therapy, significant result was observed with respect to objective parameters, which marks that *Kalka* application is as effective as suturing.

Keywords - *Sadyo Vrana, Chinna Vrana, Tila Kalka, Madhu.*

INTRODUCTION

According to the *Ayurveda*, *Vrana* (wounds or ulcers) is the discontinuation of lining membrane that after healing leaves a scar for life closely resembling the modern definition of wounds. Similarly, inflammation is considered to be an early phase in the wound pathogenesis termed *Vranashotha* (inflammatory changes of wounds). Various types of wounds as mentioned in *Ayurveda* may be endogenous in origin due to a defect in human functional units, such as *Vata*, *Pitta*, and *Kapha*, or exogenous because of trauma, such as *Viddha* (punctured wound), *Chinna* (cut wound), *Bhinna* (perforated wound), *Picchita* (contusion), *Kshata* (lacerated wound), and *Ghrista* (abrasion wound) . According to *Sushruta samhita*, classical management of wounds follow 60 therapeutic steps, starting with an aseptic dressing of the affected part of

body and ending with the rehabilitation of the normal structure and function. These therapeutic measures were concentrated not only to accelerate the healing process but also to maintain the quality and aesthetics of the healing. As described in different *Ayurvedic* classics like *Charaka Samhita* (ca. 5000 b.c.), *Sushruta Samhita* (ca. 1000 b.c.), *Ashtanga Hridaya* (ca. a.d. 600), *Dhanwantari Nighantu* (ca. a.d. 1800), *Bhavaprakash Nighantu* (ca. a.d. 1500), and *Ayurveda Siksha* (a.d. 20th century), it has been estimated that 70% of the wound healing *Ayurvedic* drugs are of plant origin, 20% of mineral origin, and remaining 10% arise from animal products. These drugs are stated to be effective in various conditions such as *Vrana* (wounds or ulcers), *Nadivrana* (sinuses), *Vranajakrimi* (maggots in wounds), *Vidradhi* (abscess), *Visarpa* (erysipelas), *Upadamsha* (syphilitic ulcers), *Netravrana* (hordeolum), *Dustavrana* (septic wounds), *Vranashotha*, *Vranavisha* (cellulitis), *Ugravrana* (purulative ulcer), *Pramehapidaka* (diabetic carbuncle), and *Bhagandara* (fistula-in-ano)[2]. Scientific investigations have also been carried out to assess the wound healing properties of some these drugs. Many *Ayurvedic* herbal plants have a very important role in the process of wound healing. Plants are more potent wound healers because they promote and enhance the repair mechanisms in the natural way. Herbal medicines in wound management involve disinfection, debridement and providing a moist environment to encourage the establishment of the suitable environment for natural healing processes. Hence keeping in mind the prevalence of wound, an attempt is made to evaluate and establish the therapeutic efficacy of *Tila kalka* and *Madhu* as a local application.

MATERIALS AND METHODS

Materials -The material selected for this study is *Tila* and *Madhu*. For the Physico-chemical analysis, methods were adopted as given in *Ayurvedic* pharmacopeia of India. *Tila beeja* were taken and crushed to make a fine paste and then sterilized by steam autoclave method. At the time of clinical trial this *Tila Kalka* was taken in a sterilized dish and the same quantity of *Madhu* is mixed thoroughly with it as per the requirement. This paste was applied locally on *Sadyo Vrana*.

Methods

Clinical source- Fifty patients of *Sadyo Vrana* were selected from OPD, Department of *Shalya Tantra*, Government Ayurved Hospital, Nagpur.

Study design- It is an open control clinical trial.

Method of collection of data (including sampling procedures)

Patients of *Sadyo Vrana* were selected randomly by lottery method, irrespective of their age, sex, caste, religion, educational, marital and socio-economic status. Detail history of all the patients were obtained about the episode of injury, causative factor and duration of *Sadyo Vrana*. To take the review of patients, special proforma was prepared. Signs and symptoms of *Vrana*, before, during and after the treatment were noted. Routine heamatological and urine examinations were carried out to assess the condition of the patient as well as to exclude other pathology. Patients were classified into two groups, Group A and Group B, each containing 25 patients. 'Group A' was taken as experimental group on which the local application of

Tila Kalka and *Madhu* was applied and 'Group B' was taken as the control group in which suturing was done with silk thread. Duration of the treatment was fixed up to 2 to 7 days

Inclusion criteria - The patients of *Sadyo Vrana* were selected on the basis of following criteria.

1. Patients having *Chinna Vrana* of maximum length 5 cm. and depth 3 cm.
2. Patients having maximum two days of duration of *Vrana*.
3. Patients without any complications.

Exclusion criteria -

1. Patients having deeper wound tearing muscle beneath.
2. Patients having profuse bleeding due to vascular injury.
3. Patients having major complications like diabetes mellitus, varicose veins.

Assessment response: The improvements of patients were assessed on the basis of relief in below mentioned objective parameters.

1. Pain
2. Tenderness
3. Colour
4. Margins
5. Floor
6. Inflammation
7. Smell
8. Discharge

According to severity, grading for the parameters was done. (Table no. 1,2,3,4,5,6,7,8)

Statistical Analysis: Descriptive data that included Mean, Standard Deviation (S.D), Standard Error (S.E), t value and p value were calculated for all the variables in trial group. Post treatment changes were assessed by paired t test. (Significance level: P>0.05)

Assessment of the overall effect: To assess the overall effect of the therapies, net results obtained on various parameters of assessment, both, before and after treatment were taken into consideration. Then it was graded in terms of percentage of relief in symptoms. (Table no. 9)

Grading of Remarks or Criteria for assessment of overall effects of the therapy

Complete cure - 100% relief
Marked improvement - >66% to <100%
Moderate improvement- >33 to <66% of relief
Mild Improvement - >1 to <33 % of relief
Unchanged - 0% of relief

Follow up study: Follow up study was undertaken for 7 days after the treatment schedule to assess the result.

RESULTS-

Effect of therapy on the objective parameters i.e. size- The trial drug – a paste of *Tila* and *Madhu* after local application on *Sadya Vrana* provided high significant result on decrease in size of the *Vrana* after 7 days treatment with $p < 0.001$. Also in control group there is high significant decrease in the size of the wound with $p < 0.001$. Thus the result in both the groups were highly significant implies that both the treatments have equal effect on the healing of the wound. (Table no. 10)

Overall result of the treatment - In experimental group, 19 patients were cured and 6 patients were relieved i.e. 76% patients cured and 24 patients relieved. In control group, 18 i.e. 72% patients were cured, 2 i.e.8% patients were relieved and 4 i.e. 16% patients were improved. In this group 1 i.e. 4% patients showed no change.Out of total 50 patients, 37 patients i.e. 74% were cured, 8 patients i.e. 16%

were relieved, 4 patients i.e. 8% were improved and 1 patient i.e. 2% showed no change during clinical study. All the patients in this series were followed the treatment regularly throughout the treatment period. (Table no 11)

Result of phytochemical analysis of *Tila* and Honey

***Tila* :-** Plants have the immense potential for the management and treatment of wounds. In most of the countries, a large number of plants are used by tribal and folklore for the treatment of wounds and burns. These natural agents induce healing and regeneration of the lost tissue by various mechanisms. These phytomedicine are not only cheap and affordable but are also very safe. The presence of wide range of life-sustaining constituents in plants has urged scientists to examine these plants with a view to determine potential wound healing properties. This small bush is indigenous to India and extensively cultivated in the warmer regions. It is an erect, pubescent annual, reaching 30 cm. to 1 meter in height. Parts used – seeds and fixed oil expressed from the seeds

Varieties – Three varieties of seeds are found, black, white and red or brown. Out of these, black variety is best for medicinal use.

Properties – *Guna - Guru, Snigdha, Vyavayi* (according to *Charaka*)

Brimhan, Sukshma, Prinana, Vrishya, Tvakaprasadana, Medhya (according to *Sushruta*)

Rasa – Madhura

Anurasa – Kashaya, Tikta

Virya – Ushna

Vipaka – Katu (Charaka and Vagbhata), Madhu (Sushruta)

Doshaghnata – Vatashamaka, Kaphaprakopaka, Pittaprakopaka

Classical reference for wound healing –

1. Paste of *Tila* and *Madhu* mixed with ghee is useful for wound healing.
2. Wounds which are free from pus but do not heal easily should be treated with the application of the paste of *Tila* mixed with Honey

Chemical composition of the *Tila* –

The seeds contain vitamins like thiamine, niacin, riboflavin, nicotinic acid, panthothenic acid, folic acid, ascorbic acid, sholine, inosital, pyridoxine, α-tocopherol & β-tocopherol. It also contains sugars like glucose, sucrose, galactose, plantiose, raffinose, fatty acids such as palmitic acid, arachidic acid, myristic acid, stearic acid, oleic acid, linoleic acid, hexadecenoic acid, linoceric acid and antioxidents like sesamol and sesamolinol.

Inorganic constituents of *Tila* seeds –

Protein – 5.1 mg/gm
Fat – 43.3 mg/gm
Minerals - 5.2 mg/gm
Carbohydrates – 25.3 mg/gm
Calcium - 1.45 mg/gm
Phosphorus - 0.27 mg/gm
Iron - 5.47 mg/gm

Many research studies have been carried out to examine the value of topical application of honey for wound healing. *Madhu* is commonly used as *Anupana* (i.e., given along with active medication to enhance activity) and also, sometimes, for its primary medical property systemically as well as locally, either alone or in combination with other drugs. It has been described to have properties like *Lekhana* (scraping), *Sandhana* (union), *Shodhana* (purification), *Ropana* (healing), and *Tridoshaghna*. It is used as an external application in *Vrana* (wound), either alone

or in combination with *Sarpi (Goghrita*, i.e., ghee made from cow's milk).

Honey is hygroscopic in nature, with a pH of 3.2–4.5. It prevents colonization and bacterial growth in tissues due to this acidic nature. Most microorganisms do not grow in pure honey because of its low water activity (a_w) of 0.6. Honey also has antibacterial properties. The presence of hydrogen peroxide and high osmotic pressure also contribute to the antibacterial effect of honey. These natural properties of *Madhu* are said to make it suitable for use in wound management.

Madhu has *Vranaropaka* properties as per the principles of the sixty *Upakramas* of *Vrana* management described in the *Sushruta Samhita*. *Madhu* is believed to act by 'pacifying' the three vitiated *Doshas*, i.e,. *Vata, Pitta*, and *Kapha* by multiple actions attributable to its *Madhura* (sweet) *Rasa, Kashaya* (astringent) *Uparasa*, *Ruksha* (dry) *Guna, Sheeta Virya, Madhura Vipaka,* and *Sukshma Marganusari* (ability to permeate in micro channels) *Prabhava. Madhura Rasa* gives nutrition to the tissue, which helps in granulation tissue formation, while *Kashaya Rasa* provides *Lekhana* (scraping) that helps in de-sloughing, preparing the wound for healing. Thus, *Madhu* has excellent properties to heal the wound by virtue of its *Sodhana* (purification), *Ropana* (healing), and *Sandhana* (union) actions.

Madhu has been described as having the ability to promote phagocytosis, detoxification, and proteolyses, all of which assist in cleaning the wound. Further, *Madhu* pacifies *Pitta Dosha* by virtue of its *Madhura Rasa* and *Sheeta Guna*. *Kapha* is taken care of with *Kashaya Rasa* and *Ruksha Guna*, which accelerate healing. Honey is a hyperosmolar medium, preventing bacterial growth. Because of its high viscosity it forms a physical barrier, and the presence of the enzyme 'Catalase' gives honey antioxidant properties. Honey has been shown to be useful in the prevention of hypertrophic scarring and post-burn contractures. Honey is a very effective agent for dressing of split-thickness skin graft. In our patient, healing occurred with minimal scar formation. This compound is found to exhibit *Rasayana* effect.

There were no adverse events throughout the management and healing occurred uneventfully. The mode of treatment was found to be cost-effective, safe, and easy to implement.

DISCUSSION

According to the *Ayurveda*, *Vrana* (wounds or ulcers) is the discontinuation of lining membrane which after healing leaves a scar for life, closely resembling the modern definition of wounds. Similarly, inflammation is considered to be an early phase in the wound pathogenesis termed *Vranashotha*. Various types of wounds as mentioned in *Ayurveda* may be endogenous in origin due to a defect in human functional units, such as *Vata, Pitta*, and *Kapha*, or exogenous because of trauma, such as *Viddha* (punctured wound), *Chinna* (cut wound), *Bhinna* (perforated wound), *Picchita* (contusion), *Kshata* (lacerated wound), and *Ghrista* (abrasion wound) . According to *Sushruta Samhita*, classical management of wounds follow 60 therapeutic steps, starting with an aseptic dressing of the affected part of body and ending with the rehabilitation of the

normal structure and function. These therapeutic measures were concentrated not only to accelerate the healing process but also to maintain the quality and aesthetics of the healing. *Tila Kalka* is from plant origin and *Madhu* is from animal origin. Both when mixed together found to have a great wound healing properties, in case of fresh wound which is not infected. After overall statistical analysis it was found that the local application of both drugs is as effective as conventional suturing/stitches. These drugs are also easily available and cost effective. Hence can be used as alternative for stitches where suture material is not easily available.

CONCLUSION

After completion of the above study we can postulate that-

1. The pain in the wound was effectively reduced due to *Madhura Rasa.*
2. There was highly significant reduction in discharge due to *Tikta anurasa* and *Ruksha guna.*
3. There was reduction in tenderness due to *Ushna veerya* of the drug.
4. The colour was significantly changed due to *Twakprasadan guna.*
5. Smell was reduced due to *Kledahara* property of *Kashaya*, *Tikta anurasa* and *Ruksha guna* of drugs.
6. There was closure of margins due to *Kashaya rasa* and *Vranropaka guna.*
7. There was effective reduction in floor size due to *Vranashodhaka* property.
8. Due to *Madhura rasa* and *Kashaya anurasa* with *Vranropaka Guna*, there was highly significant reduction in size of wound.
9. Overall no major side effects of local application of *Tilakalka* and *Madhu* were observed during the entire clinical study.
10. In experimental group, 76% patients were cured, 24% patients were relieved while in control group 72% patients were cured, 8% patients were relieved, 16% patients were improved and 4% patients were having no change in signs and symptoms.
11. All observations clearly show that *Tilakalka* and *Madhu* local application was as effective as suturing.

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Table 1 Assessment of pain

Sr no.	Observation	Score
1	No pain	0
2	Localized feeling of pain during movements only but no feeling during rest	1
3	Localized feeling of pain even during rest but not radiating	2
4	Localized continuous feeling of pain radiating and not relieved by rest	3

Table 2 Assessment of tenderness

Sr.No.	Observation	Score
1	Tolerance to pressure	0
2	Little response to sudden pressure	1
3	Wincing of face on superficial slight touch	2
4	Resist to touch & rigidity	

Table 3 Assessment of colour

Sr.No.	Observation	score
1	Normal pigmentation	0
2	Slight red	1
3	Reddish black	2
4	Pale yellow /blackish /bluish	3

Table 4 Assessment of margin

Sr. No.	Observation	score
1	Adhering margins	0
2	Smooth, even & regular	1

3	Rough, regular & inflamed	2
4	Rough, irregular & ugly look	3

Table 5 Assessment of floor

Sr. No.	Observation	Score
1	Smooth, regular with healthy granulation tissue, no need of dressing	0
2	Smooth, regular, slight discharge, less granulation tissue, need of dressing	1
3	Rough, regular, wet with more discharge, need of dressing	2
4	Rough, irregular with profuse discharge, needs frequent dressing	3

Table 6 Assessment of inflammation

Sr.No.	Observation	Score
1	No inflammation	0
2	Slight inflammation & slight red colour	1
3	More inflammation & dark red colour	2
4	Resist to touch with high inflammation & reddish angry look	3

Table 7 Assessment of smell

Sr.No.	Observation	Score
1	No smell	0
2	Bad smell	1
3	Tolerable unpleasant smell	2
4	Intolerable foul smell	3

Table 8 Assessment of discharge

Sr.No.	Observation	Score
1	No discharge, dry dressing	0
2	Scanty, occasional discharge & little wet dressing	1
3	Often discharge, needs daily dressing	2
4	Profuse, continuous discharge which needs frequent dressing	3

Table 9 Effect of therapy on signs & symptoms

Sr. No.	Signs & Symptoms	Group	Score			Relief in %
			BT	AT	Difference	
1	Pain	A	65	01	64	98.46
		B	65	03	62	95.38
2	Discharge	A	44	00	44	100
		B	63	03	60	95.22
3	Tenderness	A	51	01	50	98.03
		B	52	05	47	90.38
4	Colour	A	46	01	45	97.82
		B	59	07	52	88.13
5	Smell	A	35	00	35	100

		B	26	05	21	80.76
6	Margins	A	36	00	36	100
		B	31	06	25	80.64
7	Floor	A	35	00	35	100
		B	29	04	25	86.20
8	Inflammation	A	34	00	34	100
		B	38	04	34	89.47

Table 10 Effect of therapy on size of sadyo vrana

Sr. No.	Parameter	Group	Mean ± SD		Mean of differences	SE	t value	p value
			BT	AT				
1	Size in cm	A	2.7 ± 2.0	0.325 ± 0. 199	2.58 ± 1.916	0.391	6.598	< 0.001
		B	4.84 ± 2.99	1.598 ± 1.135	4.388 ± 2.694	0.538	8.156	<0.001

Table 11 Result of therapy

Sr. No.	Result Observed	Treated Group		Control Group		Total no. of patients	Total
		No. of patients	%	No. of patients	%		
1	Cured	19	76	18	72	37	74
2	Relieved	06	24	02	08	08	16
3	Improved	00	00	04	16	04	08
4	No change	00	00	01	04	01	02
5	Not Followed	00	00	00	00	00	00

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