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STUDY OF DIFFERENT MODALITIES OF TREATMENT OF CHRONIC VENOUS LEG ULCER

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ABSTRACT

Background : Leg ulcer caused by chronic venous insufficiency (CVI) remain a therapeutic dilemma. (CVI) affects roughly 3-4% of USA population and 10% of these patients ultimately have venous ulceration. (CVU) is one off the major problems commonly encountered in medical practice and occur in more than 50% of the victims of DVT within 10 years of the original attack.

Objectives : To assess the effectiveness of different modalities of treatment of chronic venous leg ulcer.

Patients and methods : A total of 40 patients with 40 limbs of chronic venous leg ulcer were randomly assigned to one of two groups as following (group-A) 20 patients with 20

limbs, 16 male 4 female mean age 40 years, 6 post phlebotic and 14 were primary managed conservatively by leg elevation, ulcer debridement, antibiotics according to culture and sensitivity, venotonic medication, four layer elastic compressive bandage with weekly dressing, their hospital stay ranges between 3-4 weeks.(group-B) 20 patients with 20 limbs, 15 males female, mean age 40 years, 1 post phlebotic and 19 were primary managed surgically by Trendelenburg's operation, stripping of LSV and/or SSV, subfascial perforators ligation, partial skin graft, their hospital stay ranges between 1-2 weeks.

Results : After one year follow up (group-A); 19 (95%) patients showed complete ulcer healing and 6 (30%)

patients showed ulcer recurrence. But in (group-B); 17(85%) showed complete ulcer healing and 3 (15%) patients show ulcer recurrence.

Conclusion : This study point out that all patients with CVU must be carefully selected for suitable modality of treatment and show the superiority of surgical treatment over the conservative which still to be applied either in highly selected cases or those cases very resistant to conservative measures, also the study show that multi-layer high compression was more effective than single layer.

INTRODUCTION

Chronic venous insufficiency is both prevalent, costly to individuals, society at large. The incidence of CVI in adult European population is between 0.5-3% (1)

Up to 1.5 % European adult will suffer a venous stasis ulcer at some point in their lives. Although the symptoms of CVI such as edema, leg heaviness are troublesome the skin changes and their ulcerative sequelae are the most significant. Many patients with venous ulcers show limitation of their leisure activities and earning capacity limitation. (2)

No single proposed mechanism adequately explains all the observed changes within the macro circulation or micro circulation of patients with venous ulcer. The symptoms of CVI, thereby venous ulcers are produced by venous hypertension which is itself the results of obstruction, reflux, or combination of both (3)

Venous hypertension transmitted to the cutaneous microcirculation results in a set of interrelated cellular microangiopathic and functional abnormalities that together results in the end-point of lipodermatosclerosis and venous ulceration (4)

New therapies for venous ulceration both operative, non-operative should have as their goal more rapid promotion of healing with less pain, decreased late recurrence than compression (5)

Various forms of non-operative therapy has served for decades the cornerstone of treatment for CVI and venous ulceration, They include compression therapy, pharmacological therapy (6)

Compression therapy continues to offer combination of simplicity, effica-

cy as it provides symptomatic relief, promote ulcer healing aids in preventing ulcer recurrence. Compression therapy continues to be the standard of non-operative therapy of CVI, venous ulcer against all other forms (7)

Saphenous surgery include proximal ligation of LSV, SSV, stripping. Perforator surgery includes open interruption endoscopic ligation or Duplex guided injection (8)

THE AIM OF THE WORK

The aim of this work is to evaluate the efficacy of different modalities of treatment of chronic venous leg ulcer. surgical vs. conservative compression therapy.

PATIENTS AND METHODS

During the period from (February, 2002) to (August, 2003) inclusive a total of (40) patients with (40) limbs of chronic venous leg ulcer were randomly assigned to one of the following two groups:

-*Group A* : (20) patients with (20) limbs, they were managed by conservative treatment.

-*Group B*: (20) patients with (20) limbs, they were managed by surgical

treatment.

All patients were subjected to:-

- 1- Carefull history taking including:
 - Age.-Sex.
 - Onset, Course, Duration of the disease.
 - Past history of similar condition .
 - History of medical disease.

2-Complete clinical examination :

- General examination;
- Mental state, nutritional state, built, decubitus and attitude.
- Pulse, blood pressure, respiratory rate.
- Head&neck, upper limb, chest, abdomen, pelvis.
- Local examination of lower limb;
 - Disfigurement.-Pain.-Swelling,.
 - Pigmentation.-Itching
 - Dilated veins.-Eczema.-Pigmentation.
 - Ulcer; Site. Size. Shape.
 - Edge. Base. Margin.

Discharge. Surrounding tissues.
Local lymph node.

3-Laboratory investigation :-

- Complete blood count.-Liver function test.
- Creatinine.-Fasting blood sugar.

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- Culture/ Sensitivity swab from the ulcer.
- Pathology (Biopsy) in suspected cases of malignant ulcer.
- E S R, R F and other collagen profile.

4-Radiological investigation including :-

- Plain X rays lower limb (to exclude osteomyelitis).
- Doppler ultrasound (to localize the site of reflux and perforators and ABPI measurement)
- Duplex scanning (for marking the perforators sites, detect the venous patency, blood flow velocity and anatomy of valves cusps).
- Pelvi-abdominal ultrasound (in suspected cases of pelvi-abdominal mass)

By the end of examination and investigation every patient was assigned according to CEAP classification ;(9)

CLINICAL CLASSIFICATION :

Class 0 : no visible or palpable signs of venous disease.

Class 1 : Telangiectases (interdermal venules up to 1 mm in diameter) Or reticular veins (not palpable

subdermal venules up to 4 mm).

Class 2 : Varicose veins (palpable subdermal veins > 4 mm).

Class 3 : Edema.

Class 4 : Skin changes (pigmentation, eczema, lipodermatosclerosis).

Class 5 : Skin changes as above with healed ulcer .

Class 6 : Skin changes as above with active ulcer.

ETIOLOGICAL CLASSIFICATION :

Congenital (Ec)

Primary (Ep) undetermined cause.

Secondary (Es) known cause;

ANATOMICAL CLASSIFICATION:

Superficial vein (As)

Deep vein(Ad)

Perforating veins(Ap)

PATHOLOGICAL CLASSIFICATION :

Reflux (Pr)

Obstruction (PO)

Reflux and obstruction (Pr,o)

5-Management :-

- (20) patients with (20) limbs of CVI underwent surgical treatment by Sapheno-Femoral disconnection, long and/or short saphenous Vein stripping and direct attack of perforators detected by duplex.

- Conservative treatment were done for the remaining (20) patients by multi-layers elastic compression bandage

**The operative procedures was carried out as follow;*

- Marking the all varicosities and sites of perforators with the patient in standing position pre-operatively.
- Spinal anaesthesia if not contra-indicated .
- The patient was placed in supine position.
- The diseased lower limb was sterilized up to the lower half of the abdomen.

(Sapheno-femoral disconnection);

(LSV stripping);

(SSV stripping);

(Perforators ligation by modified Linton method).

- Make direct oblique small incision on the mark of per'orator locate the perforator clamp ,ligate and disconnect all connection to it .

- Close the incision by proline 3/0.

**The multi-layer graduated elastic compression bandaging system was carried out as follow:*

- Clean the ulcer by soap and sa-

line or tap water irrigation.

- Cover the ulcer by hydrocolloid dressing.
- Make a layer of orthopedic wool or cotton on the leg to protect the bony prominences and absorb any exudates from the ulcer.
- Use crepe bandage to compress the previous layer and provide 42 mm Hg at the ankle and 17 mm Hg just blow the knee.
- Use a self adhesive elastic bandage to fix all layers in place and maintain the pressure for at least one week.

6-Follow up :-

Our patients were followed up after discharge from the hospital in the out patients clinic of the general and vascular surgery unit over one year.

The follow up data were reported: one month, 3 months 6 months, 9 months and one year after discharge in form of;

- All symptoms and signs of CVI.
- Healing rate.
- Recurrence.
- Complication. Haemorrhage. infection . DVT

RESULTS

A total number of 40 patients with clinically, biochemically and radiologically proven chronic venous leg ulcer were underwent in this study. They were diagnosed, treated and followed up during the period from (February, 2002) to (August, 2003) the follow up period ranged from 3 to 12 months with mean (7) months for each group inclusive, in general surgery department, mansoura university hospital.

Patients were randomly assigned to one of two treatment groups:

- *Group A* : (20) patients with (20) limbs were managed by conservative treatment.
- *Group B* : (20) patients with (20) limbs were managed by surgical treatment.

Demographic data.

- In group A ,age range from 16-52 years with mean age 34 years. Sixteen were male,4 were female, 11 cases were right sided and 9 cases were left sided

- In group A ,age range from 21-49 years with mean age 36 years. fifteen were male,5 were female, 7 cases were right sided and 13 cases were left sided as in (table: 1).

Healing rate among studied groups after one year.

- In group A, 19 cases show complete ulcer healing within one year, only 1 case show incomplete healing.
- In group B, 17 cases show complete ulcer healing within one year, only 3 cases show incomplete healing. (table-2).

Recurrence rate among studied groups after one year.

- In group A, 6 cases show ulcer recurrence within one year.
- In group B, 3 cases show ulcer recurrence within one year (table3).

Complication among studied groups.

- In group A, only one case with a history of DVT was found have DVT 6 weeks after treatment. .
- In group B, only two cases developed wound haematoma and infection within the first week after surgery at the site of stripping which treated by evacuation and antibiotic.

Bacteriology.

- The result of culture and sensitivity show; 85.5% mixed infection, 49% staph. Aureus.

CEAP grading among studied

groups after one year.

-All cases 40 of the two groups was evaluated according the CEAP

classification pre-operative and one year post-operative clinical outcome wa recolded as in (table-4)

Table (1): Age, sex and side.

		Group (A) Conservative		Group (B) (Surgical)	
		No	%	No	%
Age	< 30	7	35%	6	30%
	30 – 45	11	55%	12	60%
	> 45	2	10%	2	10%
Sex	Male	16	80	15	75
	Female	4	20	5	25
Side	Right	11	55	7	35
	Left	9	45	13	65

Table (2): Percent of CVU healing rate among studied groups.

Groups	Healing rate		Total
	Present	Absent	
Group A	19 (95%)	1 (5%)	20 (100%)
Group B	17 (85%)	3 (15%)	20 (100%)
Total	36 (90%)	4 (10%)	40 (100%)

U = 0.500

P = 0.000

Table (3): Percent of CVU recurrent rate among studied groups.

Groups	Recurrence rate		Total
	Absent	Present	
Group A	14	6	20
	70%	30%	100%
Group B	17	3	20
	85%	15%	100%
Total	31	9	40
	77.5%	22.5%	100%

U = 1.0 P = 0.008

Table (4): Pre and postoperative CEAP grades and clinical out-come among studied groups.

Groups	No of patients	Preoperative CEAP grades	Postoperative CEAP grades	Clinical outcome
Group A (Conservative)	13	C _{6-S} , Ep, A _{S-P} , P _r	C ₅ , Ep, A _{S-P} , P _r	E
	6	C _{6-S} , E _S , A _{S-d-P} , P _r	C ₅ , E _S , A _{S-d-P} , P _r	I
	1	C _{6-S} , Ep, A _{S-P} , P _r	C _{6-S} , Ep, A _{S-P} , P _r	U
Group B (Surgical)	16	C _{6-S} , Ep, A _{S-P} , P _r	C ₅ , Ep, A	E
	1	C _{6-S} , E _S , A _{S-d-P} , P _r	C ₅ , E _S , A _d , P _r	I
	3	C _{6-S} , Ep, A _{S-P} , P _r	C _{6-S} , Ep, A _p , P _r	U

(E): Excellent: complete ulcer healing.

(I): Improved: delayed ulcer healing.

(U): Unchanged: No healing.



Fig (1a): Patient with Lt LL chronic venous leg ulcer.



Fig (2b): Same patient 3 months after four-layer compression therapy show complete ulcer healing.



Fig (2a): Patient with LT LL chronic venous leg ulcer.



Fig (2b): Same patient 3 months after LSV striping and perforators ligation.

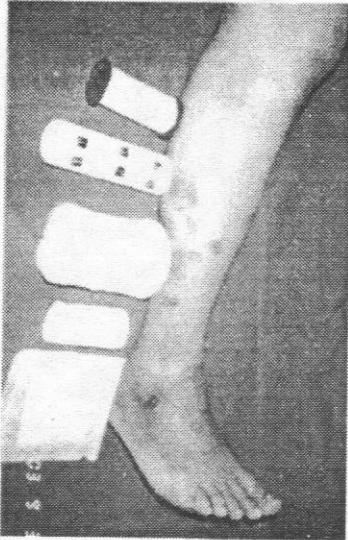


Fig (3a): All layers beside the limb.



Fig (3b): Same limb after application of all layers.

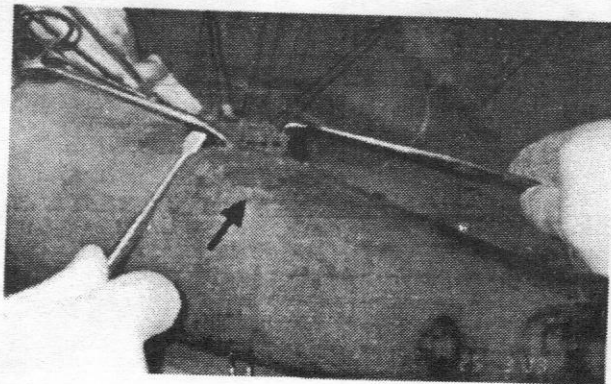


Fig (4): Identification of the perforators before triple ligation.

DISCUSSION

The incidence of CVI in the adult population based on European studies is between 0.5 % to 3%, Up to 15% of CVI patients ultimately have venous stasis ulcer at some point in their lives⁽¹¹⁾

No single proposed mechanism adequately explains all changes within the micro and macro-circulation of the patients with chronic venous leg ulcer but Chronic venous leg ulcer mostly produced by venous hypertension which is itself the results of obstruction, reflux, or combination of both⁽¹²⁾

Incompetence of the perforating veins plays an important role in venous hypertension and stasis changes of the skin and subcutaneous tissue of the leg, 90% of the incompetent perforating veins occurred in the posterior arch vein distribution⁽¹³⁾

In spite of the different types of investigation for CVI, Doppler ultrasound was a simple and non expensive device in detection of venous obstruction and valvular incompetence, but Duplex scanning considered the most sensitive diagnostic method

can easily detect the venous patency, blood flow velocity and anatomy of valves cusps, There are many other investigations like venography, PPG, direct venous pressure measurement used only in some cases⁽¹⁴⁾

Compression therapy considered to be the standard of nonoperative therapy of CVI and chronic venous leg ulcer, It is believed that optimal compression and venous ulcer healing is obtained with a multilayer graduated elastic compression bandaging system⁽¹⁵⁾

In Mayberry JC, 1991 study, One hundred thirteen patients with CVU were treated by multi-layer graduated elastic compression bandaging system over 15 years 71 (93%) experienced complete ulcer healing, with a mean healing time of (6) months, The total ulcer recurrence in patients who were complaint with long term therapy was (16%), recurrence was (100%) in patients who were non compliant⁽¹⁶⁾

In our study the conservative group; 20 patients with 20 limbs, 16 (80%) male 4 (20%) female, mean age 40 years, 6 (30%) post phlebotic and 14 (70%) primary, were treated

by leg elevation, ulcer debridement antibiotics according to culture and sensitivity, venotonic medication, four layer elastic compression bandage with weekly dressing, their hospital stay ranges between 3-4 weeks and follow up of one year during which 19 (95%) show complete ulcer healing and 6 cases (30%) show ulcer recurrence.

This different results appear between our study and the other studies could be explained by short time of follow up and in co-operative to tolerate this type of bandaging system after discharge of our patients in rural area.

Despite the fact that we service a large rural population with CVI, the majority of our patients are managed quite well with conservative therapy. Saphenous stripping is commonly offered when Saphenous reflux is noted, Although most of these patients have multilevel venous disease (superficial, deep, perforators) we routinely approach the superficial and perforating venous system first.

Surgical ablation of incompetent superficial system and perforating vein is easier than deep venous sys-

tem reconstruction, and recently these limited interventions have been noted to improve deep Venous insufficiency without deep venous repair. This is in contrast to prior studies, in significantly improve after correcting superficial and perforator disease⁽¹⁷⁾

Wilkenson and Macloren reported good long term results in 80% of patients having chronic venous leg ulcer treated with subfascial ligation of perforating veins, with modified Linton procedure⁽¹⁸⁾

Ciktrit observed complete ulcer healing in 80 % of legs during a 4 year observation period of patients treated with subfascial ligation of perforating veins, however they also reported an 18% perioperative complication rate and a 22% ulcer recurrence rate⁽¹⁹⁾

In our study the surgical group; 20 patients with 20 limbs, 15 (75%) male 5 (25%) female, mean age 40 years, 1 (5%) post phlebotic and 19 (95%) primary. were treated by Trendelenburge's operation stripping of LSV and/or SSV, subfascial perforators ligation, partial skin graft, their hospital stay ranges between 1-2 weeks and follow up of one year during which 17

(85%) show complete ulcer healing and 3 cases (15%) show ulcer recurrence.

This different results appear between our study and the other studies could be explained by short time of follow up, missed perforators without ligation and improper perforators marking by duplex due to variable experience by radiologists doing duplex in our hospital.

Bacterial contamination is a constant finding in CVU and trial to get bacterial heel ulcer is quite unfeasible and bacterial isolation almost always heterogeneous. Systemic antibiotic therapy is indicated only when there is evidence of clinical infection with local and systemic symptoms, a swab should be taken only prior to skin graft, arterial bypass or venous surgery local antiseptic should be avoided which are inhibit wound healing and lead to allergic dermatitis so the ulcer should be washed in warmed tap water and soap instead(20)

In our study a swab was taken as a routine from all patients with CVU give nearly the same results of other studies, (85.5%) had mixed infection

with high sensitivity toward anti gram positive anti biotics.

After 12 months of follow up of all patients of the two groups we found that increasing in time needed for complete ulcer healing with increased ulcer size and ulcer duration.

As regarding the morbidity between the studied groups we found that only one case (5%) with history of DVT developed another attack of DVT (6) weeks after conservative treatment and only two cases (10%) developed wound haematoma and infection within the first week after surgery at the site of stripping.

ABPI should be measured for all patients with CVI before compression therapy and the patients with ABPI (0.6-0.8) can be treated with compression but compression is contraindicated if the ABPI < 0.6 Such patients should be assessed for arterial management

CVU which fail to heal after long period of conventional therapy, which have a tendency to bleed or which have unusual features should undergo biopsy.

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دراسة الطرق المختلفة فى علاج القرحة الوريدية المزمنة بالساق

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من قسم الجراحة العامة (١) (٢) (٣) (٤) ومن وحدة جراحة الغدد

الصماء (١) (٢) ومن وحدة جراحة الأوعية الدموية (١) (٣)

أجريت هذه الدراسة فى قسم (٦) جراحة بمستشفى المنصورة الجامعى الفترة من فبراير (٢٠٠٢) الى أغسطس (٢٠٠٣) على (٤٠) مريض يعانون من القرحة الوريدية المزمنة بالساق وذلك نتيجة إرتفاع الضغط الوريدى بالساق.

وفي هذلاء المرضى تم عمل :-

- ١- دراسة كاملة للتاريخ المرضى.
- ٢- فحص إكلينيكى كامل.
- ٣- فحص كامل لقرحة الساق.
- ٤- تحاليل اشتملت (صورة دم - سكر عشوائى - وظائف كبد - وظائف كلى - مزرعة من القرحة - عينة باثولوجى - سرعة ترسيب - عامل الروماتيزم).
- ٥- مع الكل بعض الاشعات العادية - فوق الصوتية - دوبلر - ددوبلكس .

ولقد تم علاج المرضى على النحو التالى :-

- (٢٠) مريض تم علاجهم بالطرق التحفظية وخاصة الاربطة الضاغطة.
 - (٢٠) مريض تم علاجهم بالطرق الجراحية وخاصة ربط الأوردة الموصلة
- ولقد وجد أن العلاج بالأربطة الضاغطة مازال هو العلاج الاولى فى معظم حالات القرحة الوريدية المزمنة بالساق وانه لايجب بدء العلاج الجراحى الا بعد استنزاف كل طرق العلاج التحفظى .