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A RANDOMISED CONTROLLED CLINICAL STUDY ON THE EFFICACY OF HEMIGRAPHIS COLORATA LEAF EXTRACT OINTMENT IN SADHYO VRANA

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ABSTRACT

Background: Throughout history, man has suffered from dermal wounds. An injury is the adverse effect of physical force upon a person. In ancient times, substances derived from animals, plants, and minerals formed the basis of crude remedies. One of the exotic plants in our country, Hemigraphis colorata, is an excellent garden plant with healing properties. *Ghrishta* is a rib injury that only involves skin. *Chinna* contains lacerations and incision injuries. *Bhinna* is a deep injury without any perforation.

Objective: To study the wound healing effect of Hemigraphis colorata leaf extract ointment in *sadhyo vrana* and to compare the efficacy of povidone-iodine (Betadine) ointment and Hemigraphis colorata ointment in *sadhyo vrana*.

Methodology: This was a single-blind study involving 40 patients, with the selection criteria of *sadhyo vrana*. In Group A, the wound was dressed in Hemigraphis colorata ointment. In Group B, the wound was dressed in betadine ointment. The patients were cared for daily for 21 days or until granulation tissue formation. Weekly followups and statistical analysis were conducted.

Result: A significant improvement was noted in both subjective (Pain and Burning sensation) and objective (Size, Discharge, granulation tissue) outcomes.

Conclusion: Each ointment shows improvement in subjective symptoms (pain, burning sensation) as well as objective symptoms (Size, Discharge, granulation tissue)

Keywords: Hemigraphis colorata, sadhyo Varana, Fresh wounds

INTRODUCTION

Humans have been prone to injury since the dawn of life, prompting early thoughts on healing. In Ayurveda, especially by *Acharya Charka* and *sushruta*, various types of wounds and their treatments have been detailed, which are crucial in surgical practice.

Throughout history, humans have treated skin wounds using basic remedies derived from animals, plants, and minerals to stop bleeding, reduce swelling, relieve pain, and prevent infection. A wound is a break in the integrity of the skin or tissue, which may be associated with disruption of structure and function[1]. Treating wounds promptly and cost– effectively is crucial, as they are a common source of pain. The major aspect of managing a fresh wound is preventing infection and speedy healing. Reducing pain, discharge, and discoloration after healing are other important factors.

Hemigraphis colorata is a plant known for its healing properties. In folk medicine, it is believed to be highly effective in prompting wound healing. The leaves are ground into a paste and applied to fresh wounds for treatment. The drug in this study, Hemigraphis colorata, commonly known as Murikootti[2,3], fulfils the properties of Antibacterial[4], wound healing[5] and Anti-inflammatory[6,7], which are required for wound healing. Though the drug is not mentioned in the classics, according to *Aacharya Sushruth*, drugs appropriate to the disease should be included even though they are not mentioned in the text[8].

Methodology

Source of data:

• Forty patients attending the OPD and IPD of Muniyal Ayurvedic Hospital, Manipal, Udupi, with complaints of *sadhyovrana*, were taken for study. Raw drug (Hemigraphis plant) was collected from known sources in Kerela, Identified by *Dravyaguna* experts. Methanolic Extract was prepared from the dried leaves of the plant and mixed in a simple ointment base of 5%(w/w)

Method of collection of data:

Patients with fresh wounds were selected for the study based on predetermined inclusion and exclusion criteria. Eligible patients provided detailed informed consent before being enrolled in the clinical trial. The study's randomized controlled design will compare the outcomes of 40 selected patients with those of a control group. Patients will be randomised into two groups of 20 each: a) the Study group and b) the Control group. The study will assess signs, symptoms, and specified parameters before and after treatment. The outcomes of both groups will be compared, subjected to statistical analysis, and interpreted.

Design of the study: An Open labelled, randomised, comparative, interventional clinical Study.

Inclusion criteria:

- Patients 18 to 60 years of age and from either sex.
- Patients having abrasion wounds, incised or lacerated wounds.

Exclusion criteria:

- 1. Wounds with fracture complication.
- 2. Wounds that require suturing
- 3. wound > 7 days
- 4. HIV, Diabetic, Anaemia patients

Assessment criteria:

Subjective Parameters

- Pain (visual analogue scale)
- Burning sensation

Objective parameters

- Size
- Discharge
- Granulation tissue

Investigations:

- Hb%, TLC, DLC, BT, CT, RBS
- The investigation mentioned above will be done if needed.

Interventions/procedure:

• The wound was examined and cleaned with normal saline. In group A patients, a sufficient quantity of Hemigraphis colorata ointment was applied over the area, and in group B patients, betadine ointment was applied. Then, sterile dressing using gauze and cotton pads was done once a day in our hospital for the first seven days. Later, the patient was educated to do the same at home for the next 21 days or until the wound healed.

Duration of the study:

• The duration of the study is 28 Days.

Follow up:

- The wound will be assessed on the 7th, 14th and 21st day of follow-up.
- Post follow-up, i.e., on the 28th day, is to check for skin texture and any adverse effects that may be delayed.

Statistical Test:

The data collected was analysed statistically within and between groups using the Wilcoxon signed rank test and the Mann-Whitney U test.

Interpretations:

- P value < 0.001 significant
- P value >0.05 Not significant

RESULTS

1. EFFECT OF TREATMENT ON PAIN Effect on Pain in Group A

Mean score of Pain which was 6.9 on the 1^{st} day, 3.1 (55%) on 7^{Th} day, 1.1(84%) on 14^{th} day and completely reduced to 0.0(100%) on 21^{st} day of the treatment

Effect on pain in Group B

The mean score of pain was 6.0 on the 1^{st} day, 3.6(40%) on the 7th day, 1.4(76%) on the 14th day, and ultimately reduced to 0.0 (100%) on the 21st day of the treatment.

By adopting the Wilcoxon Signed Rank test, it was found that the improvement recorded in both groups was statistically significant with a p-value <0.001.

Comparing the effect of treatments between the groups

Analysis of this data shows a statistically insignificant difference (P = 0.153) between the two groups.

2. EFFECT OF TREATMENT ON BURNING SENSATION

Effect on Burning Sensation in Group A

Mean score of Burning sensation which was 2.7 on 1^{st} day got reduced to 1.25(53.7%) on 7^{th} day, 0.30(88.8%) on 14^{th} day and completely reduced to 0.0(100%) on 21^{st} day of the treatment

Effect on Burning Sensation in Group B

The mean score of burning sensation, which was 2.65, has been reduced to 1.7 (35.8%),0.75(71.6%) on the 14th day and wholly reduced to 0.00 (100%) on the 21st day of treatment. By adopting the Wilcoxon Signed Rank test, it is found that the improvement recorded in both was statistically significant with a p-value <0.001.

Comparing the effect of treatments between the groups

Analysis of this data shows a statistically significant difference (P = 0.005) between the two groups.

3. EFFECT OF TREATMENT ON SIZE Effect on Size in Group A

The meen score of size u

The mean score of size was 2.9 on the 1^{st} day,1.45(50%) on the 7th day of treatment, 0.45(84.4%) on the 14th day of treatment, and ultimately reduced to 0.00(100%) on the 21st day of treatment.

Effect on Size in Group B

The mean score of Size was 3.0 on the 1^{st} day, 1.85(38.3%) on the 7^{th} day, 0.7 (76.6%) on the 14^{th} day, and ultimately reduced to 0.0(100%) on the 21^{st} day of the treatment.

By adopting the Wilcoxon Signed Rank test, it is found that the improvement recorded in both was statistically significant with a p-value <0.001.

Comparing the effect of treatments between the groups

Analysis of this data shows a statistically significant difference (P = 0.784) between the two groups.

4. EFFECT OF TREATMENT ON Discharge Effect on Discharge in Group A

The mean discharge score was 2.5 on the first day, 0.7(72%) on the seventh day, and 0.0(100%) wholly cured until the 14th day of treatment.

Effect on Discharge in Group B

Mean score of discharge which was 2.5 on 1^{st} day, 1.25(50%) on 7^{th} day,0.3(88%) on 14^{th} day and 0.0(100%) on the 21^{st} day of the treatment.

By adopting the Wilcoxon Signed Rank test, it is found that the improvement recorded in both was statistically significant with a p-value <0.001.

Comparing the effect of treatments between the groups

Analysis of this data shows a statistically insignificant difference (P = 0.76) between the two groups.

5. EFFECT OF TREATMENT ON GRANU-LATION TISSUE

Effect on Granulation Tissue in Group A

The mean score of Granulation tissue was 2.35 on the 1^{st} day, 1.05(55.3%) on the 7th day, 0.25(89.3%) on the 14th day, and 0.00(100%) wholly reduced on the 21st day of treatment.

Effect on Granulation Tissue in Group B

Mean score of granulation tissue which was 2.2 on the 1^{st} day, 1.4(36.3%) on the 7th day, 0.5(86.3%) on the 14th day and 0.0(100%) on 21st day of treatment.

By adopting the Wilcoxon Signed Rank test, it is found that the improvement recorded in both was statistically significant with a p-value <0.001.

Comparing the effect of treatments between the groups

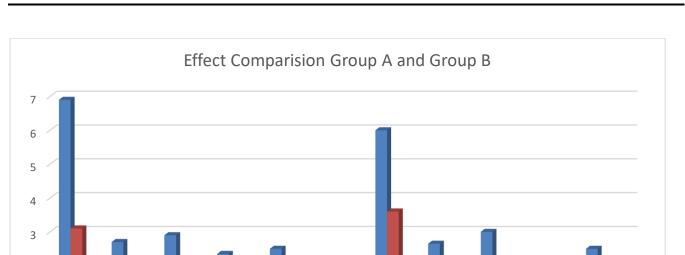
Analysis of this data shows a statistically significant difference (P = 0.59) between the two groups.

BURNING SENSATION	Mean			
	1st	7th	14th	21st
	2.7	1.25	0.30	0.0
GROUP A	% Relief	53.7%	88.8%	100%
	2.65	1.7	0.75	0.0
GROUP B	% Relief	35.8%	71.6%	100%

Size	Mean			
	1 st	7th	14th	21st
	2.9	1.45	0.45	0.00
GROUP A	% Relief	50%	84.4%	100%
	3.0	1.85	0.7	0.0
GROUP B	%Relief	38.3%	76.6%	100%

Granulation tissue	Mean			
	1st	7th	14th	21st
	2.35	1.05	0.25	0.00
GROUP A	%Relief	55.3%	89.3%	100%
	2.2	1.4	0.5	0.0
GROUP B	%Relief	36.3%	86.3%	100%

Discharge	Mean			
	1st	7th	14th	21st
	2.5	0.7	0.0	0.0
GROUP A	% Relief	72%	100%	100%
	2.5	1.25	0.3	0.0
GROUP B	% Relief	50%	88%	100%



DISCUSSION

Pain

Sensation

2

1

0

Effect on pain: P- the value of less than 0.001 was observed in both group's A and B, which were identical outcomes. No statistical difference was observed when compared between the two groups P>0.10. Pain was reduced by 55% on the 7th day, meaning the day in group A patients and reduced by 40% on the 7th day and 76% on the 14th day in Group B patients. Through this observation we can conclude that Group A patients got faster and better Pain relief than Group B.

Granuation tissue

Discharge

1st

Pain occurs due to vata vitiation, a sign of inflammation, and the body's response to injury. The hemigraphis plant contains high quantities of phenolic and flavonoid compounds. Due to its high antioxidant and free radical scavenging properties, it inhibits COX1 and COX-2 enzymes, which are considered the main enzymes responsible for pain.

Effect on Burning sensation: P- the value of less than 0.001 was observed in groups A and B, meaning

identical outcomes. No statistical difference was observed when compared between the two groups P>0.10. Burning was reduced by 53.7% on the 7th day, 88.8% by the 14th day in Group A patients and reduced by 35.8% on the 7th day and 71.6% by the 14th day in Group B patients. Through this observation, we can conclude that Group A patients got faster and better relief from burning than Group B.

Granulation Tissue

Discharge

1. Sensation

14th

Pain

7th

The plant has a bitter taste, i.e., *Tikta Rasa*, which has properties that reduce *Pitta* due to its *sheeta veerya*[9], hence providing quicker relief from the burning sensation. According to *Acharya Charaka*, *Tikta* rasa *guna* reduces itching and burning sensation, *pitta*, and has *Laghu*, *sheeta* and *rooksha* properties[10]. The bioactive compounds such as flavonoids and tannins also have potent anti-inflammatory effects, thus explaining the early impact of plants on burning sensation.

Effect of treatment on size: P- value of less than 0.001 was observed in groups A and B, meaning iden-

tical outcomes. No statistical difference was observed when compared between the two groups P>0.10. Size was reduced by 50% on the 7th day, 84.4% by the 14th day in Group A patients and 38.3% on the 7th day, 76.6% by the 14th day in Group B patients. Through this observation we can conclude that Group A patients got faster and better wound size relief than Group B.

Hemigraphis colorata plant leaves contain isolated compounds like PF1 and PF2, which stimulate cell proliferation and migration through induction of apoptosis, which could be the answer to the wound-healing activity of the plant[11]. This plant exhibits significant astringent (*Kashaya Rasa*) properties, which induce skin contraction and tighten the tissue margins around the wound, leading to faster closure of the wound edges. *Kashaya rasa* pacifies *pitta* and has healing properties[12].

Effect of treatment on discharge: A- A value of less than 0.001 was observed in groups A and B, meaning identical outcomes. No statistical difference was observed when compared between the two groups P>0.10. It was reduced by 72% on the 7th day, 100% by the 14th day in Group A patients and reduced by 50% on the 7th day, and 88% by the 14th day in Group B patients. Through this observation, we can conclude that Group A patients experienced a faster discharge reduction than Group B patients.

The astringent and bioactive properties of the Hemigraphis plant cause vasoconstriction and tissue contraction around the wound site. This tightening effect helps seal small blood vessels and reduces capillary permeability, preventing excess fluid from escaping into the wound site. The *Tikta* and *Kashaya rasa* in the plant has *Shoshana* and *stambhana* properties[13], which means they dry up excess moisture, lymph, and *shleshma* from the wound site, thus reducing the discharge amount.

Effect on Granulation: A P-value of less than 0.001 was observed in groups A and B, which resulted in identical outcomes. No statistical difference was observed when compared between the two groups

P>0.10. Tissue improved by 55.3% on the 7th day, 89.3% by the 14th day in Group A patients, 36.3% on the 7th day and 86.3% by the 14th day in Group B patients. Through this observation we can conclude that Group A patients got faster and better Pain relief than Group B.

Active compounds in the plant stimulate fibroblast proliferation and migration, which is crucial for granulation tissue formation. The anti-inflammatory properties reduce swelling and inflammation around the wound, creating a more conducive environment for granulation tissue formation. The *Tikta rasa* exhibits *Lekhana* (scraping) properties, which help remove dirty, dead and devitalised tissue, providing a sterile environment for better and faster recovery. The *Kashaya Rasa* has *Ropana* (healing) properties, which speed up the granulation tissue formation process[14].

CONCLUSION

- The following conclusions were drawn after the completion of the clinical study.
- Both the drugs showed a 100% reduction in symptoms in every parameter.
- Both drugs were effective clinically, but Hemigraphis has a significant upper hand statistically.
- The results of the hemigraphis ointment were faster during the first week of treatment, and be-tadine caught up at a similar pace in the second week.
- Hemigraphis ointment was smooth and less irritating on the skin than betadine ointment.
- Post-treatment follow-up, i.e., on the 28th day, patients treated with Hemigraphis ointment had less scar formation and better skin texture.
- The important noticeable point is that there were no side or adverse effects after or during the treatment.
- Although both drugs have wound-healing properties, hemigraphis ointment is better than betadine.

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