Original Articles

Cost- Effective Management of Venous Ulcer

SAN Alam, AHM Bashar, KM Alam, MN Sabah, GM M Hossain, ME Hakim, M Badiuzzaman, AK Azad Department of Vascular Surgery, National Institute of Cardiovascular Diseases, Dhaka. Bangladesh.

Abstract:

Keywords-Venous ulcer, Saphenofemoral ligation, Perforator ligation.

Background: Venous disorders are very common. About 20% of the population suffer from varicose veins, 2% have skin changes which may precede venous ulceration¹. Venous ulcers represent a common and debilitating condition associated with significant financial loss for the patients as well as the society. Treatment options for these patients are costly and time consuming. In this study we tried to find out cost -effective measures for treating this group of patients.

Method: To evaluate the effectiveness and safety of superficial and perforating leg venous surgery along with pharmacotherapy 66 patients with chronic venous leg ulcers are prospectively studied. After proper history taking and clinical examination all patients underwent venous duplex ultrasonography. Patients were divided into two groups. Group I (n=30) includes patients undergoing saphenofemoral ligation and stripping of the great saphenous vein (GSV). In group II (n=36) patients underwent saphenofemoral and incompetent leg perforator ligation along with stripping of the GSV. Conservative measures, local ulcer care and pharmacotherapy were common in both groups.

Result: Postoperative complications, total hospital stay and ulcer healing were studied. Ulcer healing was earlier in group II. Remarkable complications were similar in both the groups.

Conclusion: For effective and economic care of venous leg ulcers, combination of standard surgical procedures including incompetent perforator and saphenofemoral ligation with great saphenous vein stripping and standard physio-pharmacotherapeutic care is essential. This combined modality of treatment is highly effective in early and complete ulcer healing in patients suffering from venous ulcers.

(Cardiovasc. j. 2010; 2(2): 136-141)

Introduction:

Venous diseases are as old as mankind. With the emergence of Homo Erectus, man began to walk upright, and thus varices were born. In Chinese documents dating from 1500 BC, there is information regarding surgery of varicose veins by surgeons of the time. Compression bandaging is also mentioned as one of the oldest techniques.

Venous disorders are very common. About 20% of the population suffers with varicose veins and 2% have skin changes which may precede venous ulceration. At any one time 200000 people in the UK have active venous ulceration.¹

Lower extremity venous ulceration resulting from long standing venous stasis has been attributed to venous flow obstruction and reflux in the deep venous system and has been regarded as an inevitable consequence of post phlebitic syndrome.² The presence of reflux in the superficial venous system, at the saphenofemoral

junction, and in particular the great saphenous vein, has also been recognized as an important cause of chronic venous insufficiency with its characteristic lipodermatosclerosis and intractable ankle ulceration. Moreover perforator vein incompetence has been associated with venous ulceration.3 This led to the development of operations for perforators. In course of the years, various techniques were described which promoted ligature of perforating veins. For examples, Linton's, Felder's, Cockett's and Sherman's operations. Whilst the Linton's operation was described for the global treatment of perforators of the legs, Cockett's operation was proposed for the treatment of direct perforators of the distal third of the leg. Besides surgery, conservative measures were tried since the awareness of venous diseases. Different types of bandaging and venoactive drugs were tried. Until recently most of the pharmacotherapy except some form of flavonoid compounds was proved ineffective. In

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1999, with the publication of "The management of chronic venous disorder of the leg: an evidence based report of an international taskforce", it became well-known that venoactive drugs like micronized purified Flavonoid fraction like Diosmin and Hesperidine are effective and has got beneficial effects on venous haemodynamic in reducing leg oedema and skin changes. The added value of this drug with conventional therapy for treatment of active leg ulcers has also been noted.⁴

The management of all these patients relies on an accurate noninvasive venous assessment, using in particular duplex ultrasound imaging. This fast and non-invasive assessment gives anatomical and functional information and has largely replaced venography in the assessment of lower limb venous disorders. The use of duplex ultrasound to identify patients with chronic venous ulceration whom surgery might be of benefit is also reported.⁵

The present study was carried out to evaluate the effectiveness of saphenofemoral and incompetent perforator ligation, in combination with stripping for the treatment of chronic leg venous ulcer and to compare these modalities of surgery and thereby establish a standard protocol.

Materials and Methods:

The study was carried out in the vascular surgery department of the National Institute of Cardiovascular Diseases and Hospital (NICVD), (with inclusion of some patients of private clinics), Dhaka, Bangladesh during the period of January 2000 to December 2008. Total number of 89 patients with chronic leg ulcers was included in this study. All enrolled patients underwent clinical examination after careful history taking. Then anatomical and functional information of vessels of both lower limbs were gathered using duplex ultrasound imaging with "ATL-3500(USA)" and "Voluson 730 PRO V (GE, USA)" duplex machines. Broadband linear scanners were used in both arterial and venous evaluation. The examination was performed with the patient standing in most of the cases and all major vessels from groin to the ankle were evaluated. In some older patients examination was performed with the patient in the prone position on a bed tilted about 40 degree feet down. In these patients leg veins were evaluated with the patient sitting on a bed with the foot in the examiner's lap or on a stool. Based on duplex evaluation a comprehensive map of the veins with their functional status was constructed. During the evaluation Ankle Brachial Pressure Index (ABPI) was also measured along with arterial scanning. Patients suffering from ischaemic ulcer (arterial) were thus isolated and excluded from this study.

Wound care and pharmacotherapy:

At first all ulcers were swabbed for bacterological examination and culture sensitivity(c/s). Then we tried to heal the ulcer on an outpatient ambulatory basis for 4-6 weeks. Patients were started on a programme of elevation of limb, rest, external pressure and compression and ulcer care. Local care consisted of regular cleaning of ulcer with normal saline and debribement of necrotic tissues. Patients were advised not to apply antisepties, unguents or other medication directly on the wound. They were trained to apply a saline compress to the ulcer for 15-30 minutes twice daily and replace it by a sterile dry gauze and dressing placed directly over the wound. Over this a piece of foam rubber ½ inches thick was placed and both was held in place by an elastic bandage [either crepe bandage or graduated elastic stocking (compression class II)]. At the next dressing the gauze pad removed the nectrotic debris and exudates as it was taken off (soaking if painful) and thereby accomplished debribement twice daily. The pressure dressing was maintained by night also. This procedure helped in avoiding costly multilayer branded dressings.

Simultaneously all patents were prescribed a combination of 450 mg of micronized Diosmin and 50 mg of Hesperidin (Daflon/Diohes 500) twice daily for 6 weeks and multivitamins. In addition according to the C/S report of the ulcer, patients were prescribed appropriate antibiotics. Other general measures taken were close glycemic control in diabetes, effective treatment of concomitant arterial disease, weight reduction in obese patients, improvement of ankle mobility through physiotherapy and drug treatment of rheumatoid arthritis.

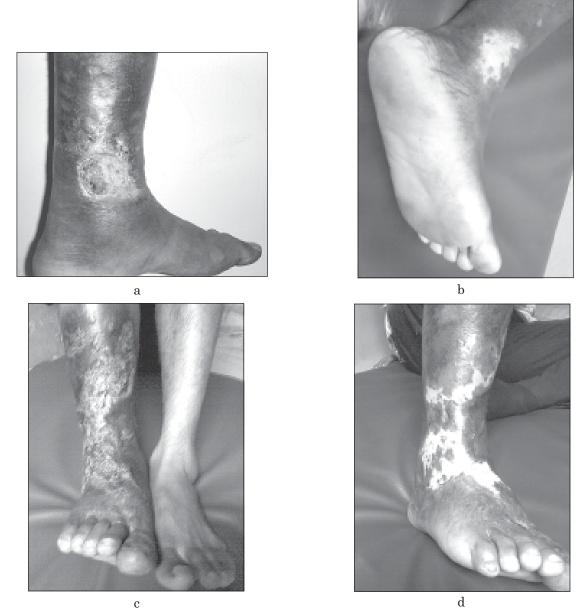


Fig 1: Venous ulcers before Fig (1a & 1c) and after treatment Fig (1b & 1d).

Surgery:

All patients in this series underwent surgery either after complete healing (Fig 1b & Fig 1d) or at the stage of healing of leg ulcers (<3cm). Patients were divided into 2 groups. Group I patients underwent long saphenofemoral ligation and stripping of the great saphenous vein. In patients of group II, in addition to above mentioned procedures isolated incompetent leg perforator surgery were also done. All surgeries were done under spinal anesthesia.

For saphenofemoral ligation and long saphenous stripping standard procedures were followed. All venous tributaries in and around the saphenofemoral junction were identified and ligated. The long saphenous vein was ligated near the saphenofemoral junction, flushed with nonabsorbable suture and then divided. Malleable vein stripper (AESCULAP, Germany) was used for long saphenous striping. Up to the early past of the year 2001 we performed standard Linton's operation for leg perforators. This open subfascial ligation as associated with local wound complications, longer hospital stay with relatively uncomfortable postoperative sequelae. This led us to practice modified incisions for medical leg perforators. The large incisions for Linton's operation were gradually replaced by small

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incisions which in addition, is located in healthy skin, away from trophic disturbances (Fig 2). This approximately 4-6 cm. incision extends to cover the median inferior perforators of Cockett and suitable to avoid causing cicatricial modifications. This partial "Cockett Surgery" have allowed us to dispense with Linton's operation with better patient compliance in terms of prolonged hospital stay and morbidity.

Isolated varicose veins were removed through small incisions. In this regard we have been practicing newer technique like "hook phlebectomy". It uses small hooks which may be inserted through incisions of only 1.5-2.0 mm. The hook is used to capture a small section of the varicosity and bring it to the surface where it may be grasped by a artery forceps, the remaining vein is then teased through the tiny incision. Closure of incision is achieved by adhesive strips (steristips) or dressing but requires no suture. The cosmetic outcome of this procedure is excellent. Patients were followed up monthly for 6 months in the post operative period. After complete healing of wound all were advised to use compression stockings (Class II) for 12 months.





Fig.-2: Showing healed venous ulcer before & after perforator surgery.

Result:

Out of total 89 patients, 12 had history of deep venous thrombosis, 8 had concomitant peripheral arterial insufficiency and 3 had Popliteal venous reflux as revealed by clinical evaluation and duplex study. So they were excluded from this study. Out of the rest 66 patients, 48 were male and 18 females. The age ranged from 30-55 years (Table-I). All patients had venous ulcer for a period 6-18 months. All had ulcers on the medial side and in addition 1 had on the lateral aspect of leg. Prior 1st reporting to us all patients consumed multiple antibiotics (both systemic and topical for 6-8 months. We strictly followed our protocol of preoperative conservative measures on an outpatient ambulatory basis for 4-6 week. Fifty two of those patients had incomplete preoperative ulcer healing. Only fourteen patients had healed ulcers. Average hospital stay in both groups of patients was 7 days (4-12 days).

Table-I

Age distribution in study population.

Age	Sex				Total
	Male	(N-26)	Female (N-12)		
	Group I	Group II	Group I	Group	II
30-39	5	3	-	-	8
40-49	12	13	5	8	38
50-55	6	10	2	2	20
	23	26	7	10	66

In both groups ulcer healing started and became evident after 4-6 weeks in group I and 3-4 weeks in group II. Complete healing of ulcers was recorded within 3-6 month in group I and 2-3 months in group II. Thus the rate of ulcer healing was significantly rapid in group II in comparison with group I (p<0.05). In postoperative period ulcer care and use of compression stocking (class II) was advised.

Patients were followed every month in first 6 months, every 3 months in next 6 months, every 6 months for at least next 2-3 years. This protocol of follow-up could be maintained for only 36 patients. Twenty patients of group I & 16 of group II were followed up. There was satisfactory ulcer healing much better and speedy in group II (Table II). There was no recurrence of ulcer in group II. Seven patients in group I had recurrence of ulcer

within 1 year of postoperative follow up. They were subjected to perforator surgery.

Table-IIVenous ulcer healing (post operative)

Duration	Mean size of ulcer in cm		p
(follow up)	Group I	Group II	
Initial	2.9 ± 1.1	2.9 ± 1.3	1
15 days	2.7 ± 1.0	2.5 ± 1.1	0.44
1 month	2.5 ± 1.8	2.1 ± 1.3	0.29
2 month	2.2 ± 1.6	1.2 ± 1.1	0.0038
3 month	1.8 ± 1.4	0.3 ± 0.5	0.0001
4 month	1.5 ± 1.2	No ulcer	0.0001
5 month	0.8 ± 0.6	No ulcer	0.0001
6 month	$0.4 \ 0.3$	No ulcer	0.0001

Discussion:

Venous ulcers represent a common and debilitating condition associated with significant financial loss for the patient as well as the society. It affects 1-2% of the population, often with a protracted course of delayed healing and multiple recurrences. Though demographic data of patients with venous leg ulcers in developing country like Bangladesh is not available, still there is quite large number of patients. That is why we undertook this study only to standardize the optimum care for these patients.

Studies show that between 40% and 60% of venous ulcers are due to superficial venous insufficiency alone and rest are due to either perforator incompetence or deep venous thrombosis with valvular incompetence. Operations to correct superficial venous insufficiency will therefore result in ulcer healing rate of between 40-60%. Here comes the surgery for perforators with additional benefit while excluding deep venous insufficiency.

A number of studies concerning only saphenofemoral ligation showed satisfactory ulcer healing by effective control of venous reflux.^{6,8} However, the slower ulcer healing rate in those series and some recurrences are also reported. Another modality of treatment combines stripping of the long saphenous vein along with saphenofemoral ligation also have similar result.^{8,9}

In our series patients in group I showed relatively slower ulcer healing. This result coincided with related reported results. In this series there were 7 cases of ulcer recurrence within 1 year of surgery. Reevaluation revealed incompetent perforator for which those patients, undergone perforator surgery.

In the history of phlebology, perforating veins were identified as responsible for the origin of trophic disturbances of the leg, secondary varicose vein and recurrences of major varicose complexes. Therefore in the course of the years, various techniques were described which promoted ligature of perforating veins. In our series of group II patient, modified Linton's and Cockett's operations were practiced with 100% success.

Newer sophisticated techniques like Subfascial Endoscopic Perforator Surgery (SEPS) are yet to be introduced in Bangladesh. This minimally invasive procedure deals with leg perforators and is efficient in healing of leg ulcer. ¹⁰ Whatever may be the surgical technique the ultimate goal was to heal venous leg ulcers completely and in shortest possible time. Our patients in group II had better and rapid recovery.

In addition to surgery, the controlled perioperative physio-pharmacotherapeutic care gave excellent result in terms of tropic skin changes and venous haemodynamic. Both groups of patients were benefited from this. Several well-conducted clinical studies confirm the clinical effectiveness of micronized purified flavonoid fraction in improving symptoms and signs of chronic venous insufficiency and also it's added value in treating venous ulcers. 4,11

This prime pharmacological arsenal along with ambulatory simple wound care gave remarkable economic benefit and effective ulcer healing in all patients.

Conclusion:

We can say that for effective and economic care of venous leg ulcers, combination of standard surgical procedures including perforator and saphenofemoral ligation with long saphenous stripping and standard physio-pharmacotherapeutic care is essential.

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