



Clinical evaluation of nirgundi oil used in ancient Indian medicine – in the management of non-healing ulcers

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ABSTRACT

The management of infected/contaminated wounds modern science is using newer & newer antibiotics are becoming ineffective due to microbial resistance. Along with these antibiotics they use NSAID'S & Multivitamin containing medicines, which are also have many adverse effect on system & they are money consuming also. Considering this, the scholar has a keen urge to reestablish one of the Drug is free from Adverse effects & very little money consuming. It was found that drug nirgundi oil has encouraging results on local application in the management of non-healing ulcers. It enhances proliferation of granulation tissue and helps for natural debridement of the necrosis tissue.

Key words: *Nirgundi, Varna, vitex nigundo wound and ayurveda*

INTRODUCTION

Ayurveda is a science of life which has got holistic tradition of guiding in the direction of ultimate happiness. Wound is a subject of Matter for Shalyatantra. It is said that the surgeon has to create or treat the wound either already occurred due to trauma or vitiated doshas or therapeutically created, everyone has to treat the wound in the management of surgical diseases. In In Ayurveda “Shalyatantra” is one of the prime branches, which includes surgical, medicinal, Para surgical & minimal invasive surgical measures, like Agnikarma, Ksharkarma, Siravedha, Jalokavacharana etc. which are the specialty of “Shalyatantra”^[1]. ‘Sushruta Samhita’ is the principle text of shalyatantra. It has dealt in detail the treatment strategy of different types of wounds. Today’s increasing fast life style & unbalanced ecosystem, problem of wound contamination & infection increasing day by day, which we compare with Dushtavrana/ Dushtavastha of vrana. Dushtavrana this topic is very important for a surgeon because susruta has told in sutrasthana. To resolve wound (Infection/contamination) is also important aim of Shalyatantra^[2]. Acharya Sushruta has described sixty measures in the management of Vrana which includes multiple procedures & multiple preparations in multiple forms. One of them is “Siddha Taila (Drug

processed oil)^[3] on careful perusal of the literature we selected – Nigundisiddhataila for the management of Dushtavrana described by Acharya yogaratnakara in his Samhita^[4]. If we go through these two statements made by madhavnindan^[5] & Sushruta^[6] then we can say that this Vrana is not simple acute vitiated doshaj Vrana. The symptoms described by them are not found in less duration vitiated Doshaj Vrana. So we can say that Dushtavran is an ulcer which presents with Abendent smelling pus-discharge, Discharge of Dushta Rakta, *utsangi* (elevated in nature), *chirasthit* means chronic in nature and this ulcer having symptoms conflicting healing ulcer. We can also say that if any Vrana (ulcer) not get treated in its Dushtavastha then it will transfer in to Dushtavrana.

MATERIALS AND METHOD

Sixty Patients of mild to Moderate wound attending Shalya O.P.D. & I.P.D. is the major material for this study. Total sixty patients are included in this study those who has reported for follow-up regularly. A separate special case record form is used for the detailed history & the findings during the course of study. An informed written consent of all patients included in the study will be taken in the language best understand by them consent form is appended. It was a Prospective open controlled

study with primary objective i.e. evaluation of nirgundi oil in the management of non healing wound . *Nirgundisiddha Tail* will be prepared according to Yogaratnakara Samhita & will be apply locally or Dushtavrana as required. Duration of Treatment was 21 days Follow up was taken Daily for 1st week; Alternate day in 2nd & 3rd week. Record of all the patients including the study will

be documented including form to meet all the requirements of the study has been designed by self. Follow up will be mentioned in the CRF. Complete clinical examination of Patients G.C. & Vrana had done to diagnose & asses patients disease condition on day first of examination & Drug administration locally will be started.

Inclusion Criteria	Exclusion Criteria
1) Sex - either sex 2) Age - No limit but preferably 10 to 80 yrs 3) Established cases of infected wounds 4) Wound / ulcer size - 3 to 15 cm 5) Pt. ready to abide by trial procedure & to give written consent 6) Wounds up to muscle	1) Patients suffering from major illness like cirrhosis liver Ascitis, Renal failure, Tuberculosis, AIDS or HIV syndrome 2) Patients with malignancy, Bleeding disorders T.A.O. 3) Multiple ulcers (More than three), Diabetic ulcers, Varicose ulcers, Arterial ulcers, Leprotic ulcers, Gonorrhoeal ulcers, Syphilitic ulcers 4) Vranas Situated over asthi, Sandhi & Koshta Marma Adhishtana 5) Burn ulcers are excluded.

Parameters: Size, Appearance of margin & edge, Slough, Discharge, Granulation tissue, Tenderness & Subjective parameter and Pain

region. 10% patients have wound's over upper extremity & 3.33% patients have wound overhead region.

Drug Nirgundi Collection: The roots & leaves of fresh Nirgundi (*Vitex nigundo*) Plant collected Roots & Leaved of Nirgundi cleaned up with water after that they are send in the Rasshastra- Bhaishjya Department for Nirgundi Siddhtaila preparation. Tila taila is used to Siddha Drug; it is taken from local market. Nirgundi Siddhtaila is prepared as per reference from yogratnakar^[7]

Tissue affected: - Distribution of tissue affected in wounds of 60 patients under study shows that 86.67% patients were of subcutaneous tissue affected wounds. 10% patients were of skin tissue affected wounds. Whereas 3.33% patients were muscle tissue affected none of the patients has wound affected with bone tissue.

Vranakarma (Wound Dressing): The cleaning of wound has carried with the Normal saline or distilled water. Devitalized tissue debridement carried out in some cases as per the indication without using anesthesia & special procedure. The Nirgundi Siddhtaila is applied considering the site & size of wound in soaked gauze pierce form Vranakarma is practiced daily for first 7 day's & later on alternate day up to 21 days. In few selected & indicated cases Antibiotics & Anti-inflammatory drugs are used. According to parameter gradation and separate documentation is done. Findings (parameters) were noted at 0, 3, 5, 7th, 9th 11, 13, 15, 19, 21st day. Complete assessment was done after 21 days; residual symptoms were noted in the special CRF.

Wound duration :- Distribution according to duration of wounds of 60 patients under study shows 20% wound patients were have 20-29 day duration wounds. 71.67 patients were of 1 to 2 month's duration wounds. 6.67% patients are of above 2 month to 11 month wound duration, 1.67% patients are of 1 years wound duration.

OBSERVATIONS AND RESULTS

Effects of Therapy on Wound Parameters: Effect of therapy on **wound size** in treated group was better than control group because percentage of relief of score in treated group was 93.33% as compared to 80.00% & control group. Effect on **slough** in treated group was better than control group because percentage of relief of score in treated group was 97.95% as compared to 97.82% of control group. Effect on wound **discharge** in treated group was better than control group because percentage of relief of score in treated group was 100% as compared to 94.18% of control group. Effect on **granulation tissue** formation in treated group was better than control group because percentage of relief of score in treated group was 97.97% as compared to 93.82% of control group. Effect on **wound edge & margin** in treated group

Total 60 patients were registered for this study. Following observations were seen.

Site of wound:- 66.67% patients were having wound over lower limbs. 11.67% Wounds occur on Gluteal region. 8.33% Wounds occur over Back

was better than control group because percentage of relief of score in treated group was 91.11% as compared to 82.23% of control group. Effect on **Tenderness** in wound was better in treated group than control group because percentage of relief & score in treated group was 100% as compared to 65.21% of control group. Effect on **pain** was better in treated group than control group because percentage of relief & score in treated group 97.40% as compared to 85.71% of control group. It is seen that effects of therapy on different hematological parameters are not shown any significance on analysis by paired 't' test. As per the criteria of assessment of this study total effect of therapy was enlighten in terms of cured & improved. In this study 73.33% patients were cured in treated group while, only 26.67% patients of control group were cured. However 26.67% patients were improved in treated group, while 73.33% patients improved in control group. After application of chi-square test to this score data where total chi-square was 13.08 where $p < 0.05$. This is highly significant means treated group drug was significantly better works on patients of Dushtavrana.

DISCUSSION

The present study entitled "To study the Role of Nirgundisiddha taila in Dushtavrana" aims to study role of Nirgundisiddha taila in Management of Dushtavrana. This taila is a pure Herbal compound prepared according to Ayurvedic principles. Demographic details in the present study suggest that incidence of Dushtavrana occurrence is more in males 75% than females 25%. The diet taken by the majority of the patient included in the trial was mixed diet 93.33% which suggest the probable diet pattern in the society. 48.33% patients belongs to age group 10 to 30 year & 26.67% in 31 to 50% year age group indicates that the problem is more in age group of 10 to 30 year & there after problem is more in age group 31 to 50 year. This age group, which of them socio-economically poor patient percentage is 46% & 43.33% patients are from middle class. People from almost all professions have been included. The incidence of 'Dushtavrana' is high in patient's worker (Majdoor) by occupation. All religion patients are selected randomly which of the 63.33% patients are from Hindu religion & very least patients are found from christian religion. The high incidence of Dushtavrana is found in patients of educational level is up to primary education status. It indicates literacy also plays major role to cause dushtavrana. The most Dushtavranas occurred on lower limbs i.e. 66.67% indicates this disease is mostly affects lower limb. In 86.67% patients of Dushtavrana, tissue affected by vrana is subcutaneous tissue is

found indication most of wound patients have subcutaneous tissue affected more than 71% patients are of 1 to 2 month wound duration indicates the maximum wound duration of 'Dushtavrana' is 1 to 2 month. In treated group effect of therapy on wound parameters is better than control group. 93.33% relief in size as compared with 80% of control group.

Slough, discharge, granulation, appearance, of margin ledge, tenderness & pain; these parameters have relief 97.35%, 100%, 97.97%, 91.11%, 100% & 97.40% respectively as compared with controlled group, which has relief in percentage 97.87% 94.18%, 93.82%, 82.23%, 65.21% and 85.71% respectively. Indicates treated groups had highly significant results than controlled group. Total 73.33% patients cured in treated group as compared with control group which was 26.67% 73.33% patients improved in control group & 26.67% in treated group indicates cure percentage is more in treated group.

Adverse effects of drug were not observed in any of the patient included in this study except WBC count is increased in treated group & ESR reduced in both groups. no any other significant change was observed in other blood tests and biochemical tests suggest that the drugs has not produced any toxicity or impairment of vital functions in patients treated for a period of 21 days in both group.

Probable Action of Nirgundisiddh Tail: - as per Ayurved View Point Vata & Kapha Doshas are playing major role in vranadushti. Nirgundi & Tilataila the contents of Nirgundisiddha taila have ushnavirya properties Kaphavataghna Doshaghna^[8] so by application of this oil help in inhibiting Doshadushti & ultimately wound healing process proceeds faster. Katu - tikta rasa of this Drug helps in wound healing by its properties of kledshoshana, krimighna shodhan properties. Nirgundi itself has a krimighna & vishaghna properties. Tila taila also helps by its prinan, Vyavayi, Vikasiguna^[9] which helps to reach Drug till depth of wound. It nourishes to the wound also by its snehana & brihana properties by granulation tissue formation. It helps in reducing pain & inflammation by its Ushnavirya & Shothaghna properties. Modern View Point may illustrate that Nirgundi has antibacterial property against many organisms so helps in reducing infection & ultimately wound heals fast. This drug has especially antimicrobial activity against E.Coli^[10]. It has an anti-inflammatory & analgesic action due to its flavanoid content which is known to act through inhibition of prostaglandin Biosynthesis. Contains Flavonoids which are helps in strengthening the new generating vessels^[11]. In short the drug

Nirgundi Siddhataila has actions Antibacterial, Anti-inflammatory, Analgesic Increases granulation tissue formation, has a property of Vrana Shodhan and Vrana Ropana.

Desloughing process also faster in treated group than control group.

CONCLUSION

- 1) The result of clinical trial proved that the Nirgundisiddhataila has significant Results in Dushtavrana (Non Healing Ulcers) Management. in various parameters of wound like size, slough, Discharge granulation, Appearance of margin & edges, Tenderness & pain.
- 2) **It was found that, this preparation has given significant results in** Early initiation of granulation process with this taila application
- 3) This Drug cures Dushtavrana of 2 to 3 month duration completely if it is not complicated by affecting muscle & bone. Dushtavrana situated on skin & subcutaneous only are also completely heals within 21 days.
- 4) The main content of this preparation Nirgundi has flavonoid & Nishindine which helps in reducing pain & tenderness due to their prostaglandin inhibitor property and also flavonoid which strengthens the delicate new generating capillaries. This taila also nourishes the local disturbed dhatu by stimulating granulation which keeps wound healthy.

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