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A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHASHASHRUTHYADI MALAHARA IN THE MANAGEMENT OF SADYOVRANA

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ABSTRACT

Management of wound probably would have been the first medico - surgical problem faced by physicians. Ever since the life originated, human being has been susceptible to injury, either from animal attacks or other causes, which made him to think about means of healing from very early stage of development. The history of wound healing is, in a sense, the history of humankind. Wounds naturally heal by themselves, unless infected. The hunter – gatherers of the ancient times incidentally would have noticed several substances of plant and animal origin would speed up the process of wound healing and reduce the pain. In the recent decades also humans are not free off injuries and accidents.

They are facing new challenges day by day with the rapid mechanization and urbanization especially in developing countries. This mechanization in their busiest life schedules invariably lead to the increased accidents and injuries. Starting from a minor cut to grievous road traffic injuries needs utmost care and attention. Even a small skin abrasion if left unattended may transform into an infected wound with complications and agony. Due to the complications that accompany the acute uncared wounds, when their healing does not progress in a timely and orderly manner, they can convert into chronic wounds, which are more difficult to manage. Of the many antimicrobial agents available, povidone iodine has remained popular after decades of use for its antisepsis.[1] A very vast description of *Vrana* and *Vranaropaka yogas* have been explained in *Ayurveda* thousands of years ago. *Acharya Sushrutha* was much aware of the importance of *Vrana* and has given a detailed description of *Vrana* and its management elaborately described in *Shashti upakrama.*[2]*Alepa* is one

among them. It is having the properties like –*Vranaropana, Vranashodhana, Vedanahara, Shophahara.*[3] An ancient *Ayurvedic* text named *Yogamrutham* mentions *Shashashruthyadi malahara* in *Vrana chikitsa adhyaya*.[4] It includes *Haridra , Yastimadhu, Karpoora Madhuchishta ,Akhukarni swaras*a and *Tila thaila*. *Akhukarni or Shashashruthi* is one among the ten sacred flowers of Kerala state commonly known as *'Dashapushpam'* which are predominantly used in *Ayurveda.* The wound healing activity of *Emilia sonchifolia* in experimentally produced wounds in rats showed significant results.[5] This can be attributed to the flavanoid content of the drug. Literature studies reveals the wound healing activity of *Shashashruthi*. In classics *Haridra* has gained place in most *Vrana Ropana Yogas*. It is universally accepted for its antimicrobial action. *Haridra* is explained in the *Nighantus* for its *Shodana, Ropana, Kushtaghna, Vishghna, Pramehahara* action.It has been accepted world wide for its antimicrobial activity. *Yashtimadhu* is also well known for its vrana ropana and shodhana actions. Karpoora is having a soothening effect and it is sheetha veerya,vatha hara by its rasa it is sthambhaka in action so reduces the srava from the wound. Also tila taila is also having vrana ropana gunas and its antioxidant activity helps to prevent oxidative damage and promote the healing process. An acceptable and at-hand mode of administering *Shashashruthyadi malahara* is to be analyzed. A near at hand wound healing agent within the reach of common population is a pressing priority. Thus, the study is intended to evaluate the efficacy of this topical preparation, *Shashashruthyadi Malahara* in *Sadyovrana* by a clinical trial.

INTRODUCTION

Management of wound probably would have been the first medico surgical problem faced by physicians.[1] Ever since the life originated, human being has been susceptible to constant wounds and injuries either from animal attacks or due to other causes, which made him to think about means of healing from very early stage of development. The history of wound healing is, in a sense, the history of humankind.

Objectives of the study

To evaluate the efficacy of Shashashruthyadi malahara in the management of Sadyovrana and its comparison with standard povidone iodine ointment.

MATERIALS AND METHODS

The drug was authenticated by the experts from the department of Dravyaguna Alva's Ayurveda Medical college, Moodbidri. The preparation of Shashashruthyadi Malahara was

done according to classical method in the pharmacy, Department of P G studies in Rasashastra and Bhaishajya Kalpana, Alva's Ayurveda Medical College Moodubidri Drug content The formulation was taken from an ancient Ayurvedic text Yogamrutham.Ingredients are Haridra, Yashti madhu, Karpoora, Akhukarni swarasa, Tila taila, madhuchishta. Clinical study 60 patients fulfilling the diagnostic and inclusion criteria of Sadhyovrana irrespective of gender, religion, occupation, marital status, socio economic status, educational status was selected for the study and randomly assigned into two equal groups; Group A Povidone Iodine Ointment and Group B Haridra Malahara using odd and even number method.

Inclusion criteria

Patients of age group 16yrs to 70yrs. Sadyovrana of following dimension maximum length:5cm, maximum width:5cm. maximum depth:5 mm. Patients of either sex were taken. Wounds occurred within 7 days. Kshataja Vrana (Laceration), Ghrishta Vrana (Abrasions). Chinna Vrana (Excised wound).

Exclusion criteria

Patients with systemic disorders like Type II DM, HTN, Bleeding disorders, wounds that require suture, Dushta Vrana, patients having Sadyovrana with other complications like fractures, Marmaghata, Pregnant women were excluded.

Assessment criteria

The subjective parameters like pain, burning sensation, edema were assessed based on the scoring(0,1, 2 and 3) and objective parameters like discharge from the wound based on grading (0,1, 2, 3), size of the wound in terms of length breadth and depth measured were assessed.

OBSERVATION AND RESULTS

In the present study 76.60% of the patients in the age group of 16-20years,: In the study, out of 60 patients, 55% were male and 45% were females, 80% patients were students. On observing the religion of the patients, maximum 88.3% of patients was Hindus, 73.3 % were reported from middle class. Among 60 patients selected for the study, 61.66% of the patients were Among 60 patients selected for the study, 41.6% patients were diagnosed as Ghrishta Vrana, 21.6% patients as Chinna Vrana, and 36.6 % patients as Kshataja Vrana suffering from wounds over lower limb, 23.33% of the patients were suffering from wounds over upper limb and 15% of the patients were suffering from wounds over the face. Among 60 patients

selected for the study, 41.6% patients were diagnosed as Ghrishta Vrana, 21.6% patients as Chinna Vrana, and 36.6 % patients as Kshataja Vrana.

Analytical study

The pH analysis was done and the results shown that the pH of the drug was around 5.

Statistical analysis

Statistical package used here is Sigma Stat version 3.1. Comparitive analysis of overall effect of the tr eatment in both groups was done statistically with **Mann-Whitney Rank Sum Test** and within the group comparison with **Wilcoxon Signed Rank Test.**

Effect of treatment in pain

In group A, after application of Povidone iodine ointment the severity of pain was reduced by 63.71% during the treatment on the 3rd day and 84.94% relief was recorded on the 5th day and on 7th day 100% result was seen. On follow up on 22nd day and 30th day also 100% relief was observed.

In group B, after application of *Shashashruthyadi malahara* the severity of pain was reduced by 70% during the treatment on the 3rd day and 100 % relief was recorded on the 5th day 100% relief was observed on the 7th day. On follow up on 22nd day and 30th day also 100% relief was observed.

Effect of treatment on edema

In group A after application of *Povidone iodine ointment* the edema was reduced by 46.7% during the treatment on the 3rd day and 53.3% relief was recorded on the 5th day 100% relief was observed on the 7th day. On follow up on 22nd day and 30th day also 100% relief was observed. After application of *Shashashruthyadi malahara* the edema was reduced by 100% during the treatment on the 3rd day and 100% relief was recorded on the 5th day 100% relief was observed on the 7th day. On follow up on 22nd day and 30th day also 100% relief was observed.

Effect of treatment in srava

In group A, after application of *povidone iodine ointment* the edema was reduced by 35.72% during the treatment on the 3rd day and 67.86% relief was recorded on the 5th day100% relief was observed on the 7th and 15th day. On follow up on 22nd day and 30th day also 100% relief was observed.

In group B, after application of *Shashashruthyadi malahara* the Srava was reduced by 28.60% during the treatment on the 3rd day and 51.79% relief was recorded on the 5th day 100% relief was observed on the 7th and 15th day. On follow up on 22nd day and 30th day also 100% relief was observed.

Effect of treatment in length of the wound

In group A, after application of *povidone iodine ointment* the length was reduced by 20.98% during the treatment on the 3rd day and 42.19% relief was recorded on the 5th day 68.71% relief was observed on the 7th and 91.13% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

In group B After application of *Shashashruthyadi malahara* the length was reduced by 21.36% during the treatment on the 3rd day and 42.94% relief was recorded on the 5th day 71% relief was observed on the 7th and 100% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

Effect of treatment in breadth of the wound

In group A, after application of *povidone iodine ointment* the breadth was reduced by 27.71% during the treatment on the 3rd day and 51.60% relief was recorded on the 5th day 100% relief was observed on the 7th and 100% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

In group B, After application of *Shashashruthyadi malahara* the breadth was reduced by 18.33% during the treatment on the 3rd day and 36.45% relief was recorded on the 5th day 100% relief was observed on the 7th and 100% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

Effect of treatment on depth of the wound

In group A, After application of *Shashashruthyadi malahara* thedepth was reduced by 63% during the treatment on the 3rd day and 96.33% relief was recorded on the 5th day 100% relief was observed on the 7th and 100% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

In group B, After application of *Shashashruthyadi malahara* the depth was reduced by 100% during the treatment on the 3rd day and 100% relief was recorded on the 5th day 100% relief

was observed on the 7th and 100% relief on 15th day. On follow up on 22nd day and 30th day 100% relief was observed.

Comparitive result of group A and B

Table 1

Percentage of improvement / relief after treatment (15th day)	Group a	Group b
Pain	100%	100%
Burning sensation	100%	100%
Edema	100%	100%
Srava	100%	100%
Length	97.13	100%
Breadth	97.0%	100%
Depth	97.11%	100%

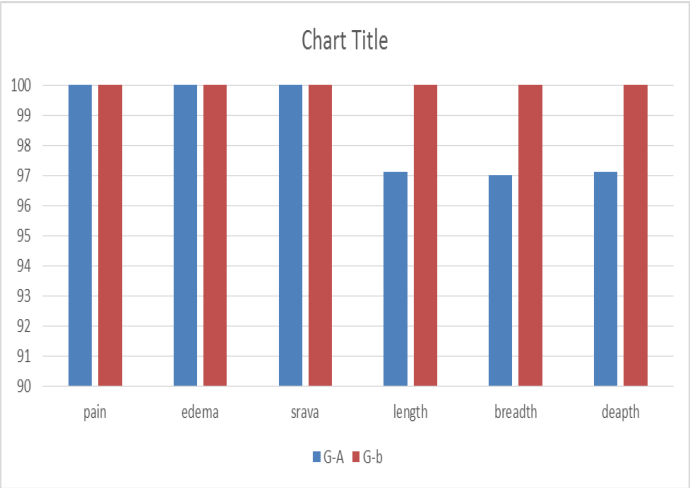

Fig. 1

DISCUSSION

Discussion on analytical study

The pH of Shashashruthyadi malahara was found to be around 5. Healthy intact skin has a slightly acidic pH between 4.0 and 6.0. This regulates the bacterial flora and prevents infection.[4]

Mode of action of povidone iodine ointment

In povidone iodine ointment Iodine forms a complex with carrier polymer povidone. Polymer povidone itself has no microbicidal action. When combined with iodine, in an aqueous medium free iodine is released which has germicidal action. This free iodine penetrates the microbial cell membrane and deactivates the proteins as well as DNA/RNA of the pathogens.

Povidone iodine has anti inflammatory activity. Although inflammation occurs as a physiological response to wound healing, microbial infection can induce excessive inflammation. Povidone iodine helps preventing this. Povidone iodine protects against the inhibition of granulation tissue formation. Invitro studies suggests that iodine has not only antibacterial effects but also counteracts inflammation caused by both pathogen and host response.

In host parameters it has inhibitory effect on human inflammatory mediators such as TNF alpha and beta galactosidase. Iodine also enhance most of healing signals from pro inflammatory citokinins, by the activation of monocytes, T lymphocytes and macrophages. In pathogens it inhibits the production and release of bacterial exotoxins. This might be the reason for reducing inflammation and accelerating healing process.

Probable mode of action of shashruthyadi malahara

In group B patients were treated with Shashashruthyadi malahara. The drug has ingredients as Haridra Yashtimadhu, karpoora, Akhukarni, Tila taila and Madhuchishta. Most of the ingredients in the formulation has thikta rasa and thus provides vrana shodhana action. Haridra is kaphavatahara in action. yashtimadhu has vatapittahara action. Akhukarni also possess kapha vatahara property Owing to the vatahara action of the ingredients the pain might have reduced.

Haridra is Tikta katu in rasa laghu ruksha in guna, Ushna veerya and Katu in Vipaka.It also has vrana shodana and Vrana ropana qualities.Laghu Rooksha guna of the ingredients Haridra and Akhukarni might have helped in vrana ropana Yashtimadhu is madhura rasa guru snigda guna, sheta veerya and madhura vipaka. Akhukarni is also Kapha vatahara and sheethala. karpoora is Tikta Katu madhura in rasa laghu teekshna Sheetha and katu in vipaka. This sheethala qualities might have reduced the kshathoshma in vrana. Tila Taila is madhura kashaya tikta katu in rasa and guru snigda in guna. Tila taila is having shodhana and ropana properties.

Tila taila is beneficial for the skin. It has anti oxidant contents and vitamin E which can penetrate the skin easily. Terpenoid present in tila taila gives it antibacterial property. Tannin present in the oil makes it antibacterial and antiviral.

Haridra-Curcumin in haridra has the ability of enhancing granulation tissue formation, collagen deposition, tissue remolding and wound contraction. Curcuma Longa has been proved to possess antibacterial activity.[8]

Yashtimadhu-Glycyrrhizin and glycyrrhetinic acid increases collagen formation and enhances healing. It also inhibit the activity of pro inflammatory prostaglandins.[9]

Beewax-Moistens the skin, and pocesses antimicrobial activity against Staphylococcus aureus, candida albicans etc.[10]

Akhukarni- The flavonoid content of Emilia Sonchifolia attribues to the wound healing action. It enhances epitheliazation process and fastens wound contraction. Flavonoids prevents cell necrosis and improves vascularis.[11]

Flavonoids in Emilia sonchfolia has nociceptive action.

- C In present study incidence of *Sadyovrana*was more in the age group between 16- 20 and in males and most of them occurred due to accidental fall.
- Patients in group A treated with (Povidone Iodine) showed the most significant effect on pain, size of wound, edema of the surrounding skin, discharge.
- Patients treated with Shashashruthyadi malahara in Group B showed the most significant effect on pain, size of wound, edema of the surrounding skin, discharge
- There was a significant difference between the various groups in terms of distribution of Time Taken for Healing.
- Thus, by considering all these aspects made a conclusion that the null hypothesis (H_0) is rejected and Alternative hypothesis (H_1) is accepted.

CONCLUSION

Karpoora causes desensitization of sensory nerves and thus relieves pain. Camphor has analgesic properties, antimicrobial antiviral and antitussive properties.[12] In present study incidence of *Sadyovrana*was more in the age group between 16- 20 and in males and most of them occurred due to accidental fall.

Patients in group A treated with (Povidone Iodine) showed the most significant effect on pain, size of wound, edema of the surrounding skin, discharge.

Patients treated with Shashashruthyadi malahara in Group B showed the most significant effect on pain, size of wound, edema of the surrounding skin, discharge.

There was a significant difference between the various groups in terms of distribution of Time Taken for Healing.

Thus, by considering all these aspects it can be concluded that conclusion that Shashashruthyadi malahara possesses very high efficacy in managing sadyo vrana.

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