MANAGEMENT OF NON HEALING WOUND WITH NYAGRODHADI KWATHA AND JATYADI GHRTA (CLASSICAL AYURVEDIC PREPARATIONS)

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ABSTRACT

Chronic wound infections not responding to conventional treatment modality are the important cause of disability and mortality. Infection is responsible for delayed wound healing. In the present study, an attempt was made to develop simple and effective treatment modality for wounds that are not responding to conventional treatment modalities by using Nyogrodhadi Kwatha {Decoction of drugs starting with Ficus benghalensis L.} and Jatyadi Ghruta {Medicated ghee prepared with drugs starting with Jasminum grandiflorum} as external wound dressing material. Nyogrodhadi contains Vata {Ficus benghalensis L.}, Udumbara {Ficus racemosa L.}, Ashwatha {Ficus religiosa L.}, Triphala (Fruits of Terminalia chebula Retz., Terminalia bellerica Roxb. and Phyllanths emblica L.), Haridra {Curcuma longa L.}, Daruharidra {Berberis aristata DC}, Nimba {Azadirachta indica A.Juss} and Yastimadhu {Glycyrrhiza glabra L.}. All these plant drugs help to clean (debridement) the chronic wounds. All the chronic wounds are considered as Dushta Vrana (non healing wound) and Jatyadi Ghruta acts as wound healing enhancer. So the combination of these two medications probably act as Vrana Shodhaka (wound cleansing) and Vranaropaka (wound healing). In this study among 28 cases 23 (82.14 %) cases have got the wound completely healed. And 03 (10.71%) cases shown the signs of healing, one case (3.17 %) underwent minor amputation, and one case (3.17 %) left the treatment. In local wound care treatment, it was found most effective and economical for the successful treatment. In the management of chronic wounds Ayurvedic drugs are also potent when compared to conventional Antibiotics and local wound care treatment.

KEY WORDS: Chronic wound, wound healing, Nyogrodhadi Kwatha, Jatyadi Ghruta.

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INTRODUCTION

Non-healing wounds are significantly problematic to all the health-care systems worldwide. In the industrialized world, almost 1–1.5% of the population will have a problem of wound at any point of time. Furthermore, wound management is expensive for instance, in Europe the average cost per episode is 36,650 pounds for leg wounds and 310,000 pounds for foot wounds, which accounts for 2–4% of health-care budgets\(^1\).

In a study to determine prevalence of diabetic foot in India, the prevalence of infection noted was 6–11% and prevalence of amputation was 3% in type 2 diabetic patients. In another Indian study, the prevalence of diabetic foot ulcers in the clinic population was 3.6 %\(^2,3\). This figure can be expected to rise with an increasingly elderly and diabetic population. There is an urgent need to review wound strategies and treatments in order to reduce the burden of care in an efficient and cost-effective way. If patients at risk are identified sooner and aggressive interventions are taken before the wound deteriorates and complications occur, both patient morbidity and health-care costs can be significantly reduced.\(^4\) The question is which interventions, technologies and dressing materials are the best from those available?\(^4\) Ongoing controversy surrounds the value of various approaches to wound management and care. There is a need to consider alternative ways of achieving the highest level of evidence required for these patient groups.

Drugs treating infections like the Penicillin’s, Cephalosporin’s, Fluoroquinolone’s, Tetracycline’s, Iodine, Hydrogen peroxide, Eusol solution etc are the common Antibacterial agents used in the treatment of various chronic wounds. Drug resistant bacteria are primarily a problem and help to spread infections. Sometimes the multiple drug resistant bacteria can become a therapeutic challenge. Attention should be directed towards discovering an agent, which will accelerate wound healing\(^4\). Chronic non healing wounds continue to pose a challenge to physician\(^6\). As the last decade created tremendous interests in Ayurvedic science, the demand of herbal medicine in the world market is on a raise.

Hence, it is necessary to create evidence to basic principles mentioned in Ayurvedic texts, for its worldwide acceptance. Ayurvedic texts are to be searched for appropriate medicines for a particular disease and these hypotheses and drugs are to be evaluated with modern research methodology.

With this point of view a study was undertaken to evaluate the wound healing property of Nyagrodhadi kwatha and Jatyadi Ghruta as these formulations are mentioned in Ayurveda Samhitas (classical ayurvedic texts) as Vranashodhaka and Vranaropaka\(^1,2,3,6,9,10\), which are easily available, cost effective and non-toxic in nature. Hence Nyagrodhadi Kwatha and Jatyadi Ghruta formulations were selected for this study.

MATERIALS AND METHODOLOGY

Nyagrodhadi Kwatha contains Vata {Ficus benghalensis L.}, Udumbara {Ficus racemosa L.}, Ashwatha {Ficus religiosa L.}, Triphala {Fruits of Terminalia chebula Retz., Terminalia bellerica Roxb. and Phyllanthus emblica L.}, Haridra {Curcuma longa L.}, Daruharidra {Berberis aristata DC}, Nimba {Azadirachta indica A.Juss} and Yastimadhu {Glycyrrhiza glabra L.}. The proper and potent drugs mentioned above were collected from the Botanical Garden of College of Ayurveda & Research Centre, Akurdi, Pune. Authentication and standardisation of these drugs were done at Indian Drug Research Association Laboratory, Pune, India to ensure its quality and identity. Nyagrodhadi Kwatha was prepared according to reference from Sharangdhara Samhita Di.Kh.2/1-2. Jatyadi Ghruta of Arya Vaidya Pharmacy, Coimbatore, Tamil Nadu, India was used. Wound was washed with Nyagrodhadi Kwatha, and Jatyadi ghruta was applied on the wound up to skin surface level, once in a day up to 60 days.

Clinical study design: Simple Randomized Open design.
Sample size: Total 28 patients of chronic Non healing wound were selected by simple randomized method irrespective of Gender, Caste, and Occupation

**Inclusion criteria**

- Age up to 75 yrs
- Gender-Both
- Non healing wound > 5–6 weeks
- Heamodynamically stable
- Patients having internal Allopathic treatment for Diabetes mellitus (Type-II), Hypertension
- Patients with I and II Grade wounds.

**Exclusion criteria of patients**

- Inadequate (Atherosclerosis) blood supply
- Poor Glycemic control
- Non-adherence with treatment plan
- End-stage renal disease
- Transplant recipients
- Differing individual goals
- Malnutrition
- Connective tissue disorders
- Systemic conditions such as sickle cell disease, Osteomyelitis, Immobility
- Heart disease, Dementia, Cancer, AIDS, Tuberculosis and advancing age > 75 yrs.

**Consent & Ethical clearance:**

Written informed consent of each patient in his own language was taken. According to ICMR-7 Points guideline. Permission of Ethics committee was taken from Institutional Ethical committee of College Of Ayurveda & Research Centre, Akurdi, Pune, (M.S.) CARC/IEC/O.No.171/09-10

**Dressing method:**

Wound cleaning and debridement was done regularly with the help of normal sterile saline water, sterile cotton, scoop and scalpel. Wound was let to dry with sterile cotton gauze. Finally Jatyadi Ghruta was applied on the wound and soaked cotton gauze of Jatyadi Ghruta was dressed on the wound with a dry bandage. Patients were advised to rest. The offloading techniques were taught to the patients.

**Period of treatment:** Sixty days in hospitalized or OPD based patients.

**Observation and Assessment criteria during treatment period:**

Daily observations of patients were done for Local as well as systemic observations and were noted and mentioned in the case sheet. Systemic examination: CVS, R/S, CNS, P/A were done daily.

**For wounds**

**Signs of inflammation:**

- Temperature: Skin temperature 4 cm away from the wound area
- Capillary refilling time normal < 5 seconds
- Edema: On pitting skin, 4 cm away from wound area
- Presence of peripheral pulse indicator of minimum 80 mm of Hg pressure on foot.
- Pain scale will range from 1–10 score
- Color Pale, Red, Ischemic

**Wound Exudates:**

- Dry: No exudates,
- Moist: Small or medium,
- Wet: Heavy.
- Serous: Clear yellow fluid without blood, pus, debris,
- Serosanguinous: Thin, watery, pale red to pink.
- Sanguineous: Bloody Purulent: Thick, cloudy yellow color.

Measurement of wounds for length, breadth, depth by paper tracing technique. Granulation tissue quality and Angiogenesis: Wound bed color Pink, Ischemic, Red, bleeds on touch, Black

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Clinical healing outcome was considered as - (15)

Healing with complete Epithilization.
Partial healing without Epithilization but wound contracture.

Major Amputation
Minor Amputation
Death of patient

Statistical analysis: It was done by using the Binomial Probability test.

OBSERVATIONS AND RESULTS

Table no 1 - Details of chronic wound patients according to various characters

<table>
<thead>
<tr>
<th>Disease</th>
<th>Male (%)</th>
<th>Female (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic</td>
<td>10</td>
<td>05</td>
<td>15 (53.57%)</td>
</tr>
<tr>
<td>Infected (Cellulites)</td>
<td>04</td>
<td>02</td>
<td>06 (21.42%)</td>
</tr>
<tr>
<td>Hanson’s</td>
<td>03</td>
<td>0</td>
<td>03 (10.71%)</td>
</tr>
<tr>
<td>Bed sore</td>
<td>02</td>
<td>02</td>
<td>04 (14.28%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>19 (67.85%)</td>
<td>09 (32.14%)</td>
<td>28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum size of wound in Sq. cm.</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78 Sq. cm.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minimum size of wound in Sq. cm.</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>08 Sq. cm.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average size of wound</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>35 Sq. cm.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| No. of Wounds                    | 30        | 12        | 42        |
| Recurrence of wound              | First time 04 | Second time 05 | Recurrent 19 |

Table no 2 - Outcome of treatment

<table>
<thead>
<tr>
<th>Type of Healing</th>
<th>Number of patients</th>
<th>Percentile (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete healing with Epithelization</td>
<td>23</td>
<td>82.14</td>
</tr>
<tr>
<td>Partial healing without Epithelization</td>
<td>03</td>
<td>10.71</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor Amputation</td>
<td>01</td>
<td>3.57</td>
</tr>
<tr>
<td>Dead</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Leave treatment</td>
<td>01</td>
<td>3.57</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td></td>
</tr>
</tbody>
</table>

Wound healing of 26 cases in days

- Within 20 days - 06 cases
- Within 40 days - 15 cases
- Within 60 days - 05 cases
Table No. -3 Wound healing according to Disease

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diabetes</th>
<th>Infected</th>
<th>Hanson’s</th>
<th>Bed sore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete healing with Epithelization (23 cases)</td>
<td>11</td>
<td>06</td>
<td>03</td>
<td>03</td>
</tr>
<tr>
<td>Partial healing without Epithelization (03 cases)</td>
<td>03</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Minor Amputation (1 case)</td>
<td>01</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Dead</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Leave treatment (1 case)</td>
<td></td>
<td>–</td>
<td>01</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>06</td>
<td>03</td>
<td>04</td>
</tr>
</tbody>
</table>

Graph No.1 Basic Graphical representation of Disease wise data-

From above diagram diabetic people are more when compared to people with other diseases.

**Statistical analysis The Binomial Probability test**

Due to small sample size i.e. less than 30, we use the binomial probability test.

- Total no of persons = 27
- Number of cured persons = 23
- \( p = \frac{x}{n} = 0.8518 \)

We considered here \( p_0 = 0.8 \) \( Q_0 = 1 - P_0 = 0.2 \)

**Hypothesis**

- \( H_0: p \geq 0.8 \) vs \( H_1: p < 0.8 \)

- \( H_0: \) Population proportion is greater than or equal to 80%
- \( H_1: \) Population proportion is less than 80%

**Test statistics**

\[ Z_{cal} = \frac{(p - P_0)}{\sqrt{(p_0Q_0/n)}} = 0.6735 \]

\( P \)- Value = 0.25143

\( P-value > 0.05 \) therefore null hypothesis \( H_0 \) is accepted.

Sample size is too small so it is not possible to use more statistical tools.
Graph No.2 multiple bar diagram showing number of persons cured, not cured versus type of disease.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cured persons</th>
<th>Non-Cured persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>Infected Cellul</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Hanson’s</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Bed Sore</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Graph No.2 shows maximum number of cured & Non-Cured persons in Diabetic disease. While in Infected and Bed Sore type cases all the patients were completely cured.

**DISCUSSION**

During the 2 month treatment period a total of 28 patients were included in study that fulfilled the inclusive criteria. When the patients were treated with the classical Ayurvedic formulations named *Nyogrodhadi Kwatha* and *Jatyadi Ghruta*, the following significant results were observed. Among the total of 28 cases, 19 (67.85%) were males and 9 (32.14%) were females. The number of male population was more in this study and it was only by chance, as the patients attending the hospital were randomly selected. The average age of included population was 57.04 years. In this population 15 (53.57%) patients had diabetic wounds which topped the cases included in the study and is because of increased prevalence rate of Diabetes mellitus in India [7]. Infected Cellulitis wound were in 6 (21.42%), Hanson’s tropical wound in 3 (10.71%) and Bed sores in 4 (14.28%) patients. In these 28 patients the total numbers of wounds were 42, which was because of more than 1 or 2 wounds in a single patient. These wounds have Minimum cross sectional area of 08 Sq. cm., Maximum of 78 Sq. cm., Average was 35 Sq. cm. Among all, 6 cases had healed in a 20 day period, 15 cases had healed in 40 days and 5 cases had healed in 60 days of treatment. One case underwent for minor Amputation due to gangrene with septicemia. One case left the treatment due to some personal family problem.

According to the diseases included, complete wound healing was found in 11 patients with diabetic wound, 06 patients with infected wound, 03 with Hanson’s disease wound and 03 patients having Bed sores. This variation was because of various factors such as Haemogram, LFT [Liver Function Tests], KFT [Kidney Function tests], BSL [Blood Sugar Level] level, Infection load and resistance of bacteria, use of offloading practice of patient which is subjective, level of Nutrition was also varying from patient to patient. Healing without epithelization was in 03 cases and all were Diabetic wounds. These patients had very poor control of BSL.

The use of *Nyogrodhadi Kwatha* and *Jatyadi Ghruta* in the management of Chronic wound for dressing purpose was found very effective i.e. 82.14%. Due to a small sample size (less than 30 patients), Binomial Probability Test was used. (n - Total no of persons = 27); P Value = 0.25143; P value > 0.05 therefore we accept null hypothesis H₀.
After application of Kwatha and Ghruta, in the initial phases pus and debris (Vrana Shodhana) were minimized. So in the initial period of application quantity and time of Kwatha application was increased. In the later stages of wound healing rapid development of granulation and epithelial tissue (Vrana Ropana) was observed. So the time and quantity of Ghruta application was increased. During the treatment period, all observations regarding wound healing which are mentioned in Methodology are mentioned in the case paper of each patient. No any local as well as systemic side effects of the drugs were observed.

Probable mode of action

The drugs in Nyogrodhadi Kwatha have Kashaya, Tikta Rasa (Astringency, Bitterness) dominancy. It has Kledaghana, Srava shoshana [drying up of exudates], Vrana sankochan [helps the wound to shrink] and krumighana [anthelmintic] actions. The Sheeta Virya [cold potency] of drugs, stop the Paka of wound. All these activities are considered as Vrana Shodhana in Ayurveda (i.e. it stops decay, reduces secretion, contracts wound, antimicrobial activity). Neem {A. indica} and Haldi {C. longa} are already proven as antimicrobial agent by modern sciences. Yastimadhu {G. glabra} and Ghruta {Ghee} have Madhura rasa {sweetness} and Sheeta Virya {potency} which acts as Vrana ropaka (Wound healing enhancer) by increasing mamsa dhatu{muscle mass} in wound i.e. granulation tissue.

CONCLUSION

The use of Nyogrodhadi Kwatha and Jatyadi Ghruta in the management of Chronic wound for dressing purpose was found very effective i.e. 82.14%. Complete healing had occurred in the presence of infection. This treatment is safe, economic and very effective. Even a common man can easily use it. This will reduce the economical and physical burden over society.

In Ayurveda Samhita various drugs are mentioned in the management of wounds according to its stages. In Dushta Vrana chikitsa these two formulations have been mentioned. So by this clinical trial, practical evidence has been generated on our ancient knowledge. Further detailed studies with control and experimental group are needed on large population.

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