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Clinical study on management of venous ulcer

Mohan Rao Voruganti, Nooruddin Mohammed*, Sushmita Tummala

Department of General Surgery, Dr. PSIMS and RF, Gannavaram, Krishna District, Andhra Pradesh, India

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*Correspondence:

Dr. Nooruddin Mohammed, E-mail: mdnoor91@gmail.com

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ABSTRACT

Background: Venous ulcer is the most common ulcer affecting the lower limbs, usually associated with varicose veins. They are diagnosed by their location, morphology, skin changes, and association with venous insufficiency. They are complicated with local scarring, ankylosis of ankle joint, and occasionally malignancy. Diagnosis is confirmed by venous duplex imaging. They significantly reduce quality of life due to pain, and reduced mobility leading to loss of income and social isolation. Cost estimates put them at upwards of 2% of national resources. Recurrence is high with conservative treatment. Surgery addressing venous valvular insufficiency plays a major role. Objectives of current study was to assess the role of conservative treatment and surgical management of venous ulcers.

Methods: A cross-sectional study of 80 patients in the period 2019 -2020 at a tertiary care center.

Results: 84% of the patients were male with maximum patients in the 6^{th} decade. 67% were overweight. Conservative treatment was done in 22% of cases and surgery for 78%. Flush ligation and venous stripping with perforator ligation was the most common surgery done. 89% of the patients achieved healing by the end of 3 months, and 97% by the end of 6 months. Wound healing time in surgical vs conservatively was 8.3 and 10.4 weeks respectively.

Conclusions: Correction of underlying venous insufficiency is the main stay of the treatment. Surgery gives best results with long term benefits.

Keywords: Chronic venous ulcer, Sapheno-femoral junction, Short saphanous vein, Great saphanous vein

INTRODUCTION

Chronic venous ulcer (CVU) is the most common ulcer affecting the lower limbs, with a prevalence of 1-2%. CVU is defined as an ulcer with duration of more than 6 weeks with evidence of chronic venous insufficiencies like varicose veins, edema, and pigmentation.1 CVU significantly reduce quality of life due to pain, loss of function, reduced mobility, and social isolation. They are complicated with local eczema. scarring. lipodermatosclerosis, ankylosis of the ankle joint, bleeding, chronic osteomyelitis and sometimes Marjolin's ulcer. Risk factors for CVU are obesity, deep venous thrombosis, phlebitis, and venous valvular dysfunction.^{1,2}

Venous ulcers are diagnosed based on clinical findings like anatomic location in Gaiter's area, morphology, and characteristic skin changes. Diagnosis is confirmed by assessing the venous system functionally and structurally using imaging.

Pathophysiology of venous disease

Proposed mechanisms include hypoxia-mediated endothelial changes, cell cycle dysfunction with inhibition of programmed cell death, changes in enzyme activity, and defects in venous tone. In secondary venous disease, both reflux and obstruction play a role in the development of ulcers. There may be congenital absence; weaknesses of valves, failure due to the sclerosis, or the

destruction due to thrombosis. Old age, obesity, asthenia, calf muscle dysfunction, and prolonged dependent posture contribute to stasis with an excess load on the ultimately leading valves, to chronic hypertension.² The severity of the chronic venous disease is based on the magnitude of venous hypertension, with 100% ulceration at pressures greater than 90 mmHg.³ The increased load results in varicosities, inflammation and ulceration. Theories that have been proposed are; white cell trapping theory: leukocytes get trapped in microcirculation resulting in venous dilatation and pooling, leading to the release of proteolytic enzymes. Inter-epithelial pore widening, deposition of fibrin and other macromolecules in the dermis trap growth factors thus rendering them unavailable for wound repair.4

Investigations

Duplex scan is the investigation of choice in venous pathology. It is a non-invasive technique that gives valuable information regarding the characteristics of venous flow, thrombotic obstruction, reflux, and patency.⁵

Management

CVUs are managed either conservatively or by surgical approaches. Conservative management; dressings: a wide range of dressings that include hydrocolloids, hydrogels, foam, growth factor pastes are available. Their use depends on local availability and personal choices. Compression therapy: inelastic or elastic or intermittent pneumatic compression therapies are found to be effective. It reduces oedema, pain, and improves venous circulation. A pressure of 35-40 mmHg is necessary in presence of an ulcer.^{6,7} In the absence of an ulcer, pressure around 25 and 30 mmHg is sufficient. Inelastic compression provides no resting pressure. Stockings are more useful as it provides a graded pressure from below upwards. Multilayered elastic bandages (MLB) are more beneficial than single layered bandaging. MLB needs expertise & frequent changing, with compression therapy, medical management plays a major role, and so does limb elevation. 6 The use of pentoxifylline and aspirin has been shown to be of added benefit.^{6,8} Intravenously administered iloprost can be used through vasodilatation and its effect on platelet aggregation. Daflon, a micronized purified flavonoid, and prostaglandins E1 are beneficial with compression therapy but not individually, Antibiotics are used, but regular use is not recommended. Negative pressure wound therapy and hyperbaric oxygen therapies can be used, but proof of their benefit is lacking.9 Surgical management; surgery is indicated for large, chronic ulcers that do not heal by medical therapy and or compression therapy. Surgical management includes debridement, split skin grafting, and surgery for venous insufficiency. Surgery has been shown to heal ulcers faster and reduce the rate of ulcer recurrence. Conventional surgery for venous insufficiency consists of

ligation of saphenofemoral/saphenopopliteal junction, stripping of veins and perforator ligation. ¹⁰ For a deep venous insufficiency, surgery, is a more difficult proposition. For primary valve failure, procedures include intraluminal repair of valves or extra luminal support of the valve. For a post thrombotic destroyed valve due to secondary valve failure, either a segment of vein with normal valves is transplanted or a normal vein is transposed in the diseased segment.¹¹ Sclerotherapy; 3% sodium tetradecyl sulphate, Ethanolamine oleate, polidocanol, and 20% hypertonic saline are commonly used. They induce venous endothelial damage with peri venous fibrosis at the site of reflux and varicosities, leading to obliteration of the vein. 12 Mixing of sclerosants with air or CO₂ in 1:4 ratio to form foam increases the efficacy of sclerotherapy. Radiofrequency ablation and endovenous laser surgery involve introducing a catheter under ultrasound guidance and heating the catheter tip with energy. Heat delivered to the vein wall will cause shrinkage, and the catheter is withdrawn until the entire vein is obliterated. Radio frequency ablation and foam sclerotherapy showed better short term results. 11,12

Objectives

Objectives of current study were to assess the role of conservative treatment of venous ulcers and to assess the role of surgical management in venous ulcers.

METHODS

A cross-sectional study was conducted at the department of general surgery, Dr. Pinnamaneni Siddhartha institute of medical sciences and research foundation, Chinaoutapalli for the period of 2019 to 2020. 80 patients were studied who were patients attending the outpatient department and casualty during the study period with venous ulcers over the leg.

Inclusion criteria

All the patients presented with venous ulcers over the lower limb with or without varicose veins were included in the study.

Exclusion criteria

Patients with; co-existing arterial disease, coexisting lymphatic disease, on steroid therapy, immuno-compromised status, pregnant patients, intra-abdominal tumors and varicose veins without ulceration were excluded from the study.

Procedure

A detailed clinical history was noted. A thorough clinical examination was done and findings were recorded. All patients had a biochemical screening which includes random blood sugars, routine hematologic indices, wound site culture &sensitivity, abdominal ultrasonography, and

chest radiographs. Venous duplex Doppler studies were done.

Biopsy of the ulcer if necessary. The treatment policy included either conservative or surgical. Conservative modalities included wound dressings, compression bandaging, antibiotics in infected cases, anti-inflammatory analgesics, pentoxifylline, and aspirin. Limb elevation and active and passive exercises were advised. Foam sclerotherapy for small or residual varicosities; surgical modalities included debridement of the ulcer, dressings followed by split skin grafting. Ligation and stripping of varicose veins and perforator ligation with subfascial ligation or multiple ligations was done. All the data was entered in Microsoft spread sheet and were analysed.

RESULTS

Age and sex distribution

In our study, the age varied from 22 years to 69 years. Out of 80 patients, 11 (13.3%) patients were from 21-30 years age group, 13 (16.6%) from 31-40 years, 16 (20%) from 41-50 years, 32 (40%) from 51-60 years and 8 (10%) from 60 and above years of age. The mean age was noted to be 48 years. There were 67 (83.75%) males and 13 (16.25%) females. Male:female ratio was 5.1:1.

Table 1: Age and gender based distribution.

Age (years)	Male	Female	Total
21-30	11	0	11
31-40	10	3	13
41-50	13	3	16
51-60	27	5	32

Weight

Total 15 (18.75%) patients had a normal BMI, 37 patients (46.25%) were overweight and 28 (35%) patients were obese. All 13 females were overweight or obese.

Table 2: BMI based distribution.

BMI	Male	Female	Total
<25	15	0	15
25.1 - 30	29	8	37
>30+	23	5	28
Total	67	13	80

Occupation

Total 41(51.25%) patients were laborers, 23 (28.75%) were farmers, 9 (11.25) were sales professionals, and 7(8.75%) were homemakers. The majority of the patients (92%) belong to occupations that demanded prolonged hours of standing for at least more than 8 hours/day.

Symptoms and signs

Along with ulceration, 32 (40%) patients had pain, 53 (67.5%) patients had edema and 57 (71%) patients had skin changes. All our patients had underlying venous abnormalities either clinically or radiologically. Of the patients, 35 (43.75%) patients had venous ulcer in the right leg, 42 (52.5%) in the left leg. 3(3.75%) had bilateral venous ulcers. In our study, 56 (70%) patients had pathology of great saphenous vein, 19 (24%) patients had perforator incompetence, and 5 cases (6%) had involvement of short saphenous vein.

Table 3: Symptomatology and investigations.

Parameters	N	%
Ulceration	80	100
Pain	32	40
Oedema	53	67.5
Skin changes	57	71
Ulcer		
Right leg	35	43.75
Left leg	42	52.5
Both legs	3	3.75
Doppler study		
GSV+ incompetent perforator	56	70
Incompetent perforator	19	24
SSV incompetent	5	6

Management

In our study, 15 patients (18.75%) underwent conservative management alone and 65 patients (81.25%) underwent surgery. Amongst 65 patients who underwent surgery, flush ligation of Sapheno-femoral junction with stripping of GSV up to knee was done in 46 (70.76%) patients. All of these patients had phlebectomy below the knee also. 5 (7.6%) cases underwent subfascial endoscopic perforator ligation (SEPS). 2 were with SFJ ligation and 3 with perforator incompetency alone. Phlebectomy alone was done in 14 (21.3%) patients. 5 cases were operated with SSV ligation. Post operative complications were seen in 18 (22.5%) patients. 16 (20%) patients had wound infection and 2 (2.5%) patients had a hematoma. 15 patients were managed conservatively. They were either not willing for surgery or unfit to undergo surgery. Patients were followed at 3 months, 6 months, 9 months, and 12 months. The majority of the patients were ulcer free by the end of 3 months. 71(88.75%) patients achieved healing by the end of 3 months. 6 (7.5%) patients achieved healing by the end of 6 months. ulcers in 3 (3.75%) patients never healed. It was observed that patients who managed surgically healed faster with a mean healing time of 8.3 weeks when compared to patients managed conservatively who had a mean healing time of 14.4 weeks. This infers that correction of underlying venous insufficiency is a mainstay in the management of venous ulcers. 5 (6.25%)

patients had a recurrence of ulcers by the end of the study period of 1 year. 3 of the 15 (20%) patients were managed conservatively and 2/65 (3.1%) patient was managed surgically. These results infer that the rate of recurrence was comparatively more in patients managed conservatively than patients managed surgically.

Table 4: Management of venous ulcers.

Surgery	N
SFJ ligation	46
Phlebctomy	60
Alone	14
With SFJ ligation	46
SEPS	5
SSV ligation	5

DISCUSSION

Venous ulcers of the lower limbs, identified as stasis ulcers, are the most severe and devastating form of chronic venous insufficiency/disease (CVI) and accounts for \approx 80% of lower extremity ulcerations.¹ The prevalence of venous leg ulcers is stable between different countries and estimated to be 1% in most populations.2 A large Indian study revealed that CVI is more prevalent at an average age of 43 years with its incidence increasing with age and it affects women more than men.¹³ Elevated venous pressure, turbulent flow and insufficient venous return due to venous occlusion or venous reflux are the proposed aetiologies, which activate inflammatory processes, triggering leukocyte activation, endothelial damage, platelet aggregation and intracellular oedema.^{1,4} Older age, obesity, previous leg injuries, deep venous thrombosis and phlebitis are the various risk factors aggravating this complication.^{1,2}

Though it has lower prevalence, the refractory nature of this disease has an expanded risk of morbidity, and a significant impact on quality of life posing a great economic burden in India. 14 Proper assessment of the extent of venous ulcers in India presents a significant challenge due to the absence of a central trauma/wound registry and quality research. Moreover, poor infrastructure, superstitions and beliefs of the rural population constrain proper management. Venous disease traditionally has been ignored or considered of less clinical importance because it is frequently not life-threatening.

The management of venous ulcer must be multidisciplinary and should include detail history, physical examination and diagnosis and basic and newer treatment modalities with proper patient education regarding diet and lifestyle modification. The management (both prevention and treatment) options include: dietary and lifestyle modification, medical management, dressings, compression therapy and operative or endovenous treatments.

Epidemiology

In our study the age group ranged from 22-69 years, of which 70% of the groups were more than 40 years of age. The mean age was noted to be 48 years which is on par with the findings of Rao et al and Zolotukhin et al. 15,16 These findings imply that there is increasing prevalence of venous ulcers with increasing age. This could be due to the fact that venous ulcers develop as a result of CVI and with progression of time, chronicity increases. In our study there were 67 (83.75%) males and 13 (16.25%) females. Males were affected more than females which was similar to findings from Chandrasekhar et al and other Indian and international studies, which challenges the age old notion of female preponderance.¹⁷ Criqui et al in 2003 conducted studies on San Diego population and noticed a prevalence of 7.8% in men and 5.3% in women.¹⁸ Studies by Baker et al in 1991 observed that female predominance occurred only in patients above 70 years of age.¹⁹ Indian men are involved in more strenuous physical activities demanding longer hours of standing when compared to women due to cultural and socioeconomic conditions prevalent at the time. In our study, majority of the patients belonged to occupations that demanded prolonged hours of standing for atleast more than 8 hours /day. Patra and Selvaraj et al. observed that daily laborers were affected most commonly. ^{20,21} Suehiro et al observed that occupations needing prolonged standing were of statistical significance in development of venous ulcers.²² According to Criqui et al CVI was 2.7 times more likely in patients who worked for more than 4 hours. 18 In contrast, studies by Styrtinova et al and Maffei et al reported no association between occupations demanding prolonged standing and sitting postures with development of venous ulcer.^{23,24} In our study, along with ulceration, 12 patients had pain, 23 patients had edema and 57 patients had skin changes. In a similar study by Reddy et al. in 2017, most common presenting complaint was skin changes. Ulceration was the most common symptom affecting 57.6% patients followed by pain affecting 56.5%.²⁵ In our study, left limb was more commonly involved, similar to findings of Samane et al and Kumar et al.^{26,27} In contrast only some studies such as one by, Rao et al observed that right limb was most commonly. 15 This infers that left lower limb is more prone to develop venous ulcers due to CVI, the reason for which is yet to be determined. We observed that majority of the cases were due to involvement of the GSV system, as observed in the studies by Rao et al and Matad et al. Perforator incompetence alone was observed in our study in 19 patients, involvement of which was not thoroughly investigated in other studies. Though many studies reported involvement of GSV along with SSV, we have observed that in some patients only SSV involvement can be seen if thoroughly evaluated. 15,17

Management

Compressive bandaging was done for all the patients who opted for conservative management. According to the

NICE guidelines (UK-NHS), compression therapy is recommended as first line therapy for varicosities. Lawrence et al. observed that 50% of patient's ulcers treated with only compression therapy healed with a 15month median period and 75% healed within a period of 36 months.²⁸ Amongst 65 patients who underwent surgery, flush ligation with stripping was done in majority of our cases. Most of the studies both in India (Patra) and elsewhere have reported adoption of similar lines of management.²⁰ The ESCHAR study established the role of surgical therapy along with compression therapy and noted high recurrence rates with the compression therapy alone.29 Nelzen et al reported decreased recurrence rates if SEPS was combined with the conventional procedure.30 According to ESCHAR study, surgery to treat superficial venous reflux significantly reduced 12 month recurrence rate of ulcers. Lawrence et al observed that patients who underwent surgery for perforator incompetence in addition to flush ligation and stripping had an ulcer healing rate of 68% at 36 months when compared to patients who did not (51%).²⁸ Post-operative complication rate in most studies was reported around 10-18%, of which the most common complication was reported as wound infection followed by heamtoma. This is similar to our study. Only Mulla et al noted complication rate to be as high as 31%, of which the most common complication was seroma.³¹

Follow up

With respect to healing rates, most studies report healing rates in conservative treatment alone to be around 73-96%, whereas healing rates in surgical group have been reported to be 83-100%. Our study has reported findings within the same range. It was observed that patients who were managed surgically healed faster with a mean healing time of 8.3 weeks when compared to patients managed conservatively who had a mean healing time of 14.4 weeks. Van Gent et al. reported mean time for ulcer healing was found to be 4.2 months for surgically managed cases and 5.7 months for cases managed conservatively.³² This infers that correction of underlying venous insufficiency is mainstay in management. There is not much evidence to support the findings in the present study with regards to ulcer healing and follow up of patients. Recurrence rates reported were 20-40% for conservative management alone and 2.5-15% for surgical therapies. The probable reasons for recurrence could be patients not complying properly with compression therapy or missed perforators radiologically or at the time of surgery. Though recurrence in the conservative group can be due to the fact that the primary pathological process is not being dealt with, the wide variation in the recurrence rates of within the surgical group can only be explained as a difference in surgical expertise.

Limitations

There were some limitations in this study which include short period of study, non compliance of patients to regularly attend the outpatient clinic. The follow-up period in our study is 1 year which is very short. Literature has studies with follow up periods ranging from 3-5 years.

CONCLUSION

Venous ulcers are common ulcers of lower limb causing a progressive disability affecting patient with pain, disability, loss of work, and social isolation. Ulcers need prompt treatment with dressings and surgery. Correction of underlying venous insufficiency is the main stay of the treatment. Surgery gives best results with long term benefits.

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