To Study the Role of Nirgundisiddhataila in Dushtavrana


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Abstract Today's increasing fast life style, poverty & imbalanced ecosystem, problem of wound contamination and infection increasing day by day. In this new era person hardly get time to look after his personal health. The present study was designed to study role of Nirgundisiddhataila in management of Dushtavrana (Non Healing Ulcers) patients in comparison with the povidine Iodine ointment. For this study 60 patients were screened divided in to two groups 30 pts in each group with follow up of 21 Days. On completion of trial the statistical analysis concludes the percentage of relief in parameter Wound size - is 93.33%, Slough - Percentage of relief is 97.95%, Discharge Percentage of relief is 100%, Granulation- 97.97% is percentage of relief, Appearance of margin & edges improved up to 91.11%, Pain is relieved up to 97.40% percentage. Tenderness also decreased almost 100%. This research work finally conclude that the Nirgundisiddhataila have a potent wound healing property in Dushtavrana (Non healing Ulcer) management as shodhana and ropana (desloughing and adequate Granulating) agent. Significantly reduction in pain also manifested by this preparation in comparison with povidine Iodine group which needs Antibiotic, NSAID & Antioxidant drugs which costs more to patient. This Nirgundi Siddhataila preparation is cost effective and easily available so this can be used in the management of non healing ulcer with appreciating results.

Keywords Infected Wound; Dushtavrana; Nirgundi; Betadine; Vitex Nigundo

1. Introduction

Ayurveda is a science of life which has got holistic tradition of guiding in the direction of ultimate happiness. 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].

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.
'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/ Dushhtavastha of vrana. Dushtavrana this topic is very important for a surgeon because susruta has told in sutralsthana. To resolve wound (Infection/contamination) is also important aim of Shalyatantra [2].

In 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.

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 Dushtavrana 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.

2. Materials and Methods

Patients of mild to Moderate wound attending Shalya O.P.D. & I.P.D. of M. A. Podar Hospital, Worli; Mumbai- 18 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.

2.1. Ethical Clearance

Clearance from ethical committee of R. A. Podar Medical College, (Ayu.), Mumbai has taken.

2.2. Consent

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.

2.3. Type of Study

Prospective open controlled study.

2.4. Drug and Dose

Nirgundisiddha Tail will be prepared according to Yogaratnakara Samhita & will be apply locally or Dushtavrana as required.

Number of Patients– 60
Duration of Treatment – 21 days
Follow up: Daily for 1st week; Alternate day in 2nd & 3rd week.

CRF - 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.

Clinical Examination: Complete clinical examination of Patients G.C. & Vrana had done to diagnose & assess patients disease condition on day first of examination & Drug administration locally will be started. Patients undergoing study will be examined clinically in every follow up & a record will be maintained.

- **Inclusion 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

- **Exclusion Criteria**
  1) Patients suffering from major illness like cirrhosis liver, Ascitis, Renal failure, Tuberculosis, AIDS or HIV syndrome
  2) Patients with malignancy
  3) Bleeding disorders
  4) Multiple ulcers (More than three)
  5) Diabetic ulcers
  6) Varicose ulcers
  7) Arterial ulcers
  8) T.A.O.
  9) Leptotic ulcers
  10) Gonorrheal ulcers
  11) Syphilitic ulcers
  12) Vranas Situated over asthi, Sandhi & Koshta Marma Adhishtana
  13) Burn ulcers are excluded.

### 2.5. Parameters

**Objective** -

1) Size
   2) Appearance of margin & edges
   3) Slough
   4) Discharge
   5) Granulation tissue
   6) Tenderness

**Subjective** -

1) Pain

**Drop – Out**

Any dropout during treatment will was not found.
Drug Nirgundi Collection

The roots & leaves of fresh Nirgundi (Vitex nigundo) Plant collected from rural area of Nanded District, Maharashtra. Roots & Leaved of Nirgundi cleaned up with water after that they are send in the Rasshastra- Bhaishya Department of R. A. Podar Medical College (Ayu.) Worli, Mumbai 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] under the guidance of H.O.D. Rasshastra Bhaishya Dept. R. A. Podar Ayurved Medical College, Worli, Mumbai– 18.

2.6. Probable Action of Nirgundisiddh Tail

Ayurved View Point

Vata & Kapha Doshas are playing major role in vranadushti. Nirgundi & Tilataila the contents of Nirgundisiddha taila have ushnavirya properties Kaphavataghna Doshaghnata [8] so by application of this oil help in inhibiting Doshadushti & ultimateray 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

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 vessles [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.

2.7. Methods

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.

**Statistical Analysis**

Student t-test & Chi-square applied to the data generated. Significance of improvement was studied.

**3. Observations and Results**

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

**3.1. Wound Sites**

66.67% patients were having wound over lower limbs.
11.67% Wounds occur on Gluteal region.
8.33% Wounds occur over Back region.
10% patients have wound's over upper extremity & 3.33% patients have wound over head region.

**3.2. Affected Tissue**

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.

**3.3. Duration of Wounds**

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.

**3.4. Effects of Therapy on Wound Parameters in Terms & Percentage of Relief of Score**

Effect & 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 of therapy 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 of therapy 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 of therapy 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 & therapy on wound edge & margin in treated group was better than control group because percentage of relief & score in treated group was 100% as compared to 65.21% of control group.
Effect of therapy 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.

### 3.5. Total Effect of Therapy

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.

### 3.6. Antimicrobial Activity

Antimicrobial activity of Nirgundisiddha taila was tested upon three organisms i.e. E.coli, streptococcus Aureus & Pseudomonas Aeruginosa. This Drug has Antimicrobial activity again E.coli culture but not effective against cultures of s. Aureus and Psudomonas in the above test using culture medium as sterile soya bean casein Digest med.

### 4. Discussion

"Dushtavrana" is the type of vrana mentioned in our ancient texts, with holds prime importance in Shalyatantra, because wound or vrana is the subject matter in surgery. A detailed description of vrana & Dushtavrana right from its etiology, symptomatology, pathophysiology, complication and management is available in ancient classical texts, which resembles with 'Infected wound' & chronic non - healing ulcers. If we left vrana untreated, it goes into Dushtavstha & then due to its chronicity & typical symptoms, it is called as 'Dushtavrana'. In modern system of medicine to treat chronic non - healing ulcers/ infected wounds they use newer medicine, antibiotics, antioxidants even some wounds needs surgical produce also. If we analyze this statement it indicates it is a costly and has some side effects also it's time consuming also and results are not similar in all patients. So there is need to find some alternative Medicine/ procedure to rule out this adverse effects. The whole medical fraternity is looking towards 'Ayurved' with a ray of hope.

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 Dushtavras 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.

Antimicrobial activity of Nirgundisiddha taila was tested upon three organisms i.e. E.coli, streptococcus Aureus & Pseudomonas Aeruginosa. This Drug has Antimicrobial activity against E.coli culture but not effective against cultures of s. Aureus and Psudomonas in the above test using culture medium as sterile soya bean casein Digest medium.

Control group drug providing Iodine have already proven. It's antibacterial activity.

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.

4. Conclusion

1) The result of clinical trial proved that the Nigrundisiddhataila has significant Results in Dushtavrana (Non Healing Ulcers) Management as compared to Povidine Iodine ointment.

2) It was found that, this preparation has given significant results in various parameters of wound like size, slough, Discharge granulation, Appearance of margin & edges & Tenderness. It also gives significant results in subjective parameter pain, compared with control group.

3) Early initiation of granulation process with this taila application than povidine iodine application.

4) Desloughing process also faster in treated group than control group.
5) This Drug cures Dushtavrana of 2 to 3 month duration completely if it is not complicated by affecting muscle & bone.

6) Dushtavrana situated on skin & subcutaneous only are also completely heals within 21 days.

7) 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 strengthens the delicate new generating capillaries. with tilataila it nourishes the local disturbed dhatu by stimulating granulation and keep wound healthy.

8) In vitro this preparation has established Antimicrobial property, against E.coli bacteria.

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