

EVALUATION OF CLINICAL EFFICACY OF PARADADI
MALHARAM IN DUSTA VRANA

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ABSTRACT :

As per Ayurveda concern, healing of *vrana* is a natural process of the body supported by *doshas* and *dhatus*, but it should be protected from *Dosha Dusti*, *Dhatudusti* and *sankramana* of different forms(*Rakshas*;micro-organisms) can afflict the *Vrana* and delay the *Vrana Ropana*. In Ayurveda, chronic ulcer is dealt under *Dusta vrana*, chronic ulcer has got all characteristic features of *Dustavrana*, a frequently encountered problem. Chronic ulcers are shown to be the most common cause for hospitalization and prolonged stay for proper wound care. Still wound management continues to be a subject of speculation in chronic ulcers. An effective external application (An ulcer which is not cured by treating with hundreds of drugs is cured definitely by this efficacious drug as per the sloka reference) *Paradadi Malharam* was prepared with *rasoushadi*es as rasa drugs can combat the diseases with high absorption rate and quick action. The pharmaceutical procedures adopted in this study are *Shodhana*, *Mardana*, *Nimajjana* and *Malhara nirmana*. An attempt has been made to study its efficacy clinically on *Dustavrana* through “Non- Randomised open labelled clinical trial over a sample of 30 patients with restricted/purposive sampling. *Paradadi Malharam* gives statistically highly significant relief in all the symptoms ($p<0.0001$). This therapy had shown moderate improvement in 53.33% of patients and Marked improvement in 46.66% patients.

Key words: *Dustavrana*, *Paradadi Malharam*,

INTRODUCTION: The term “*vrana*” is derived from “*vrana gatra vichurne*”¹. In literal sense, it means a gap or discontinuity of tissues. This seems to be the most common or earliest amongst the ailments mankind has faced. Many Researches and discoveries have been made in wound healing since *Vedic* era. Soon after trauma, the post traumatic metabolism comes into play. As knowledge progressed it was understood that infection, lack of skin opposition, presence of dead tissue, foreign bodies, deficient blood supply etc., factors

may play a potential primary role in the process of wound healing. *Susruta* the father of surgery had done considerable research and developed the methods in treatment of wounds. This includes proper “*Shodhana*” and “*Ropana*” of the wound .He also explained 8 *vrana adhistanas*² or seats,5 cardinal factors³ of *vrana* and 60 management procedures⁴.It is emphasized that the success of wound healing is mainly based on the maintenance of the general health, good diet and administering the drug .In *Ayurveda*, a non-healing,

chronic ulcer can be compared with “*Dustavrana*” as it has a conglomeration of so many signs and a symptoms and is a problem to the doctor and the patient. *Dustavrana* also covers varicose ulcers, deep vein thrombotic ulcers, tubercular ulcers, syphilitic ulcers etc.

AIM AND OBJECTIVES:

- To evaluate the therapeutic efficacy of *Paradadi Malharam* in *Dustavrana*.
- To conduct an open labeled clinical trial to obtain data for overall assessment of drug effect on the above disease.

MATERIALS:

• Patients- Patients attending the O.P.D of P.G Department of & *Rasashastra* and *Bhaishajya Kalpana*, I.P.D & O.P.D of P.G .Department of *Shalya Tantra* of S.V Ayurvedic College, Tirupati were selected, irrespective to Sex, Religion, and Occupation etc.. Drug- *Paradadi Malharam*. The drug was prepared in the Department of *Rasashastra* and *Bhaishajya Kalpana*, S.V. Ayurvedic college, Tirupati.

METHODS:

Study design: A Non – Randomized open-Label clinical study.

Sampling: Restricted/Purposive sampling

Sample Size: 30. Total 30 Patients with symptoms of *Dusta Vrana* were registered.

Criteria for selection of Patients:

- **Inclusion Criteria:** Patients with typical features narrated in the classics under the heading of *Dustavrana*. and irrespective to Sex, Religion, and Occupation were selected.
- Patients aged 10-70 years were selected.

Exclusion criteria:

- Malignant ulcer
- Tubercular ulcer

- Syphilitic ulcer
- Soft sores
- Actinomycosis etc.
- Patients suffering by systemic diseases such as AIDS, Heart diseases,HTN, Psychic disorders ,Epilepsy are excluded.

Intervention

External Application : *Paradadi Malharam*

Dosage form : *Malahara*(Local application for dressing)

Dose : Depending on the size of ulcer
Administration time : One time per day

Duration : 45 days

Advices : Maintain strict cleanliness
To wash clothes in boiling water

Follow up : Once in every 15 days for a total Period of 45 days.

Preparation of Paradadi Malharam:
Chief reference of *Paradadi Malharam* was taken from *Rasa Yoga Sagara*⁵. The main ingredients are *Parada*, *Gandhaka*, *Mriddarashringa*, *Kampillaka*, *Tuttha*. *Kajjali* was prepared with shoditha *Parada*⁶ and shoditha *Gandhaka*⁷. *Kajjali* and other components (shodita *Mriddarashringa*, *Kampillaka* and *Tuttha*) of *Paradadi Malharam* are taken in the khalwa yantra and made into the Homogeneous mixture. This Homogeneous mixture was added with molten *goghrita* and triturated (Rapid trituration is needed) up to *Malharam* Consistency.

Criteria for assessment and Grading:
The results of the therapy were assessed after completion of treatment on the basing on two considerations.

- 1] Demographic parameters: General assessment of patients is carried out basing on various parameters like age, education, sex, location, religion, marital status, occupation etc.

2] Subjective and objective Parameters: Criteria of assessment were kept based on relief in the sign and symptoms of *Dustavrana* before & after the treatment. For this purpose, cardinal signs and symptoms were given scores.

Assessment of severity (Gradation): The severity in respect of gradation has been recorded as per the following

Table no.1: Showing the scores for the signs and symptoms of *Dustavrana* Assessment scale: The clinical signs as stated are examined and assessed the degree of affection and intensity in the first day,fifteen days,thirty days and forty five days in order to know the effectiveness of the drug.

Table no.1: Showing the scores for the signs and symptoms of *Dustavrana*

Grade	Sign	Grade point	Remarks
G₀	-	0	Normal/Absent
G₁	+	1	Mild
G₂	++	2	Moderate
G₃	+++	3	Severe

Table No : 2 Showing the criteria for assessment of the Result

S.NO	Interpretation of effect	Result of drug in percentage
1.	Complete remission	76% to 100%
2.	Markedly improved	51% to 75%
3.	Moderately improved	26% to 50%
4.	Unchanged	Below 25%

Statistical evaluation of results: The obtained information was analyzed statistically in terms of mean score (x), Standard deviation (S.D),Standard error (S.E),Paired t test was carried out at the level of 0.005,0.01, and 0.001 of 'P' levels. For the more effectiveness of therapy paired t test was carried out. The results were interpreted as

Insignificant: P > 0.05

Significant: P < 0.05

Highly significant P < 0.01, P < 0.001

OBSERVATIONS: Maximum number of patients i.e.33.33% were from the age group of 61-70 years. Out of 30 patients 19 patients (63.33%) were males and 11 patients (36.66%) were females. The incidence of marital status shows that 27 patients (90 %) were married and 3 patients (10%) were unmarried. In this study 4 patients (13.33%) were of high income

group,14 patients (46.66%) were of medium income group and 12 (40 %) were of low income group. Maximum number of Patients were uneducated. and doing agriculture. More number of patients i.e.20 patients (66.6%)were from rural habitat and maximum no of patients were Hindus29 patients (96.66%). Maximum no of patients i.e. 18 patients (60%) are addicted to tobacco and maximum no of patients i.e. 19 patients (63.33%) were taking mixed diet. Maximum number of Patients came to OPD with chronic condition of ulcer. 29 patients (96.66%) were observed suffering from ulcer at lower extremity. Maximum i.e 18 patients (60%) were having *vata-kapha prakriti*. Out of 30 Patients 29 patients (96.66%) were having nija type of ulcer. More number of patients i.e 16 (53.33%) were with irregular shaped ulcer and More number of Pa-

tients 15 (50%) are having slopping edge. Maximum number i.e. 22 patients

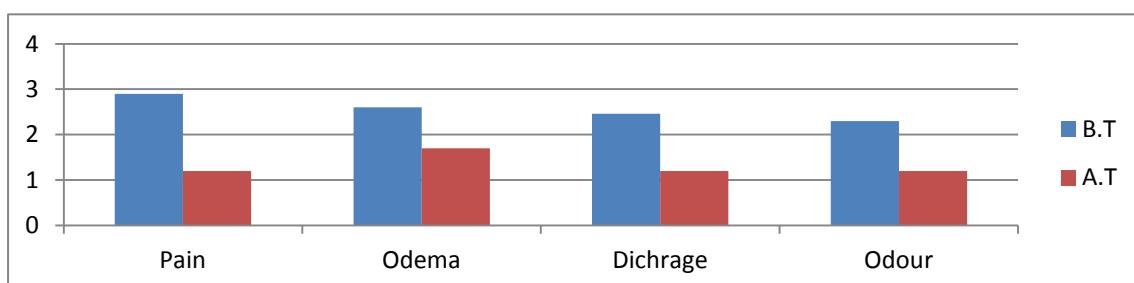
(73.33%) contain non-odematous edge.

Table No. 3: Showing effect of Paradadi Malharam on Subjective parameters in 30 patients

Chief symptom	N	B.T	A.T	Mean	% Relief	S.D	S.E	't'	P
Pain	30	2.9	1.2	1.6	55.17%	0.75	0.138	12.04	<0.0001
Oedema	30	2.6	1.7	0.9	34.6%	0.71	0.130	6.92	<0.0001
Discharge	30	2.46	1.2	1.2	48.7%	0.73	0.135	9.37	<0.0001
Odour	30	2.3	1.2	1.1	47.8%	0.60	0.11	9.91	<0.0001

Note: -n- No. of patients suffering with symptom, **B.T.:** Arithmetic mean of scoring Before Treatment, **A.T.:** Arithmetic mean of scoring After Treatment, **S.D.:** Standard Deviation, **S.E.:** Standard Error, **P-value:** Indicates significance of treatment on specific symptom.

S.D, S.E, t and p-value are calculated substituting 'n' value as actual number of patients suffering from that specific symptom (But not the total number of patients)



Graph no. 1. Showing the effect of Paradadi Malharam on subjective parameters in 30 patients

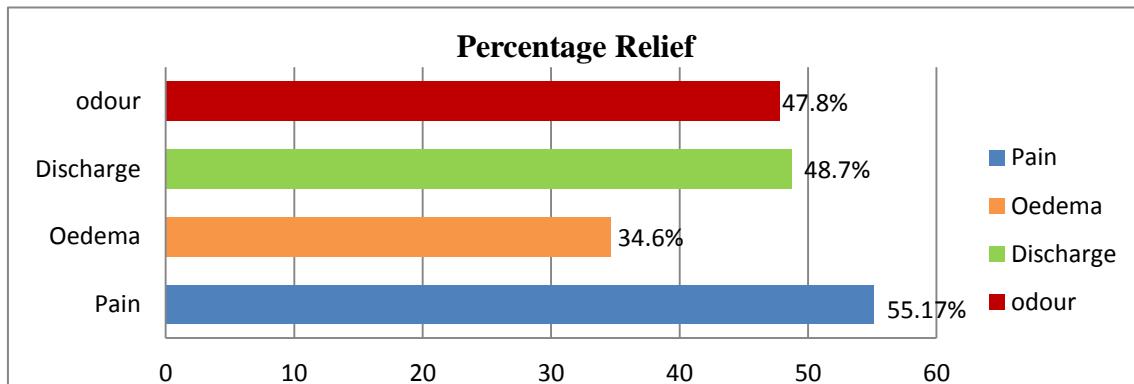


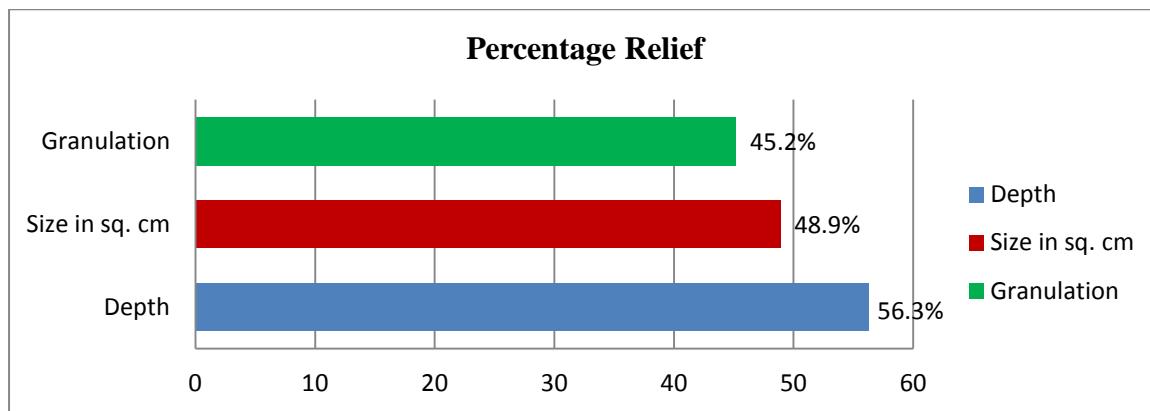
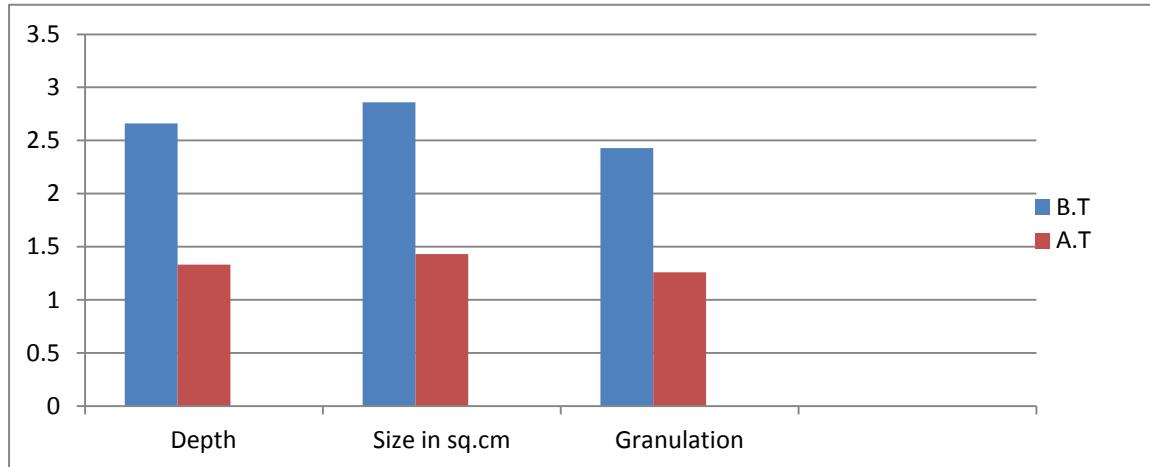
Table No. 4: Showing effect of Paradadi Malharam on objective parameters in 30 patients

Chief symptom	N	B.T	A.T	Mean	% Relief	S.D	S.E	't'	P
Depth	30	2.66	1.33	1.5	56.3%	0.68	0.12	12.32	<0.0001
Size in sq.cm	30	2.86	1.43	1.4	48.9%	0.72	0.13	10.78	<0.0001
Granulation	30	2.43	1.26	1.1	45.2%	0.79	0.14	8.074	<0.0001

Note: -n- No. of patients suffering with symptom, **B.T.:** Arithmetic mean of scoring Before Treatment, **A.T.:** Arithmetic mean of scoring After Treatment, **S.D.:** Standard Deviation,

S.E.: Standard Error, **P-value:** Indicates significance of treatment on specific symptom. S.D, S.E, t and p-value are calculated substituting 'n' value as actual number of patients suffering from that specific symptom (But not the total number of patients)

Graph no. 2. Showing the effect of *Paradadi Malharam* on objective parameters in 30 patients.

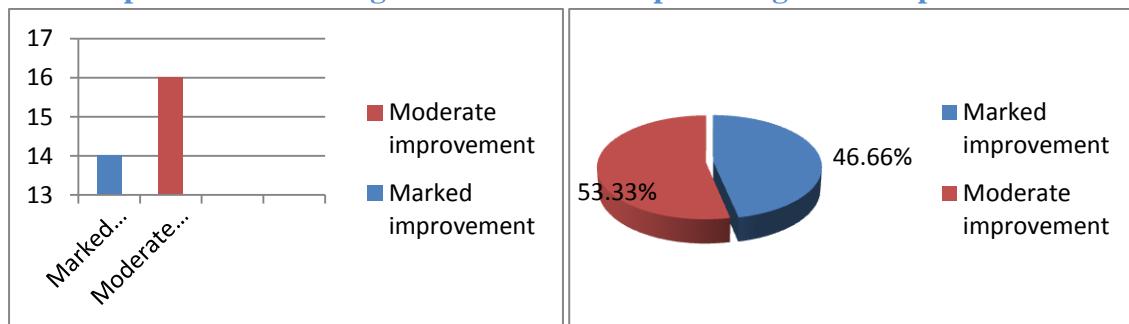


Inference of statistical reports: Above data clearly shows that *Paradadi Malharam* has given statistically highly significant relief $p<0.0001$ in all the symptoms.

Table no.4: Showing the overall assessment of percentage of therapeutic effect.

S.NO	Result obtained	No of Patients	% of Patients
1	Complete remission	00	00
2	Marked Improvement	14	46.66%
3	Moderate improvement	16	53.33%
4	No relief	00	00

Graph no : 3 Showing overall assessment percentage of therapeutic effect



The therapy had shown moderate improvement in 53.33% of patients and Marked improvement in 46.66% patients.

DISCUSSION:

- Highest incidence is in age group between 51-60 years. It suggests old aged people are most likely to be prone to *Dustavrana*. Most of the registered patients are Hindus. This is due to high ratio of Hindus in sample collected geographical region. No specific reason can be attributed to this.
- The sex wise distribution of the patients reveals that 63.33% of the patients were male while 36.66% patients were female. So it can be said that sex has no role in manifestation of *Dustavrana*. Majority of the patients i.e. 90% were married and 10% are unmarried. But it cannot be said that married person were more prone to this disease.
- Maximum number of patients i.e, 26.66% were Agriculture , It is affecting more in the laborers due to their lack of knowledge in hygienic conditions. Due to ignorance of healthy life style, uneducated are more prone to *dustavrana*. Patients from rural area are more susceptible for *Dusta vrana*.
- More number of patients were having chronic onset as *Dustavrana* is chronic in nature Maximum number i. e 60% were smokers , these addiction of tobacco chewing and smoking contain Nicotine which is a vasoconstrictor and can cause delay in proliferation of RBC, formation of fibroblasts and macrophages ultimately delaying healing process. In the clinical study, maximum numbers of patients were of *Vata-kaphaja* i.e. 60% . It can be interpreted that *Vata-Kapha prakruti* is more prone to this disease.
- In the clinical study, maximum numbers of patients i.e. 96.66% had *vrana* at lower limb, 3.33% had lesion at buttock. Due to venous valve in competence, Poor circula-
- tion, Pressure caused by lying in one position for too long, infection more number of patients had *dustavrana* at lower extremity. In the clinical study, maximum number of patients i.e 96.66% were having *nija vrana* , 3.33% were having *agantuja* type of *vrana*.
- The origin of ulcer may be different in form of *Nija* and *Agantuja* .However at the time of registering the case, all the ulcers found to be *Nija* type as *Agantuja* ulcers will change over to *Nija* type immediately after 7 days of time. It is observed that in most of cases, the shape of ulcer was irregular showing its chronicity and *vata, pitta dosha* predominance. It indicates in spite of the chronicity other non healing factors, many of the ulcers has shown a tendency to heal. So slopping edge could be found in the study. The presence of punched out, rolled out, undermined edges indicate that on chronicity the ulcers become callous in nature.
- As floor of ulcer was concerned, it was found much of pus and slough which is important feature for non healing or callous ulcer. The presence of granulation tissue in few cases indicates some earlier treatment taken. It is observed that the margins were non-oedematous in majority of cases indicating that majority of ulcers become callous and non healing nature.
- *Parada* is *Krimighna, Tridosaghna, Yogavahi*⁸. *Parada* is used as Antiseptic, preservative, bactericide, Fungicidal in the form of organic salts.
- *Gandhaka* is *vishahara* & *krimihara*⁹.
- Recent studies have proved that *Kajjali* showed *Yogavahi* effect¹⁰.
- *Mriddarashringa* is *Vata kapha hara, Phirangi vrana* *hrith, vrana* *ropanothamam, Bhagna sandhana janana*¹¹. As *Saindhava* *lavana* is indicated

in *Vrana*¹², it was selected for *Shodhana* of *Mriddarashringa*¹³.

- *Kampillaka* is indicated in *Vrana*¹⁴. As *Hareethaki* is having *Vranaropana* property¹⁵, *Hareethaki kashaya* was selected for *Kampillaka Shodhana*¹⁶.

- *Tuttha* belongs to the group *Maharasa*. It is *lekhana*, *Krimighna*, *Vishaghna*, *Kshareeya*¹⁷. *Tuttha Shodhana*¹⁸ was done with *gomutra* as it contains Anti bacterial, Anti fungal, Wound healing properties.¹⁹

- *Ghrita* is lipophilic and this action of *ghrita* facilitates transportation of ingredients of formulation to target organ and final delivery inside the cell, because cell membrane also contains lipids. This lipophilic nature of *ghrita* facilitates entry of

formulation in to the cell and its delivery to mitochondria, microsome and nuclear membrane. Formulations having *ghee* or oil as *Malhara* base facilitate drug Penetration for easy and uncomplicated wound healing.

CONCLUSION: All the ingredients of *Paradadi Malhara* are having *Vrana Shodhana* and *Vrana Ropana* property. By the synergistic action of the ingredients, *Paradadi Malharam* gave statistically highly significant effect on both subjective and objective parameters of *Dustavrana*. It was observed in the clinical study that there was Moderate relief in 53.33% and marked improvement in 46.66% of patients.

Photograph showing results of *Paradadi Malharam*

Before treatment



After treatment





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Declared