Chapter 1. Introduction

The study to determine the global prevalence of diabetes in all age-groups all over world shows, 285 million people in the year of 2010. This figure will raise upto 438 million in 2030. The rate of urbanization among developing countries will raise upto two times till 2000 - 2030.¹

One of the major complications of DM is foot ulceration. It is a major social, medical, and economic burden on people. However, the rate of foot ulceration and amputation differs significantly. The study from India, for the prevalence of DM shows that the chances of infection in ulcer is 6-11% and occurrence of amputation was 3% in type 2 diabetic patients. In another study from India, shows the incidence of diabetic foot ulcers in the clinic population was 3.6%. The causes of ulceration among Indian people are barefoot walking, religious faith like walking on fire, use of improper footwear and lack of awareness and negligence about foot-care. This increase prevalence of foot ulceration and its complications in DM type II patients. This study also reflects increasing incidences for infection on DM patient’s ulcers upto 52%.¹

The global burden for amputation among DM foot ulcer patient is million per year. That means at every 30 seconds a limb is amputated in the world.²

The Indian Study shows that the prevalence of amputation in DM patient is nearly about 40,000 per every year with increasing numbers.³

In United states study shows, that the rough estimated cost of ulcer healing is $ 8,000 that of an infected ulcer healing is $ 17,000 and that of a major amputation is $ 45,000.In the United States, Nearly about 80,000 amputations are performed per year for diabetic foot ulcer, and the possibility of ulceration with infection in another leg in this patient is 50% within 18 months.Among these 58% causes have possibility of reamputation in 5 year from first amputation.The mortality rate for reamputated case is 20-50%. Despite of much research and development in ulcer and DM management, this ratio is static since last 30 yrs. ⁴

The study for expenses in hospitalized patients of DM II with complications says the hospital stay is longer in such cases.

The hospitalized patient’s expenses for ulcer (19020 INR) with any two Diabetic complications (17633 INR) spent four times more. The patients having diabetic complication like Nephropathy (12690 INR), cardiovascular complication
(13135 INR) and retinopathy complications (13922 INR) pays three times more expenses than the patients without any complications (4493 INR).

The hospital expenses in the last two years are high and if complication of DM II it will be highest.\(^5\)

The early intervention of diagnosis and treatment in DM Ulcer can reduce mortality rate and economical burden also\(^6\). The evidences also indicates that the multidisplinary and active management in foot ulceration can reduces its possibility of amputation.\(^7, 8\).

Even though of various modern techniques and antibiotics development, chronic non-healing ulcers continue to pose a challenge to physician. The Multidrug resistance to antibiotic is also increasing.\(^9\)

- **Need of study:**
  
  As the last decade creates tremendous interest in Ayurvedic science. The demand of herbal medicine in world market is also increasing. Now a day’s it is necessary to create evidences to basic principles mentioned in Ayurvedic texts, for its worldwide acceptance. To achieve above stated goal, we must reopen the Ayurvedic texts and search for appropriate medicines for a particular disease; and evaluate these hypothesis and drugs with modern research methodology.

- **Selection of drug:**
  
  In Ayurveda Samhita, various drugs have been mentioned as Vranashodhak and Vranaropak which are helpful in Chronic Ulcer healing. In this study, the drugs were selected on following criteria.

  - Easily available.
  - Less adultery in market.
  - Any person should be able to prepare and use the medicine easily.
  - Non-toxic.
  - Drug having both Vranashodhak and Ropak activity is selected because all chronic Ulcers are infected and Non-healing.
So Nimbadi Kalka formulation mentioned by Sharangdhar Samhita III /11/86 and Bhaishajya Ratnavali, 47/45 was selected. This formulation fulfilled all above stated drug selection criteria.

In this study, Non-Healing Diabetes ulcers in group-A were treated with above formulation as a kalka for external application. The observed results were compared with the treatment group B, which were treated with modern medicine drugs for local Ulcer Dressing.