



A Randomized Controlled Clinical Study of Karanjadhya Ghrita in the management of Dushta Vrana (chronic wounds).

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Abstract:

Background: Dushta Vrana (Chronic wounds) are frequently encountered problem in the present era produced due to the complications of trauma or pathological injury and it causes long-term agony to the patients. Chakradutt has mentioned the wound healing properties of Karanjadhya Ghrita. In the present study Karanjadhya Ghrita was prepared and its wound healing properties were studied on various chronic wounds.

Methods:

Karanjadhya Ghrita was prepared using the standardization procedure the effects were studied on 40 patients with chronic wounds (wounds more than 3 weeks old) selected from Outpatient and inpatient department of department of Shalya Tantra, National Institute of Ayurveda, Jaipur. The patients were divided into two groups – Group A (Karanjadhya Ghrita dressing) and Group B (Hydrogen peroxide and EUSOL and dry Gauze bandage). The drug was applied topically and patients were studied daily for 30 days and results were analyzed.

Results:

In Chronic Wound the size was decreased 69.23% which was statistically highly significant. There was considerable improvement (> 80 %) in swelling and unhealthy margin. Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds

Conclusion:

From the studies made from clinical cases, it was concluded that, the drug “Karanjadhya Ghrita” possess sufficient efficacy in Vrana Shodhan and Vrana Ropana properties without producing any adverse effects.

The drug also increase the rate of contraction produces healthier granulation tissue and rapid healing time. Hence, this study conclude that application of Karanjadhya Ghrita is highly effective on chronic wounds.

Key Words: Karanjadhya Ghrita, Chronic Wounds, Wound healing

INTRODUCTION

Ayurveda is a science of life and is believed to exist as long as the origin of life on this earth as is mentioned in Charak Samhita. Ever since the life originated, human being has been susceptible to injury, which made him to think about healing from very early stage of development. The destruction/break/rupture/discontinuity of body tissue/part of body, is called “*Vrana*”¹. It may have features of chronic in nature, foul smell, loss of normal colors, excessive discharge of pus and impure blood, excessive pain, elevated from surface, irregular shape with cavities, everted base and margins of wound (*Charak Chikitsa 25/83*², *Madhav Nidan 42/7*³, *Vaidyaksabdasindhu*⁴). In Ayurveda, particularly Sushruta has mentioned various types of *vrana*⁵ and their management⁶, which is of prime importance in any surgical practice/procedure. Wound management is a significant and growing health burden on the community⁷. Delayed wound healing and wound infection place a substantial financial burden on health care systems, as a result of increasing dependency and increased hospital admissions. Chronic wounds also have a very large social and quality of life impact on individuals and carers⁸. After injury, healing is a natural phenomenon and continues in sequential manner until the formation as a healthy scar. Usually defense mechanisms of body takes complete care in order to keep the scar clean. But at times, when infection is massive, surface area of wound is very large and slough or necrotic tissue is too much, this auto cleansing mechanism becomes inadequate⁹. According to Acharya Sushruta among the 60 measures of wound treatment, “*Kalka*” (application of paste) is a measure indicated for non-healing wounds located in muscle and having slough. The paste performs both functions of “*Shodhana*” (cleaning) and “*Ropana*” (healing) in *Dushta Vrana*¹⁰. A close study of Ayurveda reveals that a number of plants were used to achieve the goal *Vrana-Ropana*. Acharyas have given beautiful description about wound and wound healing. For good healing, the drug must have three following properties:

1. *Vrana Shodhana*
3. *Vrana Ropana*

It is important to find a single and simple composition, which have these two properties viz. *Shodhan*, and *Vrana ropana* properties. In the present study *Karanjadhya Ghrita*^{11, 12} is selected to study its effects on chronic wounds that described in *Chakrdutt Ratanprbha*, *Vranshoth Rogadhikar*.

AIMS AND OBJECTIVES:

To evaluate the efficacy of *Karanjadhya Ghrita* in the management of chronic wounds.

MATERIALS AND METHODS -

The work was carried out in the department of Rasa Shastra & Bhesaj Kalpana, National Institute of Ayurveda, Jaipur.

Drug Contents –

Karanjadhya Ghrita^{11, 12} contains:-

Nakta mala (leaves and tender fruits) , Maltipatra (leaves) , Patola (leaves,)Arista (leaves) , Haridra ,Daruharidra ,Madhuka, Tikta rohini ,Manjistha ,Candana ,Krisna sariva , Swet , Sariva ,Trivrit , Utpala, Ushira. Bee-wax, gau Ghrita.

Method of Preparation –

The Karanjadhya Ghrita was prepared in the National Institute of Ayurveda Pharmacy under the guidance of Dr V Nageshwar Rao, Associate Professor and Guide, Department of Rasa Shastra & Bhesaj Kalpana. For the preparation of medicated oils/ghritas, following steps were done:-

First the Ghrita has to be subjected to MURCHANA¹³ and then followed by following steps to prepare the Karanjadhya Ghrita.

Procedure:

- a) Wash and grind fresh leaves of ingredients 1 to 3 of the formulation composition (Kalka dravya) in a wet grinder and convert in paste form. And, all other Kalka dravyas were made into the powder form.
- b) The paste and powder of Kalka drugs are mixed with water and bolus is prepared. Madhuchista keep aside for addition during snehapāka. Murchita Ghrita was taken in a steel vessel and heated over Madhyam agni till complete evaporation of moisture content, at this stage temperature gone up to 130° C. The bolus of Kalka were added to the Ghrita after slight cooling, and constant stirring is carried.
- c) Then four times quantity of water to ghrita is added to the above vessel.
- d) It is kept over (Mandagni) fire and slowly stirred to mix well.
- e) After 3 hrs. and 40 minutes heating it is allowed for self-cooling and a plate is covered to prevent from any dust fall.
- f) On the next day, heating is again continued and 2½ hrs. heating is carried on this day and constant stirring is carried to avoid sticking of the Kalka drugs
- g) On 3rd day, the heating process is continued till the ghirta becomes water free and gets the Laksanas of Snehasiddhi. Stop heating when the kalka breaks down into pieces on attempting to form a varti and the froth subsides, the vessel is taken out from the fire and Filter while hot (about 70⁰) through a clean cloth. Add small pieces of Siktha, in the warm-stage and filter through clean cloth and allow to cool.
- h) Obtained Karanjadhya Ghrita is preserved in tightly closed glass jar to protect from light and moisture.

Clinical Study:-

Source of data: For the study 40 patients were randomly selected from the Out-patient and in-patient departments of Departments of Shalya Tantra and Kaya Chikitsa, National Institute of Ayurveda, Jaipur.

Method of collection of data: Detailed clinical history and clinical examination was carried out using the special Performa which was prepared before assessing the case and starting the proper treatment with trial drugs.

Grouping: The patients were randomly divided into two groups, each group having 20 patients – Group A (Karanjadhya Ghrita dressing) and Group B (Hydrogen peroxide and EUSOL and dry Gauze bandage). After selection of patients, they were informed about the study and their written consent was obtained. Further, the patients were made to understand that they are able to withdraw from the study any time without prior notice.

Intervention: The Group A patients were asked to apply the Karanjadhya Ghrita locally on the wounds two times a day for 30 days and compared with the Group B patients.

Duration of study: The duration of study was 30 days.

Follow up: All the out-patients were asked to follow-up at the interval of every 10 days in 30 days. All IPD patients, who were included in study, were studied daily for 30 days.

Inclusion Criteria: All types of chronic wounds (wounds more than 3 weeks old) patients including lacerated wound ,Post-operative wounds ,Fissure, Burn, Pressure Sores, Trophic ulcer, Varicose ulcer were selected.

Exclusion Criteria: Diabetic patients, malignant ulcers, HIV and TB patients, patients suffering from hepatitis and patients with signs of gangrene.

Assessment Criteria: The wounds were assessed using the following parameters.

1. Symptom Rating Scale:

- 0-No Sign & symptoms
- 1-Mild Sign & symptoms
- 2-Moderate Sign & symptoms
- 3- Severe Sign & symptoms

2. Assessment of Size:

- 0 - No discontinuity of skin/mucous membrane,
- 1 - 1/4 of previous area & depth of the wound.
- 2 - 1/2 of previous area & depth of the wound.
- 3 - 1/2 of previous area & depth of the wound.

3. Assessment of Pain:

- 0 - No pain,
- 1 - Localized feeling of pain during movement only but no feeling during rest.
- 2 - Localized feeling of pain even during rest but not disturbing the sleep.
- 3 - Localized continuous feeling of pain, radiating & not relieved by rest.

4. Assessment of Tenderness:

- 0 - Tolerance to pressure,
- 1 - Little response on sudden pressure.
- 2 - Wincing effect on super slight touch.
- 3 - Resists to touch & rigidity.

5. Assessment of Burning:

- 0 – No burning,
- 1 - Little, localized & some time feeling of burning sensation.
- 2 - More localized & often burning sensation which does not disturbed sleep.
- 3 - Continuous burning sensation with disturbed sleep.

6. Assessment of Itching

- 0 - No itching,
- 1 - Slight, Localized itching sensation which is relieved by rest.
- 2 - More, Localized & often itched but not disturbs sleep.
- 3 - Continuous itching with disturbed sleep.

7. Assessment of Color:

- 0 – Normal pigmentation & of skin,
- 1 - Slight red.
- 2 - Reddish black.
- 3 - Pale yellow! Blackish / Bluish

8. Assessment of Margin & Surface:

- 0 – Adheres margin,
- 1 - Smooth, even & regular.
- 2 - Rough, regular & inflamed.
- 3 - Rough, irregular & angry look.

9. Assessment of Base/Floor:

- 0 - Smooth, regular & with healthy granulation tissue,
- 1 - Smooth, irregular, slight discharge, less granulation tissue, needs dressing & soft scar.
- 2 - Rough, regular wet with more discharge, needs dressing & having firm scar.
- 3 - Rough, irregular with profuse discharge, needs frequent dressing & having hard scars.

10. Assessment of Smell:

- 0 - No smell,
- 1- Bad smell
- 2 - Tolerable unpleasant
- 3 - Foul smell which is intolerable.

11. Assessment of Swelling:

- 0 – Absent,
- 1 - Slight red, tender & hot with painful movement & without indurations.
- 2 - More red, having painful movement, with more local temperature & with indurations.
- 3 – Angry look, hot, resist to touch & with more indurations.

12. Assessment of Discharge:

- 0 - No discharge / dry dressing,
- 1 - Scanty occasional discharge & little wet on dressing.
- 2 - Often discharge & with blood on dressing
- 3 - Profuse, continuous discharge which needs frequent dressing.

13. Assessment of unhealthy Granulation Tissue:

- 0 - Healthy granulation tissue,
- 1 - Smooth less & irregular granulation base covered with slight discharge.
- 2 - Little unhealthier granulation tissue & discharge which needs dressing.
- 3 - Rich unhealthy granulation tissue with profuse discharge, & needs frequent dressing.

STATISTICAL ANALYSIS:

All information which are based on various parameter was gathered and statistical was carried out in terms of mean (X), standard deviation (S.D.), standard error (S.E.), paired test (t-value) and finally result were incorporated in term of probability (p) as – $p < 0.05$ - Insignificant $p < 0.01$ - Significant $p < 0.001$ - Highly Significant.

RESULTS:

Based on the statistical analysis, the effects of the drug on various parameters were studied and following results were obtained.

Table 1 showing Effect on cardinal sign and symptoms of Group A patients (Karanjadhya Ghrita):

| Cardinal symptoms | Mean Score (BT) | Mean Score (AT) | Percentage Relief | SD | SE | T | P |
|------------------------------|-----------------|-----------------|-------------------|------|------|------|--------|
| Size | 0.9 | 0.28 | 69.23 | 0.99 | 0.22 | 4.04 | <0.001 |
| Pain | 1.9 | 0.76 | 60 | 1.18 | 0.26 | 7.21 | <0.001 |
| Tenderness | 1.75 | 0.61 | 65 | 0.99 | 0.22 | 7.87 | <0.001 |
| Burning sensation | 1.5 | 0.98 | 35 | 0.81 | 0.18 | 8.32 | <0.001 |
| Swelling | 0.35 | 0.05 | 84.61 | 0.57 | 0.13 | 2.74 | <0.001 |
| Color (Abnormal) | 1.1 | 0.35 | 68.42 | 0.77 | 0.17 | 6.4 | <0.001 |
| Margin (Unhealthy) | 0.75 | 0.3 | 80 | 0.62 | 0.14 | 5.39 | <0.001 |
| Base (Abnormal) | 0.8 | 0.27 | 66.66 | 0.6 | 0.13 | 5.96 | <0.001 |
| Smell | 0.45 | 0.23 | 50 | 0.67 | 0.15 | 3.01 | <0.001 |
| Discharge | 1.5 | 0.47 | 68.42 | 0.87 | 0.19 | 7.75 | <0.001 |
| Unhealthy granulation tissue | 0.1 | 0.04 | 64.28 | 0.44 | 0.09 | 1.03 | >0.05 |
| Itching | 0.85 | 0.51 | 40 | 0.65 | 0.15 | 5.81 | <0.001 |

BT = No of Patients before Treatment, AT = No of Patients after Treatment, SD =Standard Deviation, SE = Standard Error of Mean, T = Paired T Test, P = Probability Value

Result: In Chronic Wound the size was decreased 69.23% which was statistically highly significant. There was considerable improvement (> 80 %) in swelling and unhealthy margin. Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds.

Table 2 showing Effect on cardinal sign and symptoms of Control group (Group B)

| Cardinal symptoms | Mean Score (BT) | Mean Score (AT) | Percentage Relief | SD | SE | T | P |
|------------------------------|-----------------|-----------------|-------------------|------|------|------|--------|
| Size | 0.87 | 0.33 | 62.31 | 0.98 | 0.12 | 4.06 | <0.001 |
| Pain | 1.8 | 0.76 | 58 | 1.23 | 0.28 | 6.23 | <0.001 |
| Tenderness | 1.99 | 0.71 | 64.1 | 0.87 | 0.24 | 7.87 | <0.001 |
| Burning sensation | 1.09 | 0.73 | 33.25 | 0.86 | 0.16 | 7.32 | <0.001 |
| Swelling | 0.43 | 0.08 | 82.13 | 0.76 | 0.11 | 2.32 | <0.001 |
| Color (Abnormal) | 1.24 | 0.42 | 66.23 | 0.97 | 0.19 | 5.9 | <0.001 |
| Margin (Unhealthy) | 0.76 | 0.16 | 78.6 | 0.66 | 0.14 | 5.12 | <0.001 |
| Base (Abnormal) | 0.87 | 0.31 | 64.1 | 0.58 | 0.12 | 6.23 | <0.001 |
| Smell | 0.45 | 0.25 | 45 | 0.67 | 0.14 | 2.99 | 0.422 |
| Discharge | 1.6 | 0.68 | 57.8 | 0.89 | 0.16 | 6.57 | <0.001 |
| Unhealthy granulation tissue | 0.1 | 0.05 | 53.2 | 0.54 | 0.06 | 1.01 | >0.05 |
| Itching | 0.82 | 0.52 | 36.9 | 0.67 | 0.14 | 5.86 | 0.641 |

Table 3: table showing improvement in various types of the wounds

| Diagnosis | Cured Patients | Cured % | Markedly improved Patients | Markedly improved % | Improved Patients | Improved % | Unchanged Patients | Unchanged % |
|-----------------------|----------------|---------|----------------------------|---------------------|-------------------|------------|--------------------|-------------|
| Lacerated wound. | - | - | - | - | - | - | - | - |
| Post-Operative wounds | 2 | 66.67 | 1 | 33.33 | - | - | - | - |
| Fissure | 8 | 72.72 | 3 | 27.28 | - | - | - | - |
| Burn | - | - | - | - | - | - | - | - |
| Pressure sores | 1 | 50 | - | - | 1 | 50 | - | - |
| Trophic ulcer | - | - | - | - | 2 | 100 | - | - |
| Varicose ulcer | - | - | - | - | - | - | 1 | 100 |
| Other (wart etc.) | - | - | - | - | 1 | 100 | | |

Overall Result of Therapy in Chronic Wound Group: It has been concluded that 72.72% of treated cases of fissure were cured, followed by 66.67% of cases of post-operative wound were cured. Similarly some

cases (50%) of Pressure sores were also reported cured; all the patients of varicose wound were unchanged after treatment.

DISCUSSION:

Wound healing is a normal physiological event which outsets immediately after injury till the formation of healthy scar. Karanjadhya Ghrita contains 16 ingredients including Go-ghrita. “Vrana Ropana” property of Karanjadhya ghrita is primarily due to Haridra, Nimba, Karanja and Yashthimadhu and “Vrana Shodhana” property is due to Anantmool, Raktchandan, Patola and Jati. “Vrana Pachan” property is mainly attributed to Haridra, Patola, Ushira and Krishana Sariva¹⁴. Go-ghrita is used in most *ayurvedic* formulations. Cow ghee’s regenerative properties are also useful for healing wounds and promoting the growth of healthy cells. This wound healing ability has also been clinically proven^{15, 16}.

Mode of Action: The mode of action (karmukta) of Karanjadhya Ghrita along with its properties is given below –

Table showing the properties of Karanjadhya Ghrita

| S.No. | Ingredients | Karmukta |
|-------|------------------------|--|
| 1 | Karanj and other drugs | Vedanasthapaka, Sothahara, Dipana, Dahahara, Vrana Shodhaka, vrana ropaka. Putihara, Krimighna, Kandughna, Shoolhara and Ama Pachaka. |
| 2 | Go ghrita | Agnidipaka, Varnya, Dhatuvaradhaka, Shothahara, Jivaniya, Balya, Vishaghna, Vrana Ropaka, Prasadak, Dhatuvaradhaka, Prinana and Vranaya. |

In order to achieve the main goal of wound healing, it is necessary to remove maximum debridement at the site of Vrana (Vrana Shodhan). By virtue of Lekhana Putihara, Dahahara, Kandughana and Vrana Ropana properties of Karanjadhya Ghrita contents, the sthaniya Dhatu Dushti is ceased. The second step in the path of healing is Vrana Pachan and is due to Ama Pachaka properties of the contents. The third step of healing is to enhance (Vrana Ropana) and for this purpose, Go-ghrita is made easy way. Lipophilic action of ghee easily facilitate transportation to a target organ and final delivery, inside the cell, because cell membrane also contains lipid. This lipophilic nature of ghee facilitates entry of the formulation into the cell and its delivery to the mitochondria, microsomes and nuclear membrane. According to Ayurveda, Go-ghrita is beneficial for Rasa Dhatu and Rakta Dhatu. It possess Sheta Guna as well. With all these properties, Ghrita enhance the Rasagni and Raktagini and thus increase the Ropana Karma¹⁷.

CONCLUSION:

Observation, analysis and results of the present study can be concluded as follow –

- Topical application of Karanjadhya Ghrita is found efficacious in the wound healing. It possesses sufficient efficacy in “Vrana Shodhan and Ropana” without producing any adverse effects.
- Analysis of types of wounds showed that 72.72% of treated cases of fissure were cured, followed by 66.67% of cases of post-operative wound were cured. Similarly some cases (50%) of Pressure sores were also reported cured.
- The size was decreased 69.23% which was statistically highly significant.
- There was considerable improvement (> 80 %) in swelling and unhealthy margin.
- Pain, tenderness, discharge and unhealthy granulation tissue showed moderate effect (between 60 to 70 percent) in the chronic wounds.

Hence, from the present study, it can be speculated that Karanjadhya Ghrita possess sufficient efficacy in Vrana Shodhan and Vrana Ropana without producing any adverse effects.

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