Randomized controlled clinical study of gandiradi tail in the management of dushta vrana with special reference to infected wound.

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ABSTRACT:
Wound is a common encountered problem faced in a surgical practice. Treatment of wound healing is probably the first medical problem faced by a human being. Treatment of Dushtavrana is one of them. According to Sushruta Acharya Vrana is of two types Nija and Agantuj. Acharya Sushrut considered Vrana as a prime disease in the domain of surgery and that is why he has described 60 measures for wound management. Treatment with local application of Gandiradi tail have shown effective result during and post follow up of treatment in reducing sign and symptoms. The aim and objective of this clinical study is to evaluate efficacy of a local application of Gandiradi tail in the management of Dushtavrana. Total 66 patients were selected as open random clinical study, out of 66 patients, 33 patients were treated by application of Gandiradi tail and 33 patients were treated by application of Nirgundi tail for 7 days daily and assessment was done on 3rd, 5th, 7th and 14th day. Both the drug found effective in the management of infective wound. The percentage of patients of the healed wound was 48.48% in Gandiradi's Taila and 36.36% in Nirgundi Taila.

Key words: Dushtavrana, Infected wound, Gandiradi tail

INTRODUCTION:
Ayurveda focuses more on healthy living than the treatment of disease. The main concept of Ayurveda is to personalize the healing process. According to Sushruta Acharya Vrana is of two types Nija and Agantuj [1]. Acharya Sushruta has explained 16 types of Nija Vrana, depending on the Vatadi Doshic involvement, and also included Shuddha-Vrana in it.[2]
Suddhavarna which if delayed in proper Chikitsha may get converted to Dustavrana.

Vrana is *Gatravichurne, Vranayateti Vranah*. [3] In this “Gatra” mean body, *Vichurne* means destruction, break, rupture and discontinuity. The destruction break or discontinuity of body part is called “Vrana.” Wound is a break in integrity of the skin or tissue often, which may be associated with distruption of structure and function. Wound healing is a body response to injury in an attempt to restore normal structure and function. Wound healing is divided in three phase inflammatory phase, proliferative phase, and remodeling phase.

*Nija Vrana* due to Doshas and Agantuj vrana are caused by shrap weapons, stone, poison etc. In Ayurveda simulates ulcers or wound; which may get converted into *Dushta vrana* i.e infectious or complicated wound in due course of time if left untreated. *Sushruta* has explained sixty measure for wound management. Precise management of *Dushta Vrana* has been described in various ayurvedic texts. Many formulation are in use for centuries for *Dushta vrana*. One of these is described in *Chakradatta* is *Gandiradi tail*. The objective of study is to evaluate the effect of *Gandiradi tail* on the basis of relief of sign and symptoms of *Dushta Vrana*. All content of *Gandiradi tail* are Ushna virya and Tikta- Katu Ras Pradhan so its effect is Kaphvatshaman, Vranasodhan and *Vranropan* so helps in wound healing process. According to Materia Medica, the contents of *Gandiradi Tail* drugs has antiseptic, anti-inflammatory, and disinfectant properties so ultimately help to wound heals faster.

AIM:

To study the wound healing effect of *Gandiradi Taila* in the management of *Dushta Vrana* with special reference to an infected wound.

OBJECTIVES:

Primary Objectives:

To study the wound healing effect of *Gandiradi Tail* local application for 7 days in comparison with *Nirgundi Tail* in *Dushta Vrana* with special reference to an infected wound.

MATERIAL AND METHOD:

A complete clinical examination of the patient's general condition and examination of *Vrana* had been done on the day first of examination. In the trial group, *Gandiradi tail* has been taken for study and in the control group *Nirgundi tail* has been taken for the study. The dressing is done by the local application of *Gandiradi Taila* and *Nirgundi Taila* with soaked gauze for 7 days daily. Patients undergoing study were examined clinically in every follow- up & record was maintained.
Trial group:
Group A (Trail Group) = 33 patients
Drug - Gandiradi Tail
Route - Local application (Dressing) of Gandiradi Tail with sterile gauze.
Duration - Once daily for 7 days

Group B (Control Group) = 33 patients
Drug - Nirgundi Tail
Route - Local application (Dressing) of Nirgundi Tail with sterile gauze.
Duration –Once daily for 7 days

Procedure:
The first wound was cleaned with N.S. then it was dried with a sterile pad. Then gauze soaked Tail was applied on the wound and dressing was done.

Sample size: 66

Study design: Randomized controlled clinical trial

Inclusion criteria:
1. Gender: Irrespective to Gender
2. Age: no limit but preferably 18 to 40 yrs established cases of infected wounds.
3. Wound / ulcer size: 3 to 15 cm².
4. Patient ready to abide and to give written consent.
5. Wounds up to muscle.

Exclusion criteria:
- Patients suffering from a major illness like cirrhosis liver, ascites, renal failure, DM, tuberculosis, AIDS, or HIV syndrome.
- Patients with malignancy
- Bleeding disorders
- Multiple ulcers (More than three)
- Diabetic ulcers
- Varicose ulcers
- Arterial ulcers
- T.A.O.
- Leprotic ulcers
- Gonorrhreal ulcers
- Syphilitic ulcers
- Vranas situated over Asthi, Sandi, Koshta, and Marma, Adhisthana.
- Age group < 18 years and > 40 years old.

Investigations
- Hb - CT - BT - ESR
- BSL – R - HIV - I and II
- HbsAg

ASSESSMENT CRITERIA:
1. Size in cm²: The size of the wound was plotted on trace paper and that area was measured with the help of Xerox of graph paper on a transparent overhead project sheet.
2. Pain: VAS Scale applied.
3.

Table no. 1: Showing Gradation of parameters:
| Grade | Slough | Discharge | Granulation |
|-------|--------|-----------|-------------|
| 0     | Absent | Absent    | Wound closed / Healthy granulation tissue |
| 1     | Slough covered up to 25% of wound | Sero Sanguineous | 75% wound covered with granulation tissue |
| 2     | Slough covered 25 to 50% of wound | Serous | 50% wound covered with granulation tissue |
| 3     | Slough covered up to 50 to 75% of wound | Purulent discharge without smelling | Unhealthy granulation with slough. |
| 4     | Slough covered all over wound | Purulent discharge with foul-smelling | Absent. |

**CRITERIA FOR ASSESSMENT OF RESULT (Overall Assessment Criteria):**

1. Healed–Wound completely healed, scab formation.
2. Improved–Wound size reduced, baseline form
3. Not improved- No reduction in size or complication e.g. increase pus formation.

**OBSERVATIONS AND RESULT**

Table no 2: showing statistical data presentation of before and after treatment in trial and control group.

| Sr. No. | Criteria | Group | Mean | SD | SE | W   | p-value | Significant |
|---------|----------|-------|------|----|----|-----|--------|-------------|
|         |          |       | BT   | AT | BT | AT  |        |             |
| 1       | Pain     | Trial | 3.48 | 0.45 | 1.18 | 0.70 | 0.21 | 0.12 | -561.00 | <0.0001 | Significant |
|         |          | Control | 3.18 | 0.48 | 0.70 | 0.68 | 0.18 | 0.12 | -561.00 | <0.0001 | Significant |
| 2       | Slough   | Trial | 2.52 | 0.39 | 0.94 | 0.77 | 0.16 | 0.13 | -561.00 | <0.0001 | Significant |
|         |          | control | 2.70 | 0.61 | 0.85 | 0.78 | 0.15 | 0.14 | -561.00 | <0.0001 | Significant |
| 3       | Granulation | Trial | 2.52 | 0.39 | 0.94 | 0.83 | 0.16 | 0.14 | -561.00 | <0.0001 | Significant |
|         |          | Control | 2.70 | 0.83 | 0.85 | 0.56 | 0.15 | 0.10 | -561.00 | <0.0001 | Significant |
| 4       | Discharge | Trial | 1.97 | 0.12 | 0.85 | 0.72 | 0.15 | 0.12 | -496.00 | <0.0001 | Significant |
|         |          | Control | 1.82 | 0.21 | 0.70 | 0.60 | 0.12 | 0.10 | -561.00 | <0.0001 | Significant |
### Table no 3: showing statistical data presentation of before and after treatment in trial and control group.

| Group | N  | Mean Rank | Sum of Ranks | Mann-Whitney U | P-Value |
|-------|----|-----------|--------------|----------------|---------|
| Pain  |    |           |              |                |         |
| Group A | 33 | 39.64     | 1308.00      | 450            | 0.1990  |
| Group B | 33 | 27.36     | 903.00       |                |         |
| Total  | 66 |           |              |                |         |
| Slough|    |           |              |                |         |
| Group A | 33 | 35.38     | 1167.50      | 514.500        | 0.6490  |
| Group B | 33 | 31.62     | 1043.50      |                |         |
| Total  | 66 |           |              |                |         |
| Discharge |    |           |              |                |         |
| Group A | 33 | 36.00     | 1188.00      | 480.000        | 0.3813  |
| Group B | 33 | 31.00     | 1023.00      |                |         |
| Total  | 66 |           |              |                |         |
| Granulation |    |           |              |                |         |
| Group A | 33 | 35.36     | 1167.00      | 527.000        | 0.7681  |
| Group B | 33 | 31.64     | 1044.00      |                |         |
| Total  | 66 |           |              |                |         |

### Table no 04: Showing Statistical data presentation of size of wound

| Size of Wound (sq.cm) | Mean | N  | SD  | SE  | Z-Value | P-Value | % Effect |
|-----------------------|------|----|-----|-----|---------|---------|----------|
| Group A               |      |    |     |     |         |         |          |
| BT                    | 6.52 | 33 | 2.47| 0.66| 3.55    | p<0.05  | 69.90    |
| AT                    | 1.96 | 33 | 2.83|     | 2.52    | p<0.05  | 58.59    |
| Group B               |      |    |     |     |         |         |          |
| BT                    | 6.60 | 33 | 2.33| 0.67| 2.52    | p<0.05  |          |
| AT                    | 2.73 | 33 | 2.96|     |         |         |          |

### Table no 05: Showing Statistical data presentation of size of wound

| Group | N  | Mean | SD  | SE  | Z-Value | P-Value | Result |
|-------|----|------|-----|-----|---------|---------|--------|
| Group A | 33 | 4.56 | 1.32| 0.22| 2.097   | 0.024   | Sig    |
| Group B | 33 | 3.87 | 1.61| 0.28|         |         |        |
### Table No. 06: Showing Statistical data presentation of foul smell

| Foul smell | Trial Group | Control group |
|------------|-------------|---------------|
|            | BT          | AT            | BT          | AT          |
|            | N   %       | N   %         | N   %       | N   %       |
| Absent     | 4  12.12    | 30  90.91     | 6  18.18    | 27  81.82   |
| Present    | 29  87.88   | 3   9.091     | 28  84.85   | 6   18.18   |
| TOTAL      | 33  100     | 33  100       | 33  100     | 33  100     |

### Table No. 07: Showing Statistical data presentation of Tenderness

| Tenderness | Trial Group | Control group |
|------------|-------------|---------------|
|            | BT          | AT            | BT          | AT          |
|            | N   %       | N   %         | N   %       | N   %       |
| Absent     | 0   0       | 20  60.61     | 0   0       | 17  51.51   |
| Present    | 33  100     | 313 39.39     | 33  100     | 16  48.48   |
| TOTAL      | 33  100     | 33  100       | 33  100     | 33  100     |

### Table No. 08: Showing Overall assessment

| Result     | Group A | Group B |
|------------|---------|---------|
|            | Frequency | Percentage | Frequency | Percentage |
| Healed     | 16       | 48.48   | 12       | 36.36      |
| Improved   | 17       | 51.52   | 21       | 63.64      |
| TOTAL      | 33       | 100.00  | 33       | 100.00     |

before treatment, on 0th day,

After treatment, on 7th day
DISCUSSION:

**Gandiradi Tail** [4]
According to Ayurveda, Gandiradi Tail is effective in the management of Dushtavrana. It is due to the properties of the content of Gandiradi Tail.

**Snuhi:** [5]
Rasa – Katu, Vipaka – Katu, it has Ushna Virya and Laghu and Tikshna Guna. It act as Sothhara and Kaphvatahara. It act as a Vedanasthapan so reduces pain.

**Arka:** [6]
Rasa- Katu, Tikta, Vipaka- Katu, it is having Katu Viapaka and Ushna Virya and Laghu, Ruksha and Tikshna Guna so by having this properties it act as a Vedanasthapan, Shothhara and Vranashodhana.

**Chitrak:** [7]
Chitrak has Rasa- Katu, Vipaka- Katu, it is having Ushna Virya and Laghu, Ruksha, and Tikshna Guna and by these properties, it acts as a Shothhara and Krimighna.

**Bhringraj:** [8]
Bhringraj has Rasa- Katu, Tikta, and Vipaka- Katu, Virya- Ushna, and having Ruksha and Laghu Guna, and by these properties, it acts as Vranasodhan, Vranaropan and reduces pain. It is also responsible for Savarnikaran.

**Kutaj:** [9]
Rasa- Tikta, Kashya, Vipaka-Katu, Virya- Sheeta and Laghu, and Ruksha guna. By having these properties it acts as a Vranaropan.

**Kushta:** [10]
Rasa- Katu, Tikta, and Madhur, Vipaka- Katu, Virya– Ushna and Laghu, Ruksha, and Tikshna Guna so by these properties, it is Kaphavatshamak and act as Durgandhanashak, Jantughna, and Vedanasthpan.

**Til Tail:**
It has Rasa Katu, Tikta, Madhura, its Anurasa is Kashaya. Til Tail has properties of Vata Kaphahara Doshaghnta and Karmuktas are Twakprasadana, Mardavkara, Balya, Brihana, Prinana, Vranashodhana, and Vranaropana. Tila Taila also has Prinan, Vyavayi, Vikasi guna which helps to reach drugs till the depth of the wound. It helps in reducing pain & inflammation by its Ushnavirya & Shothaghna properties.

**Nirgundi:** [11]
Rasa- Katu, Tikta, Virya-Ushna, Vipaka-Katu, Guna-Laghu, Ruksha, Kaphavatashamak. Nirgundi itself has Krimighna & Vishaghna properties.

Nirgundi and Gandiradi Taila collectively have the property of Tridoshashamaka. Vata & Kapha Doshas play a major role in Vranadushti so by application of this oil help in inhibiting the Doshadushti & ultimately wound healing process progresses faster.
CONCLUSION:
It was concluded that Gandiradi Tail is more effective in reducing sign and symptoms than Nirgundi Tail.

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