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A COMPARATIVE CLINICAL STUDY OF *TILA-KALKA LEPA* AND *KARAVIRA AVACHOORNANA* IN THE MANAGEMENT *DUSHTA-VRANA*

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ABSTRACT

In practice, *Dushta-Vrana* is one of the most common encountered problem faced by Surgeons. *Vrana* is the condition associated with *Dhatu nasha* (Destruction of tissue), and characterised by *Vedana* (Pain), *Srava* (Discharge) and *Vikriti* (Deformity). Commonly, poor hygiene and malnourished conditions increases the infection in *Vrana*, causes delayed healing, and ultimately converts *Vrana* into *Dushta-Vrana* (Non-healing wounds). In modern surgical practice, cases of *Dushta-Vrana* are managed by dressing with antiseptic solutions, administration of anti-inflammatory and analgesic drugs, debridement, skin grafting, amputation, etc. Many of such techniques are expensive and also not successful in many cases. Hence, there is a need of appropriate *Ayurvedic* management to cure *Dushta-Vrana*. In the present research "A COMPARATIVE CLINICAL STUDY OF *TILA-KALKA LEPA* AND *KARAVIRA-AVACHOORNANA* IN THE MANAGEMENT OF *DUSHTA-VRANA*" has been evaluated which is free from above mentioned drawbacks. Total 30 patients were taken and randomly divided into two equal groups based on inclusion and exclusion criteria. Local application of selected drugs was done in respective groups after *Nirgundi Kwath prakshalana*, followed by sterile bandaging once daily. Assessment was done according to subjective and objective parameters. The observations showed that 100% patients got cured in Group A; and 86.67% were cured and 13.33% were markedly improved in Group B, without any complications. Result was observed on the basis of subjective parameters (Pain, Itching) and Objective

parameters (Tenderness, Discharge, Size, Floor/Granulation, and Smell) and analysed statistically. Although *Tila-Kalka Lepa* and *Karavira Avachoornana* both showed magnificent results in curing patients suffering from *Dushta-Vrana*, but on the basis of overall effect of therapy, it was found that *Tila-Kalka Lepa* showed better result than *Karavira Avachoornana*. Moreover, both classical herbal formulations were well accepted by all patients and did not produce any side effect during study period as well as follow up.

KEYWORDS: *Dushta-Vrana, Tila-Kalka Lepa, Karavira Avachoornana*.

INTRODUCTION

While explaining the scope of *Shalya Tantra*, *Acharya Sushruta* has mentioned *Vrana Vinischayartham* as a major part of *Shalya Tantra*. The history of medical science start with the art and skills of wound healing. The frequency of injuries is more common than any other diseases. In *Sushruta Samhita*, *Acharya Sushruta* –'Father of Indian Surgery', has explained its complications and management in great detail. *Vrana* is the most important part of *Shalya Tantra* and authentic texts have emphasised a lot on wound care occurring either due to trauma or a result of vitiated *Doshas. Vrana* has been described as *"Vranagatravichurnane Vranayatiti Vranah*"[1], "*Gatra"* means part of the body or tissue; "*Vichurnane*" means destruction, break or discontinuity. So, *Vrana* is defined as the destruction, break or discontinuity of the body tissue.

CONCEPT OF *DUSHTA-VRANA*

Wounds which need extra therapeutic effort in their management are considered as *Dushta-Vrana.* They need an extra attentive approach for their management.[2]

If the patient of *Vrana* is treated by ignorant *Vaidya*, then *Shuddha Vrana* gets converted into *Dushta-Vrana* due to the involvement of *Doshas.*[3]

Acharya Charaka has defined *Dushta-Vrana* as foul smelling, discoloured, with excessive discharge and extremely painful.[4]

Acharya Madhavkar defines *Dushta-Vrana* as having discharge of pus, pus mixed with blood, deep seated with hollow cavity, chronic in nature, foul smelling and opposite to *Lakshana* of *Shuddha Vrana*.[5]

The failure of the natural wound healing mechanism leads to chronicity of the wound. Several factors affect the natural process of wound healing such as the site of wound, contamination (foreign bodies/bacteria etc.), vascular insufficiency, previous radiation, Diabetes mellitus, etc. All these factors interfere in the normal process of wound healing and may lead into a complex stage, viz. *Dushta-Vrana*. Here, *Ayurveda* comes to rescue by providing proper treatment with nil or minimal adverse effects along with other preventive measures to avoid recurrence. It has become more significant in exploring effective formulations which possesses both *Vrana Shodhna* and *Vrana Ropana* properties. *Acharya Sushruta* has described *Shashti-upkramas* for complete wound management[6], of which, for the purpose of *Shodhana* and *Ropana* of *Vrana*, seven measures are mentioned. These are *Kashaya, Kalka, Varti, Rasakriya, Avachoornana, Taila* and *Sarpi.*[7] *Tila Kalka Lepa* and *Karavira Avachoornana* are among them. These have their own specific indications in the management of *Vrana* and contain the drugs possessing *Shodhana* and *Ropana* properties. Thus, it is considered as a best virtue of curative measures for local treatment of *Vrana*.

MATERIAL AND METHODS

AIMS AND OBJECTIVES

- To evaluate the efficacy of *Tila-Kalka Lepa* after *Nirgundi kwath prakshalana* in the management of *Dushta-Vrana.*
- To evaluate the efficacy of *Karavira-Avachoornana* after *Nirgundi kwath prakshalana* in the management of *Dushta-Vrana.*
- To compare the efficacy of *Tila-Kalka Lepa* with *Karavira-Avachoornana* in the management of *Dushta-Vrana*.
- To find out any adverse effect of *Tila-Kalka Lepa* in the management of *Dushta-Vrana.*
- To find out any adverse effect of *Karavira-Avachoornana* in the management of *Dushta-Vrana*.
- To find out an alternative cost effective, affordable & easily available curative conservative management for *Dusta-Vrana.*

SELECTION OF PATIENTS

The Patients with signs and symptoms of *Dushta-Vrana* which were fulfilling the clinical criteria of diagnosis were randomly selected and registered irrespective of their sex, religion, occupation, education, etc. from O.P.D and I.P.D of P.G Department of Shalya Tantra,

Rishikul Ayurvedic College and Hospital, Uttarakhand Ayurved University, Haridwar [U.K] India. Total 30 patients were selected for the study.

An elaborative case taking proforma was specially designed for the purpose of incorporating all aspects of the disease on *Ayurvedic* and other classical literature with relevant modern medical literature. Written informed consent was taken from all the registered patients for the trial.

SAMPLING TECHNIQUE

A total number of 30 patients with signs and symptoms of *Dushta-Vrana* were registered and randomly divided into two groups, viz.

Group A – In Group A, Patients (15) were treated with *Tila-Kalka Lepa* (local application) after *Nirgundi Kwath prakshalana* for the management of *Dushta-Vrana*.

Group B- In Group B, Patients (15) were treated with *Karavira Avachoornana* (local application) after *Nirgundi Kwath prakshalana* for the management of *Dushta-Vrana*.

INCLUSION CRITERIA

- Patient suffering from *Dushta-Vrana,* on any part of the body.
- All age groups, irrespective of sex.
- Non –specific ulcers.
- Abscess wound

EXCLUSION CRITERIA

- Malignant ulcer
- Tubercular ulcer
- Leprosy
- HIV, HbsAg, HCV Positive patients
- Underlying bony lesions

NATURE OF THE STUDY

The clinical study was divided into three phases.

1) Diagnosis phase
2) Interventional phase
3) Assessment phase

1) DIAGNOSIS PHASE

All patients of *Dushta-Vrana* were diagnosed on the basis of clinical presentation of *Dushta-Vrana*, by both *Ayurvedic* and Modern parameters.

A) EXAMINATION OF PATIENT

Each case was thoroughly examined and investigated as per the detailed proforma designed for this present clinical study on *Dushta-Vrana.*

B) INVESTIGATIONS

Laboratory Investigations

- Hematological investigation- Hb%, TLC, DLC, ESR.
- Biochemical investigation- B.sugar, S.bilirubin, B.urea, S.creatinine.
- Viral marker - HbsAg, HCV, HIV 1&2.

2) INTERVENTIONAL PHASE

Group A- In this group dressing was done with *Tila-Kalka Lepa* after *Nirgundi Kwath prakshalana*.

Group B - In this group dressing was done with *Karavira-Avachoornana* after *Nirgundi Kwath prakshalana.*

PLAN OF WORK

Collection of Drugs

- ***Nirgundi*** **–** *Nirgundi* leaves was collected from herbal garden of Rishikul Ayurvedic College and Hospital Haridwar.
- ***Tila-Kalka Lepa***- *Tila* was collected from an authentic store and *Madhu* was collected from honeycomb, at vatika of Rishikul campus, Haridwar.
- ***Karavira- Avachoornana*** **–** *Karavira* root bark was collected from herbal garden of Rishikul Ayurvedic College and Hospital, Haridwar.

All the drugs were identified and verified by Head of the *Dravya Guna* department, Rishikul Ayurvedic College and Hospital, Haridwar. The clinical trial was approved by Institutional Ethical Committee (IEC approval letter No. UAU/RC/IEC/2018-19/03/17.11.18 dated 30/10/2018) & registered in Clinical Trials Registry-India (No.:CTRI/2019/05/019046).

Storage of Drugs

- *Tila-Kalka Lepa* and *Karavira Churna* were stored in sterile air tight jar at cool dry place.
- *Nirgundi Kwath* was freshly prepared before each procedure of dressing (*Tila-Kalka Lepa* and *Karavira Avachoornana*).

Method of preparation of *Nirgundi Kwath*

First of all, raw dried drug *(Nirgundi Patra)* was made into coarse powder form. Then sixteen times of water was added and the whole mixture was left for soaking for one whole night. Next morning, it was boiled under mild heat until it remains 1/8th of original. After that, it was strained through three layered folded clean cotton thin cloth and then collected in a sterilized container for *Vrana-Prakshalana*.

Method of applying of *Nirgundi Kwath*

Irrigation of freshly prepared luke warm *Nirgundi Kwath* was done over *Dushta-Vrana.*

Method of preparation of *Tila-Kalka Lepa*

At first, clean seeds of *Krishna Tila* were converted into *Kalka* first by grinding alone, and then mixing with appropriate quantity of *Madhu* in Mortar & Pestle under all aseptic precautions. As a result *Tila-Kalka Lepa* was obtained. This *Lepa* was stored in air tight sterile container.

Method of applying *Tila-Kalka Lepa*

It was applied over the *Dushta-Vrana* in appropriate thickness according to the size of *Dushta-Vrana* after *Nirgundi Kwath Prakshalana*.

Method of preparation of *Karavira Avachoornana*

First of all, *Shodhana* of *Karavira* was done with *Go-dugdha* by *Dola-Yantra* procedure. Then dried and *Shodhita Karavira* was subjected to grinding for formation of *Churna.* This *Karavira Churna* was stored in air-tight sterile container.

Method of applying *Karavira Avachoornana*

This powdered form of *Shodhit Karavira* (*Churna*) was sprinkled over *Dushta-Vrana* in appropriate amount according to the size of *Dushta-Vrana* after *Nirgundi Kwath Prakshalana.*

MANAGEMENT OF *VRANA*

- Under all aseptic precautions, *Vrana* was cleaned with freshly prepared *Nirgundi Kwath* irrigation.
- Devitalized dead tissue debridement was carried out in some cases as per the indication without using anesthesia.
- Area was dried by a sterile gauze piece.

Group A- *Tila-Kalka Lepa* was applied over the wound surface in appropriate quantity according to the size of *Vrana*, over it a sterile gauze and pad was placed and bandaging was done.

Group B- *Karavira Churna* was sprinkled over the wound surface in appropriate quantity according to the size of *Vrana*, over it a sterile gauze and pad was placed and bandaging was done.

SUBJECTIVE PARAMETERS

1. Pain
2. Itching

OBJECTIVE PARAMETERS

1. Tenderness
2. Foul Smell
3. Floor/Granulation
4. Size
5. Discharge

Grading For Assessment of Pain

Grade-0- No Pain.

Grade-1-Localized feeling of pain during movement only but no feeling during rest.

Grade-2- Localized feeling of pain even during rest but not disturbing the sleep.

Grade-3- Localized continuous feeling of pain, which disturbs sleep also.

Grading for Assessment of Itching

Grade-0-No Itching

Grade-1 -Slight and localized

Grade-2-More and localized but not disturbs sleep

Grade-3-Continuous itching, disturbs sleep

Grading for Assessment of Tenderness

Grade-0-Tolerence to pressure

Grade-1-Little response on sudden pressure

Grade-2-Wincing on face on super slight touch

Grade-3-Resists to touch

Grading for Smell

Grade-0- No smell.

Grade-1-Little smell

Grade-2-Unpleasent but tolerable

Grade-3-Foul smell which is intolerable

Grading for Granulation

Grade-0- Smooth, regular, healthy granulation tissue

Grade-1- Smooth, irregular, with less granulation tissue

Grade-2-Rough, irregular with moderate discharge, firm scar

Grade-3-Rough, irregular with profuse discharge, hard scar

Grading for Discharge

Grade-0-No discharge

Grade-1-Scanty occasional discharge

Grade-2-Often discharge

Grade-3-Profuse continuous discharge

Grading for Size

Grade-0-No discontinuity of skin

Grade-1-up to 5 cm

Grade-2-More than 5cm but less than 10cm

Grade-3-More than 10cm

3) ASSESSMENT PHASE

ASSESSMENT

- The overall improvement was assessed by the patients sign and symptoms according to subjective and objective parameters.
- It was done on every 15 days.

DURATION OF STUDY

The duration of treatment was 6 months, maximum.

FOLLOW-UP STUDY

Follow up patients were asked to come at an interval of 15 days for a period of two months after completion of therapy.

STATISTICAL ANALYSIS

All information which were based on various parameters were gathered and statistical analysis was carried out in terms of Mean (X), Standard deviation (S.D), Standard error (S.E), Wilcoxon test and finally result were incorporated term of probability 'P' as –

P > 0.05 – Insignificant

P 0.01-0.05 – Significant

P <0.001 – Highly significant

PRESENTATION OF DATA

All collected clinical data was compiled, distributed and presented as follows:

- Distribution of studied cases category and group wise
- General observations
- Effect of therapies on subjective and objective parameters
- Overall effect of therapy

RESULT

Table No.1: Group A - Subjective parameters.

Group A	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Pain	2	0	-3.482[a]	<0.001	94.29	H.S
Itching	2	0	-3.345[a]	<0.001	92.86	H.S

- Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group A. From above table, it is clear that P-Values for all parameters are less than 0.001. Hence, it is concluded that effect observed in Group A is Highly significant.

Table No. 2: Group A - Objective parameters.

Group A	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Tenderness	2	0	-3.482[a]	<0.001	93.10	H.S
Foul Smell	2	0	-3.464[a]	<0.001	93.33	H.S
Floor/ Granulation	2	0	-3.542[a]	<0.001	92.59	H.S
Size	2	0	-3.542[a]	<0.001	92.59	H.S
Discharge	2	0	-3.397[a]	<0.001	91.67	H.S

- Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group A. From above table, it is clear that P-Values for all parameters are less than 0.001. Hence, it is concluded that effect observed in Group A is Highly significant.

Table No. 3: Group B - Subjective parameters.

Group B	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Pain	2	0	-3.508[a]	<0.05	85.19	S
Itching	2	0	-3.473[a]	<0.05	86.67	S

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group B. From above table it is clear that P-Values for all parameters are less than 0.05. Hence, it can be concluded that effect observed in Group B is significant.

Table No. 4: Group B - Objective parameters.

Group B	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Tenderness	2	0	-3.482[a]	<0.05	87.10	S
Foul Smell	2	0	-3.578[a]	<0.05	86.67	S
Floor/ Granulation	2	0	-3.535[a]	<0.05	90.00	S
Size	2	0	-3.508[a]	<0.05	88.46	S
Discharge	2	0	-3.542[a]	<0.05	89.29	S

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group B. From above table it is clear that P-Values for all parameters are less than 0.05. Hence, it is concluded that effect observed in Group B is significant.

Table No. 5: Comparison between Group A and Group B.

	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Pain	Group A	15	19.33	290.00	55.000	0.008
	Group B	15	11.67	175.00		

	Total	30				
Itching	Group A	15	19.40	291.00	111.000	0.039
	Group B	15	15.40	231.00		
	Total	30				
Tenderness	Group A	15	19.50	292.50	112.500	0.035
	Group B	15	15.50	232.50		
	Total	30				
Foul Smell	Group A	15	18.90	283.50	103.500	0.037
	Group B	15	14.90	223.50		
	Total	30				
Floor/ Granulation	Group A	15	20.33	305.00	100.000	0.025
	Group B	15	16.33	245.00		
	Total	30				
Size	Group A	15	18.50	277.50	97.500	0.025
	Group B	15	14.50	217.50		
	Total	30				
Discharge	Group A	15	20.67	310.00	95.000	0.024
	Group B	15	16.67	250.00		
	Total	30				

For comparison between Group A and Group B, we have used Mann Whitney U Test. From above table it can be observed that P-Values for all parameters are less than 0.05. Hence, it is concluded that there is significant difference between Group A and Group B. Further, it is also observed that mean rank for Group A is greater than Group B. Hence, it is concluded that effect observed in Group A is more than Group B.

Table No. 6: Percentage (%) wise comparison between Group A and Group B.

	% Effect	
Parameters	**Group A**	**Group B**
Pain	94.29	85.19
Itching	92.86	86.67
Tenderness	93.10	87.10
Foul Smell	93.33	86.67
Floor/ Granulation	92.59	90.00
Size	92.59	88.46
Discharge	91.67	89.29

In all subjective and objective parameters, it is observed that % effect for Group A is greater than Group B.

Table No.7: Overall effect of the therapy.

Overall Effect	Group A		Group B	
	N	%	N	%
Cured	15	100.00	13	86.67
Marked Improvement	0	0.00	02	13.33
Moderate Improvement	0	0.00	0	0.00
Mild Improvement	0	0.00	0	0.00
Unchanged	0	0.00	0	0.00
TOTAL	15	100.00	15	100.00

Further, it is also observed that in Group A 100% patients were cured, and in Group B 86.67% were cured and 13.33% were marked improved.

DISCUSSION ON RESULT

GROUP A – SUBJECTIVE PARAMETERS

Pain – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 94.29% relief, P-value is <0.001 which is statistically Highly significant.

Ushna virya of *Tila*, *Madhur rasa* of *Tila* and *Madhu* pacify the *Vata dosha*, thus relieving Pain; as there is no pain without *Vata*. In *Tila* Sesamine, Sesaminol, Gama tocopherol, Cephalin, Lecithin etc. compounds are present which show Analgesic action through inhibition of prostaglandin synthesis.[8]

Itching – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 92.86% relief, P-value is <0.001 which is statistically Highly significant.

Tikta rasa of *Tila* and *Krimighna karma* of *Madhu* reduced itching of *Dushta-Vrana*. In *Tila* Sesamin, Sesaminol, Gamma tocopherol, Cephalin and Lecithin are present which have Anti-bacterial property.[9] In *Madhu*, Hydrogen peroxide and low ph are Anti-bacterial and effective against E.coli, Enterobacter aerogenes, Staphylococcus aureus, which helped to reduce itching of *Dushta-Vrana*.[10]

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group A. P-Values for all parameters are less than 0.001. Hence, it is concluded that effect observed in Group A is Highly significant.

GROUP A – OBJECTIVE PARAMETERS

Tenderness – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 93.10% relief. P-value is <0.001 which is statistically Highly significant. *Tila* has *Tikta rasa*, is *Ushna virya* which have *Shothhar* property. In *Tila*, Sesamine, Sesaminol, Gama tocopherol, Cephalin, Lecithin etc. compounds are present[11], and Gallic acid present in *Madhu* have Anti-inflammatory property which reduce the tenderness in *Vrana*.[12] Thus, it reduces the inflammatory phase of wound healing through prostaglandin inhibition and promotes rapid wound healing.

Foul smell – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 93.33% relief. P-value is <0.001 which is statistically Highly significant.

Krimighna property is present in *Madhu. Tila* has *Tikta, Kashaya rasa* which helped to control the local infection and ultimately the bad odour. *Madhu* has *Kashaya anurasa* which also helped to control the local infection and ultimately the bad odour.

Floor/ Granulation – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 92.59% relief. P-value is <0.001 which is statistically Highly significant.

Ushna virya is present in *Tila*, which removes *Srotorodha* & provides better circulation to *Vrana*, thus improving nutrition and resulting in healthy granulation tissue formation. Syringic acid is a phenolic compound in honey that acts pharmacologically as an oxidant to clear free radicals and promote the healing process.[13]

Size – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 92.59% relief. P-value is <0.001 which is statistically Highly significant.

Due to *Kashaya rasa, Sandhaniya* property is present in *Tila* and *Madhu*. *Sandhan* karma is helpful in contraction of *Vrana* after converting *Dushta-Vrana* into *Shuddha Vrana. Madhur rasa* have *Dhatuvardhana & Dhatuposhana* action which is essential for *Vrana* contraction and maintaining minimal scar**.**

Discharge – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 91.67% relief. P-value is <0.001 which is statistically Highly significant.

Shoshna, Lekhana, Stambhana, Puyapshodhana properties are due to *Tikta, Kashaya rasa* in *Tila & Kashaya anurasa* in *Madhu,* thus helpful in scrapping and de-sloughing of debris and reducing discharge. In *Tila* -Sesamin, Sesaminol, Gamma tocopherol, Cephalin and Lecithin have Anti-bacterial property and reduces discharge of *Dushta-Vrana.*[14]

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group A. P-Values for all parameters are less than 0.001. Hence, it is concluded that effect observed in Group A is Highly significant.

GROUP B – SUBJECTIVE PARAMETERS

Pain – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 85.19% relief. P-value is <0.05 which is statistically significant.

Karavira have *Ushna virya* which helps to pacify the *Vata Dosha*, thus relieving Pain; as there is no pain without *Vata*. *Karavira* gives Analgesic effect due to alpha Amyrin. Amyrins are abundant naturally occurring two isomeria pentacyclic triterpenes. Alpha amyrins has 25- carbon at the 20 positions. They are considered to have broad spectrum analgesic properties through inhibition of prostaglandin synthesis.[15]

Itching – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 86.67% relief. P-value is <0.05 which is statistically significant.

Karavira have *Tikta, Katu rasa***.** *Tikta, Katu rasa* have *Kanduhar* property. *Ruksha* and *Laghu guna* which helps to reduce *Kapha* that causes *Kandu-hara* karma in *Vrana*. *Karavira* contains Kaempherol which act as antimicrobial. Kaempherol is a natural flavonol, a type of flavonoid.[16]

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group B. P-Values for all parameters are less than 0.05. Hence, it can be concluded that effect observed in Group B is significant.

GROUP B – OBJECTIVE PARAMETERS

Tenderness – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 87.10% relief. P-value is <0.05 which is statistically significant.

Karavira has *Katu, Tikta rasa* and *Ushna virya*, and all of these possess *Shoth-har* property due to *Shoshan karma*. *Karavira* contains Oleanolic acid, which is an inhibitor of cellular inflammatory process of wound healing and thus promotes wound healing.[17]

Foul smell – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 86.67% relief. P-value is <0.05 which is statistically significant.

In *Karavira, Krimighna* activity is present and it has *Tikta, Katu rasa* which helped to control the local infection and ultimately the bad odour.

Floor/Granulation – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 90.00% relief. P-value is <0.05 which is statistically significant.

Karavira has *Lekhana* property due to *Tikta, Katu rasa* which removes slough and cleans the wound floor. *Katu rasa* also removes *Srotorodha* & provides better circulation to *Vrana*, resulting in healthy granulation tissue formation. *Karavira* contains Kaempherol, an anti-oxidant component. Oxidation process hampers the wound healing; antioxidants protect the tissue from the oxidative damage and helps in healthy granulation tissue formation.[18]

Size – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 88.46% relief. P-value is <0.05 which is statistically significant.

Karavira has *Lekhana* property due to *Tikta, Katu rasa* which removes slough and cleans the wound floor, and its anti-oxidant component protects the tissue from oxidative damage and they helps in healthy granulation tissue formation followed by contraction of *Vrana.*

Discharge – The median score was 02 before treatment which reduced to 0 (zero) after treatment with 89.29% relief. P-value is <0.05 which is statistically significant.

Shoshna, Lekhana, Stambhana, Puyapshodhana properties are due to *Tikta, Katu* rasa of *Karavira* which scrap debris and helps in reducing discharge. *Karavira* also has Kaempherol, a natural flavonol, (a type of flavonoid) which helps to reduce discharge from *Dushta-Vrana.*[19]

Since observations are on ordinal scale (gradations), Wilcoxon Signed Rank is used to test efficacy in Group B. P-Values for all parameters are less than 0.05. Hence, it is concluded that effect observed in Group B is significant.

COMPARISION BETWEEN GROUP A AND GROUP B

For comparison between Group A and Group B, we have used Mann Whitney U Test. P-Values for all parameters are less than 0.05. Hence, it is concluded that there is significant difference between Group A and Group B.

- It was observed that subjective parameter Pain had more relief (94.29%) in group A, as compared to group B (85.19%).
- It was observed that subjective parameter Itching had more relief (92.86%) in group A as compared to group B (86.67%).
- It was observed that objective parameter Tenderness had more (93.10%) relief (93.10%) in group A as compared to group B (87.10%).
- It was observed that objective parameter Foul smell had more relief (93.33%) in group A as compared to group B (86.67%).
- It was observed that objective parameter Floor/Granulation had more relief (92.59%) in group A as compared to group B (90.00%).
- It was observed that objective parameter Size had more relief (92.59%) in group A as compared to group B (88.46%).
- It was observed that objective parameter Discharge had more relief (91.67%) in group A as compared to group B (89.29%).

  Further, it is also observed that mean rank for Group A is greater than mean rank of Group B. Hence, it is concluded that effect observed in Group A is more than effect observed in Group B.

OVERALL EFFECT OF THE THERAPY

- In group A, out of total 15 patients, all patients were cured (100%).
- In group B, out of total 15 patients, 13 patients were cured (86.66%), and 02 patients were markedly improved (13.34%).
- None of the patients remained Unchanged in both the treatment groups. In none case, no sign and symptom of the recurrence was noticed during follow up. No side effects of trial drugs were reported during the study period.

CONCLUSION

Group A (***Tila-Kalka Lepa***) and Group B (***Karavira Avachoornana***), both were very effective in management of *Dushta-Vrana.* But on the basis of overall effect of the therapy it

was found that ***Tila-Kalka Lepa*** had better result than ***Karavira Avachoornana*** in subjective and objective parameters, and cured all the patients.

There is an authentic reference available regarding *Tila-Kalka Lepa* and *Karavira Avachoornana* for the management of *Vrana* in *Sushruta Samhita. Tila-Kalka* and *Karavira* possess various properties like *Shodhana, Ropana, Krimighna, Vedana-sthapana, Shoth-har, Lekhana, Shoshana,* etc. which helps in early healing. This study may open a new path of the treatment in the field of *Dushta-Vrana* management. Keeping this in mind, clinical study was done and positive results were observed. In statistical analysis *Tila-Kalka Lepa* showed Highly significant result and *Karavira Avachoornana* showed Significant results. This therapy is cost effective, can be easily prepared and devoid of side effects during treatment and follow up, and no recurrence has been reported. It is worth mentioning that even after follow up period, patients come for routine check up at our *Shalya* department, and no sign of recurrence has been observed.

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