Chapter 4. Materials and Methodology

Drug formulation mentioned in Sharangdhar Samhita III /11/86 was selected for this study, it contains:

Table No.58: Drugs used for Nimbadi Kalka

<table>
<thead>
<tr>
<th>Drugs:</th>
<th>Latin Name:</th>
<th>Family</th>
<th>Part used:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nimba</td>
<td>Azadiricha indica (Linn.)</td>
<td>Meliaceae</td>
<td>Patrachurna (Leaves) Powder</td>
</tr>
<tr>
<td>Ghrut (Ghee)</td>
<td>-</td>
<td>-</td>
<td>Cow Ghee</td>
</tr>
<tr>
<td>Kshodra (Honey)</td>
<td>Apisindica Mellifera</td>
<td>Apiadae</td>
<td>Honey</td>
</tr>
<tr>
<td>Darvi (Daruharidra)</td>
<td>Barberis aristata (DC.)</td>
<td>Berberidaceae</td>
<td>Kashta and Mula Powder (Steam &amp; Roots )</td>
</tr>
<tr>
<td>Madhuka (Yashtimadhu)</td>
<td>Glycrrhiza glabra (Linn.)</td>
<td>Leguminosae</td>
<td>Mula (Roots) Powder</td>
</tr>
<tr>
<td>Tila (Sesame Seed)</td>
<td>Sesamum indicum (Linn.)</td>
<td>Pediliaceae</td>
<td>Beeja (Seed) Powder</td>
</tr>
</tbody>
</table>

The proper and potent drugs mentioned above are collected personally to insure about its quality. They are authentified from Agharkar research institute Pune Maharashtra. ---Annexure-I

1. Method of drug preparation:

Nimbadi Kalka is prepared according to reference of Sharangdhar Samhita Di.Kh.5/1-2 and Bhaishajya Ratnavali 47/45

2. Apparatus: Mortar and pestle, spoon, Bowels, Dressing tray.

All the above-mentioned drugs are weighed properly on weight balance. In mortar with the help of pestle a homogenous paste is prepared. The finished product is taken out in sterile bowels and used for patients dressing purpose.

The minimum standardization of Nimbadi Kalka is done according to Ayurvedic Pharmacopeia of India Part-II, Vol-I, 2007 from Indian Drug Research Laboratory Pune Maharashtra. ---Annexure-II
3. **Sample size:**
Total 260 patients of chronic Non-Healing Diabetes ulcer are selected by simple randomized method irrespective of Gender, Cast, and Occupation etc. These 260 patients are divided into two equal groups on patient’s willingness. Group A-130 patients have received Ayurvedic treatment for ulcer care. Group B-130 patients have received Allopathic treatment for ulcer care.

4. **Clinical study design:**
Randomized Experimental trial with two arms

5. **Dose:** Local application as a paste on ulcer area up to skin level. Once in a day for maximum 60 days.

6. **Period of treatment:**
Maximum sixty days in hospitalized patients

7. **Place of work:**
MIMSR Medical College and YCR Hospital, Ambajogai Road, Latur, District: Latur, State: Maharashtra 413512, India.

8. **Inclusion criteria for patients:**
- Age below 75 yrs
- Gender-Both
- Non-healing diabetic ulcer for > 5-6 week
- All Diabetes Type-I and II patients
- Hemodynamically stable
- All diagnosed patients were hospitalized
- Patient’s receiving modern medicine (oral hypoglycemic agent) for Diabetes II
- I and II Grade of ulcers: ---Annexure IV

8. **Exclusion criteria:**
Known cases of following disease condition
- Inadequate 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 and
- Advancing age (age above 75 years)

9. Consent:
Written informed consent of each pt. in his own language is taken. According to ICMR-7 Points guideline: ------------Annexure III

10. Permission of Ethics committee:
Is taken from concerned authority: --------Annexure IV

11. Case paper: -----------Annexure V

12. Dressing method:

1) Ayurved treatment group: (Group-A)
Ulcer cleaning and debridement was done regularly as per ulcer need with the help of normal saline water, sterile cotton, forceps, scoop and blade. Ulcer was dried with sterile cotton gauze. After that Nimbadi kalka was apply on ulcer area up to the superficial skin and dry bandage was applied on it. Patients were advised for rest and offloading techniques were taught to patients.

2) Treatment group : (Group-B)
Ulcer cleaning and debridement was done regularly as per ulcer need with the help of normal saline water, H₂O₂, Eusol solution, Betadine solution, Forceps, blade sterile cotton, and scoop. Ulcer was dried with sterile gauze and Ointment Betadine was applied to all ulcer area. After that a dry bandage was applied on it. Patients were advised for rest and offloading techniques were taught to patients.

Regular internal treatments of diabetes for both groups of patients were followed as per Allopathic physician’s opinion.
13. **Observation and Assessment during treatment period**:326,327

**i) History:**
The chronicity of Diabetes and poor control of Diabetes result in complication of Diabetes like Neuropathy, Vasculopathy and Nephropathy, Retinopathy etc. The history of Hypertension, Habits like Alcohol, Tobacco, Smoking, and Obesity is also important in Vasculopathy and defense mechanism. Family history is also important in disease prognosis. Occupation history is important for pressure distribution on ulcer and Glycemic control.

**ii) Occupation:**
Pressure phenomenon, work culture-Venous ulcer in long standing people, Neuropathy in drivers etc.

**iii) General examination:**
The Nutrition, Gait, Psychological, Edema, Anemia, Pigmentation

**iv) Systemic examination:** CVS, RS, PA, CNS

Feet Examination: Shape, Size, Deformity, Thickening, Callosity

**V) Ulcer examination:**

a) Shape- Oval, Circular, Irregular (Arterial, Venous, Diabetic, Pressure, Other)
b) Size - Length, Depth, Breadth, Fistula.
c) Skin-Healthy, Dry, Ischemic, Pigmentation, Maceration, Nails.
d) Location- Medial malleolus- venous ulcer,
    Lateral malleolus-Arterial ulcer.
    Planter surface- Diabetic ulcer,
    Sacrum - Pressure ulcer.
f) Edges: Slopping-Venous,
    Punched-Arterial,
    Rolled-Basel cell Carcinoma,
    Everted- Squamous Cell Carcinoma,
    Purple-Vasculitis,
    Undermining -Tuberculosis, Syphilis ulcer.
g) Bed- Necrotic, Slough, Black
h) Secretion: Serous, Pus, Hemosangio
I) Granulation: Pink Colour-Healthy Granulation, Red Ischemic-Unhealthy infected, Black -Necrotic tissue, absent, Over granulation-Non-healing tendency

j) Odour: Mild, Moderate, Sever, Foul,
k) Post healing pigmentation.
l) Surrounding Skin colour: Pink, Ischemic, Red, Black, and Exzematic.

VI) Vascular Assessment:
1) Pallor 2) Ischemic Changes 3) Peripheral pulse 4) Capillary refilling time.

VII) Neurological Assessment:
1) Sensory Assessment: Pain, Touch with 10 gm. Monofilament.
2) Motor Assessment: A) leg deformity- Claw, Charcot B) Ulcer pressure points C) Tendon reflux D) Muscle power.

IX) Assessment-Dry skin, hair loss, hyper pigmentation, local temperature

X) Infection: Sigs of Inflammation-- Fever, pain, redness, edema etc. pus discharge Osteomyelitis: X-ray examination.

XI) Systemic examination: CVS, RS, CNS, PA was done daily.

14. Variables for Ulcer healing Assessment Criteria:

1. Ulcer Size Sq. cm: Ulcer size in square center meter
   1) 1-20 sq. cm= 1 grade,
   2) 21-40 sq. cm= 2 grade,
   3) 41-60 sq. cm= 3 grade,
   4) >61 sq. cm= 4 grade

2. Ulcer shape: O=Oval shape, C=Circular, I=Irregular

3. Ulcer Bed: Ulcer bed colour
   1) Pink colour =1 Grade,
   2) Red Ischemic =2 Grade,
   3) Black colour= 3 Grade,
   4) Yellow/Green= 4 Grade

4. Granulation tissue: Granulation colour
   1) Pink colour= 1 Grade,
   2) Red Ischemic = 2 Grade,
   3) Absent= 3 grade,
4) Over granulation= 4 Grade

5. Secretion:
   1) No secretion= 1 Grade,
   2) Serus secretion= 2 Grade,
   3) Hemosangionus=3 Grade,
   4) Pus secretion=4 Grade

6. Pain: On Pains Scale
   1) 0-1= 1 grade (No pain),
   2) 2-4= 2 Grade (Mild pain),
   3) 5-7= 3 Grade pain (Moderate pain),
   4) 8-10= 4 Grade pain (Sever pain).

7. Smell:
   1) No smell = 1 Grade,
   2) Mild smell =2 Grade,
   3) Intolerable smell=3 Grade,
   4) Foul smell= 4 Grade

Daily observations of patients from both groups for Local as well as systemic observation are noted and mention in case paper.

15. Laboratory investigations before treating a wound:

Hemoglobin, White cell count, Platelet count, ESR, C- reactive protein, KFT, LFT, Glucose fasting and post prandial, HbA1C, Urine analysis, Wound swab culture and sensitivity of infective organism. All above observations are mentioned in case paper.

16. Ulcer healing outcome consideration:

Reduction in Ulcer area approximately 20-40% after 2-4 week is a good sign of healing. The healing outcome assessment is done at interval of 20 days, 40 days, and 60 days.

Clinical healing outcome was considered as:

- Healing with complete Epithelization.
- Partial healing without Epithelization but wound contracture
- Minor Amputation
- Major Amputation
- Death of patient
All observations noted were presented in information tables.

17. **Statistical method:**

The Variables were compared by using Chi-square test, paired T-test, Wlicox test, and proportionate test. P value of <0.05 was considered as significant. For this open controlled design with two arm study.
Figure No: 2 Drugs constituents of Nimbadi Kalka

Daruharidra root

Daruharidra branch

Nimba patra

Yashtimadhu plant

Yashtimadhusistem
Figure No:3 Drugs constituents of Nimbadi Kalka

Tila Plant and seed

Ghee

Honey

Nimbadi kalka
Figure No: 4 Patients Ulcer and its healing outcome

Foot Ulcer on 8th day treatment

Foot Ulcer on 38th day of treatment

On 16th Day

On 36th Day
Figure No: 5 Patients Ulcer and its healing

After 19th day of treatment

After 21st days of treatment

After 13th day of treatment

After 31st days of treatment
Figure No: 5 Patients Ulcer and its healing

Bed Sore after 49th day

Measurement of tracing technique

1st day of treatment

48th day of treatment