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A prospective comprehensive assessment of clinical features and management of ulcers of the lower limb

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Abstract

Aim: To determine the clinical features and management of ulcers of the lower limb.

Methods: This prospective cross sectional study which was carried in the Department of General Surgery, Shadan Institute of Medical Sciences India, for the period of 12 months. 100 patients of chronic leg ulcers were selected randomly with the help of computer generated random numbers from the patients attending OPD or took admission in surgical ward. After diagnosis of primary cause of the leg ulcers, management of ulcers by proper antibiotic coverage for gram positive, gram negative and anaerobic organisms, proper glycemic control, elevation of leg, compression bandaging, total cessation of smoking and causative drugs, nutritional support, vasoactive agents to restore blood flow, nerve stimulation, proper wound care with debridement slough excision and dressing.

Results: The mean (mean±SD) age of the patients was 52.34±12.05 years with range 20-75 years and the median age was 52.0 years. Test of proportion showed that the proportion of the patients with age between 40-70 years (84%) was significantly higher ($Z=9.51$; $p < 0.0001$). Only 5% and 5% of the patients were with age <30 years and ≥70 years respectively. Thus leg ulcers were more prevalent in the age group 40-70 years. Test of proportion showed that proportion of males 85% was significantly higher than that of females 15% ($Z=9.74$; $p < 0.0001$). Thus the leg ulcers were more prevalent among males. Ulcers in the left leg (49%) was higher than that of right leg (47%) but it was not significant ($Z=0.28$; $p=0.77$). Only 3% of the patients were having ulcers in both legs. Most of the patients (61%) had ulcer at foot followed by gaiter (20%) and leg (19%). ($Z=6.14$; $p < 0.0001$). Most of the ulcers were diabetic (37%) followed by venous (22%) ($Z=2.31$; $p=0.01$). Only 5% and 3% were malignant and trophic ulcers. Peripheral neuropathy (23%) was the most common type of ulcer followed by venous hypertension (22%). Only 1 (1%) case of sickle cell disease was found.

Conclusion: With the availability of arsenal of investigation wide range of antibiotics and with ever improving dressing material, there is certainly a great improvement in treatment of chronic leg ulcers.

Keywords: Lower limb ulcer, leg ulcer, chronic ulcer, ulcer treatment

Introduction

Chronic leg ulcer (CLU) also known as chronic lower limb ulcer is a chronic wound of the leg that shows no tendency to heal after 3 months of appropriate treatment or is still not fully healed at 12 months^[1]. The incidence of ulceration is rising as a result of the ageing population and increased risk factors for atherosclerotic occlusion such as smoking, obesity, and diabetes. Ulcers can be defined as wounds with a “full thickness depth” and a “slow healing tendency”. Ulcers of skin can result in complete loss of the epidermis and often portions of the dermis and even subcutaneous fat^[2]. Chronic ulceration of the lower legs is a relatively common condition amongst adults, and ulcer symptoms usually include increasing pain, friable granulation tissue, foul odor, and wound breakdown instead of healing. This results in social distress and considerable healthcare and personal costs^[3]. Since numerous factors lead to lower leg ulceration, it is essential that health professionals adopt an interdisciplinary approach to the systematic assessment of the individual in order to ascertain the pathogenesis, a definitive diagnosis, and optimal treatment required. A correct diagnosis is essential to avoid inappropriate treatment that may delay wound healing, cause deterioration of the wound, or harm the patient. CLU is reported to have impact on virtually every aspect of daily life: pain is common, sleep is often impaired, mobility and work capacity tend to be restricted, and personal finances are often adversely affected. It is also known that social activities are restricted due to fear of injury and negative body image.

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CLU is usually associated with significant morbidity, high cost of healthcare, loss of productivity, and reduced quality of life [1, 2].

Chronic ulceration of the lower limb including the foot is a frequent condition leading to pain, social discomfort and generating significant cost implications. Prevalence number (all ulcers) range from 1 % in the adult population to 3-5 % in the population over 65 years of age [4, 5]. It has been reported that lower limb ulcers related to venous insufficiency constitutes 70% of cases, arterial disease 10%, ulcer of mixed etiology 15% and 5% of leg ulcers occur due to lesser known pathophysiological causes [6]. Thus, the later group comprises of considerable diagnostic challenge. For, a rationale approach towards patients with leg ulcers, it is important to have detailed knowledge about clinical picture, pathogenesis, diagnostic possibilities and treatment modalities of common causes, but at the same time to be aware of the large differential diagnosis of leg ulceration. Because an incorrect diagnosis usually leads to incorrect treatment and crucial time is lost leading to complications. Since numerous factors lead to lower leg ulceration, it is essential that health professionals adopt an interdisciplinary approach to the systematic assessment of the individual in order to ascertain the pathogenesis, a definitive diagnosis and early treatment.

Material and methods

This prospective cross sectional study which was carried in the Department of General Surgery, Shadan Institute of Medical Sciences, India, for the period of 12 months, after taking the approval of the protocol review committee and institutional ethics committee. A total of 100 patients were included who fulfilled study obligations.

Inclusion and exclusion criteria

All patients presenting with ulcer of the leg were included in the study. Patients unwilling to consent for the study were excluded.

Methodology

100 patients of chronic leg ulcers were selected randomly with the help of computer generated random numbers from the patients attending OPD or took admission in surgical ward.

Method of measurement of outcome of interest- The outcome of interest was morbidity and mortality of leg ulcer patients, the information of which was collected from case history sheet, relevant investigations and treatment. Limb salvage, amputation, poor control of diabetes mellitus, walking inability, poor pain management, recurrence of ulceration were considered as patient outcome. For calculation of risk factors likely to be associated with leg ulceration and calculation of patient outcome, patient's age, occupation(outdoor and indoor activities), smoking and drinking habits, presence of controlled or uncontrolled diabetes mellitus, ulcer location and characteristics, clinical examinations, arterial and venous circulation studies, biopsy of ulcer and medical and surgical treatments were taken into consideration.

After diagnosis of primary cause of the leg ulcers, management of ulcers by proper antibiotic coverage for gram positive, gram negative and anaerobic organisms, proper glycemic control, elevation of leg, compression bandaging, total cessation of smoking and causative drugs,

nutritional support, vasoactive agents to restore blood flow, nerve stimulation, proper wound care with debridement slough excision and dressing. For large ulcers, as soon as the wound bed was ready, skin grafting had been considered. Specific treatment for venous insufficiencies, arterial disease with lumbar sympathectomy/transluminal angioplasty, malignant ulcers was investigated and workup done. They were treated accordingly by wide local excision/superficial radiotherapy/treatment of metastasis/multimodality treatment. Amputation was considered as a last resort for non-healing/spreading/ gangrenous/malignant ulcers. Rehabilitation with adjunctive foot wear was provided appropriately in selected cases. Education regarding foot care was provided to prevent future recurrence. Patients were reviewed on 7th day and 21st day after discharge and was found ulcer free.

Statistical analysis

Using this software, basic cross-tabulation and frequency distributions were prepared. T-test was used to compare the means. $P \leq 0.05$ was considered statistically significant.

Results

The mean (mean \pm SD) age of the patients was 52.34 \pm 12.05 years with range 20-75 years and the median age was 52.0 years. Test of proportion showed that the proportion of the patients with age between 40-70 years (84%) was significantly higher ($Z=9.51$; $p < 0.0001$). Only 5% and 5% of the patients were with age < 30 years and ≥ 70 years respectively. Thus leg ulcers were more prevalent in the age group 40-70 years.

Test of proportion showed that proportion of males 85% was significantly higher than that of females 15% ($Z=9.74$; $p < 0.0001$). Thus the leg ulcers were more prevalent among males.

Corrected chi-square test showed that there was no significant association between age and gender of the patients ($p=0.22$). Thus the leg ulcers were evenly distributed over ages among both in males and females.

The mean (mean \pm SD) age of the male patients was 52.65 \pm 12.21 years with range 20-75 years and the median age was 52.0 years. The mean (mean \pm SD) age of the female patients was 53.16 \pm 13.55 years with range 27-73 years and the median age was 52.5 years (Table 1).

T-test showed that there was no significant difference between mean age of males and females ($t_{191}=0.47$; $p=0.60$).

Table 1: Age and gender distribution

Age group (in years)	Gender		Total (%)
	Male	Female	
Below 20	1	0	1
20-30	3	1	4
30-40	6	0	6
40-50	20	6	26
50-60	26	4	30
60-70	22	6	28
Above 70	2	3	5
Total (%)	80	20	100
Mean \pm SD	52.65 \pm 12.21	53.16 \pm 13.55	

chi square=8.12; $p=0.23$ (not significant).

Most of the patients were engaged in agriculture (25%) followed by business (22%) and service (14%).

44% of the patients had habit of smoking, chewing tobacco and drinking of alcohol. Out of 44 patients having any kind

of personal habit 12% had smoking followed by chewing tobacco (9%) (Table 2).

Table 2: Distribution of personal habit

Personal habit	Number	%
Smoking	12	12
Chewing tobacco	9	9
Smoking+alcohol	7	7
Smoking+chewing tobacco+alcohol	6	6
Alcohol	5	5
Chewing tobacco+alcohol	5	5
No habit	56	56
Total	100	100

Ulcers in the left leg (49%0 was higher than that of right leg (47%) but it was not significant ($Z=0.28$; $p=0.77$). Only 3% of the patients were having ulcers in both legs. Most of the patients (61%) had ulcer at foot followed by gaiter (20%) and leg (19%). ($Z=6.14$; $p < 0.0001$). Most of the ulcers were diabetic (37%) followed by venous (22%) ($Z=2.31$; $p=0.01$). Only 5% and 3% were malignant and trophic ulcers (Table 3).

Table 3: Distribution of diagnosis of ulcers.

Diagnosis of ulcers	Number	%
Diabetic	37	37
Venous	22	22
Traumatic	15	15
Arterial	13	13
Malignant	5	5
Trophic	3	3
Others	5	5
Total	100	100

Peripheral neuropathy (23%) was the most common type of ulcer followed by venous hypertension (22%). Only 1 (1%) case of sickle cell disease was found (Table 4). In 79% of the ulcers microorganisms were found which was significantly higher than that of no growth (21%) ($Z=8.31$; $p < 0.0001$). Out of the microorganisms *Staphylococcus* (28%) was most common followed by *Pseudomonas* (14%)

Table 6: Type of floor of ulcers

Floor of ulcers	Number	%
Unhealthy granulation tissue and slough	36	36
Pale granulation tissue and slough	22	22
Minimal slough	18	18
Necrotic tissue	7	7
Unhealthy granulation tissue	5	5
Fresh granulation tissue	4	4
Foul smelling slough	3	3
Raised granulation tissue at the wound edges	3	3
Raised abnormal granulation tissue extending beyond the margin	2	2
Total	100	100

Most of the floors of the ulcers were unhealthy granulation tissue and slough (36%) followed by pale granulation tissue and slough (22%). Only in 2% of the cases it was raised abnormal granulation tissue extending beyond the margin. ($Z=2.01$; $p=0.02$) (Table 6). 55% of the ulcers had shallow edge followed by sloping (21%) ($Z=5.05$; $p < 0.001$). Only 2% was undermined. Most of the margin of the ulcers were irregular (38%) which was

and *Klebsiella* (11%). Only in 2% of the ulcers, *Morganella* and *AFB* were present (Table 5). Most of the patients (68%) had pain which was significantly higher than of no pain (32%) ($Z=5.16$; $p < 0.001$).

Table 4: Distribution of pathology of ulcers.

Pathology of ulcers	Number	%
Peripheral neuropathy	23	23
Venous hypertension	22	22
Atherosclerosis	14	14
Peripheral neuropathy +atherosclerosis	11	11
Trauma	7	7
TAO	6	6
SCC	4	4
Bony defect	3	3
Pressure sore	3	3
Tubercular ulcer	2	2
Vasculitis	2	2
Poor hygiene	1	1
Leprosy	1	1
Sickle cell disease	1	1
Total	100	100

Table 5: Distribution of microorganisms

Microorganisms	Number	%
<i>Staphylococcus</i>	28	28
<i>Pseudomonas</i>	14	14
<i>Klebsiella</i>	11	11
<i>MRSA</i>	9	9
<i>Streptococcus</i>	7	7
<i>Proteus</i>	6	6
<i>Morganella</i>	2	2
Acid fast <i>Bacilli</i>	2	2
No growth	21	21
Total	100	100

Muscle (40%) was the most common base of the ulcers followed by bone (27%) and subcutaneous tissue (26%). Bone with tendon and only bone base was found in 7% of the cases. ($Z=1.41$; $p=0.12$).

significantly higher ($Z=2.37$; $p=0.0127$) followed by thin bluish irregular (22%). Only 3% of the margin of ulcers was regular. 22% of the surrounding area was lipodermatosclerosis and hyper-pigmentation with itching. 32% of the discharge was slough with purulent discharge followed by serous (26%). In most of the cases debridement with dressing (30%) was done (Table 7).

Table 7: Type of surgical management

Surgical management	Number	%
Debridement+dressing	30	30
Debridement+dressing+skin grafting	12	12
Debridement+dressing+disarticulation	11	11
Stripping Gsv/Ssv+hook phlebectomy	10	10
Hook phlebectomy	8	8
Stripping Gsv/Ssv	5	5
Id+debridement+transmetatarsal amp	5	5
Debridement+dressing+below knee amputation+angiography+balloon angioplasty	4	4
Wide excision+skin grafting	3	3
Debridement+dressing+lumbar-sympathectomy	2	2
Debridement+dressing+midtarsal amputation+angiography+balloon angioplasty	2	2
Debridement+skin grafting+dressing	2	2
Debridement+dressing+below knee amputation	1	1
Below knee amputation	1	1
Debridement+dressing+angiography+balloon angioplasty+skin grafting	1	1
Midhigh amputation	1	1
Debridement+dressing+angiography+balloon angioplasty	1	1
Debridement+dressing+midhigh amputation	1	1
Total	100	100

Most (57%) of the ulcers were in the Grade-II followed by Grade-III (35%). Only 1%, 2% and 5% were in the grade of V, I and IV respectively ($Z=3.12$; $p=0.0021$) (Table 8).

Table 8: Status at last contact.

Status at last contact	Number	%
Healed	93	93
Dead	3	3
Disease Free	3	3
Recurred	1	1
Total	100	100

Discussion

In this study test of proportion showed that the proportion of the patients with age between 40-70 years (84 %) was significantly higher ($Z=9.51$; $p< 0.0001$). Only 5% and 5% of the patients were with age<30 years and ≥ 70 years respectively. Thus leg ulcers were more prevalent in the age group 40-70 years Cornwall *et al.* in their study found that 70% of the patients were over the age of 70 years and according to a study done by Callam *et al.* ulceration began before the age of 40 years in 22% of the patients [7, 8].

Test of proportion showed that proportion of males 85% was significantly higher than that of females 15% ($Z=9.74$; $p< 0.0001$). Thus the leg ulcers were more prevalent among males.

Chronic leg ulcers are more prevalent in female than male, as reported in various literatures [7, 8]. In our study where male to female ratio is 5.67:1, showing male predominance. A hospital based study in India reported male to female ratio of 5.7:1, which is similar [9]. This may be because of the fact that in India males are more engaged in outdoor activities compared to female who remain indoors.

Corrected Chi-square test showed that there was no significant association between age and gender of the patients ($p=0.22$). Thus the leg ulcers were evenly distributed over ages among both in males and females. The mean (mean \pm SD) age of the male patients was 52.65 \pm 12.21 years with range 20-75 years and the median age was 52.0 years. The mean (mean \pm SD) age of the male patients was 53.16 \pm 13.55 years with range 27-73 years and the median age was 52.5 years. T-test showed that there was no significant difference between mean age of males and

females ($t_{191}=0.47$; $p=0.60$).

Most of the patients were engaged in agriculture (25%) followed by business (22%) and service (14%). As per the study conducted in China majority of leg ulcers were among the farmers and agricultural workers as in the present study [10].

44% of the patients had habit of smoking, chewing tobacco and drinking of alcohol. Out of 44 patients having any kind of personal habit 12% had smoking followed by chewing tobacco (9%). In a study on Indian patients found that there is a positive relationship between smoking and diabetes.¹¹ Cigarette smoking has been reported to have an impact on wound healing through impairment of tissue oxygenation and local hypoxia via vasoconstriction.¹² Tobacco smoke has high concentration of carbon monoxide, which binds hemoglobin, forming carboxyhemoglobin. Carboxy-hemoglobin binds to oxygen with high affinity and thereby interferes with normal oxygen delivery to hypoxic tissues [13]. Higher proportion of patients with smoking and drinking habit may be associated with greater population of diabetic leg ulcers in our study.

Ulcers in the left leg (49%) was higher than that of right leg (47%) but it was not significant ($Z=0.28$; $p=0.77$). Only 3% of the patients were having ulcers in both legs. In a study from Nigeria showed 17 ulcers on Left leg (51.5%), 15 ulcers on right leg (45.5%) and 1 (3%) ulcer on both leg in a population of 33 patients. But laterality of leg ulceration has no impact on the outcome of leg ulcer [14].

Most of the patients (61%) had ulcer at foot followed by gaiter (20%) and leg (19%). ($Z=6.14$; $p< 0.0001$). Our study was conducted in a government district hospital where most of the patients seeking medical advice belong to lower socioeconomic class. Beedi smoking is prevalent in lower socioeconomic class people who also walk and work bare footed, so more vulnerable to trauma to foot. Poor education and poverty prevents them to attend health care facility promptly.

Most of the ulcers were diabetic (37%) followed by venous (22%) ($Z=2.31$; $p=0.01$). Only 5% and 3% were malignant and trophic ulcers. Distribution of different type of ulcers in different studies varies 70% to 90% for venous ulcer, 5% to 15% for arterial ulcers and 1% to 5% for other ulcers [15]. All of these are based on population in western countries. But Indian study in prevalence of leg ulcer is limited to only one hospital based study. The study suggested that leprosy

(40%), diabetes (23%), venous disease (11%), and trauma (13%) were among the causes of lower extremity wounds in patients attending that hospital. Thirteen percent of wounds were not directly linked to any known cause^[8]. Arterial ulcer is seen among 13% patient in our study. In region where our hospital is present, prevalence of tobacco usage is about 50-65% in the population^[16]. Higher rate of smoking and use of tobacco products, especially use of beedi smoking in Indian male could be the cause of more number of male patients compared to female and higher number of arterial ulcer in our study^[17]. Also incidence Burger's disease among peripheral arterial disease is more in India (45-63%) than Europe (0.5- 5.6%)^[18]. Beedi smoking is prevalent in lower socioeconomic class people who also walk bare footed, so more vulnerable to trauma to foot. Poor education and poverty prevents them to attend health care facility promptly. The above mentions causes may be the reason of more arterial ulcer in our study. Venous ulcers are significantly lower in our study (22%) compared to western studies. Only one study available in literature done by Malhotra on prevalence of varicose veins in Indian population, which showed the prevalence of varicose vein in rail road workers found to be 25.08% in south Indian and 6.8% in north Indian workers^[19]. Leg ulcer due to malignancy, tuberculosis, neurotrophic causes are seen rarely.

Peripheral neuropathy (23%) was the most common type of ulcer followed by venous hypertension (22%). Only 1 (1%) case of sickle cell disease was found. In a community-based study from Chennai, south India, Pradeepa *et al.* measured the prevalence of DPN using VPT by biothesiometer. The prevalence in newly diagnosed patients was 19.5% and 27.8% in those with known diabetes.²⁰ However, the frequency of DPN in the subjects without diabetes was not studied. The higher proportion of peripheral neuropathy is due to higher proportion of diabetic leg ulcers in our study.

In 79% of the ulcers microorganisms were found which was significantly higher than that of no growth (21%) ($Z=8.31$; $p < 0.0001$). Out of the microorganisms *Staphylococcus* (28%) was most common followed by *Pseudomonas* (14%) and *Klebsiella* (11%). Only in 2% of the ulcers, *Morganella* and *AFB* were present. Similar result was reported by Mathangi *et al.* in their study^[21].

Most of the ulcers were muscle deep containing unhealthy granulation tissue and slough with serous or purulent discharge, irregular or thin bluish margins, shallow edge followed by sloping edge, associated with lipodermatosclerosis and hyperpigmentation or induration. These findings were associated with more numbers of diabetic and venous leg ulcer patients in this present study.

Conclusion

Thus, the study of various cases of leg ulcers arouses lot of interest and is mind boggling as far as the treatment of these cases are concerned. With the availability of arsenal of investigation wide range of antibiotics and with ever improving dressing material, there is certainly a great improvement in treatment of chronic leg ulcers.

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