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(Article begins on next page)

REPARATIVE SURGERY OF VALVES IN THE TREATMENT OF SUPERFICIAL VENOUS INSUFFICIENCY

External banding valvuloplasty versus high ligation or disconnection. A prospective multicentric trial

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ABSTRACT :

Reparative surgery of valves in the treatment of superficial venous insufficiency. External banding valvuloplasty versus high ligation or disconnection. A prospective multicentric trial.

Objective. A prospective study was performed in order to compare results obtained in the treatment of early and/or limited primary varicose veins of the lower limbs using two different procedures : external valvuloplasty and high ligation or disconnection of the sapheno-femoral junction.

Materials and Methods. 116 limbs (113 patients) were selected. 57 with normal cusps in dilated valves were subjected to external valvuloplasty with Silicone prosthesis under Doppler control (intraoperative angioscopy in 16 cases) ; 59 limbs were subjected to high ligation or disconnection of the junction ; 57 limbs out of 116 were subjected to complementary procedures.

Duplex and photoplethysmographic examinations were performed before and after the surgical procedures in all patients. Doppler venous pressures were measured in 36 limbs and invasive pressures in 40 limbs.

Patients were postoperatively followed up every 4 months until the 12th month.

Results. Indications for valvuloplasty were found in 8,2 % of cases and in 66,3 % of the early varices.

Clinical results were slightly superior in the reparative surgery group.

Thrombotic occlusion of the proximal long saphenous vein was significantly higher in the ligation-disconnection group.

Results from photoplethysmography and venous pressure measurements indicated that both operations are equally effective in the elimination of reflux in the junction.

This paper has been presented during the following meetings :

- 17th World Congress of the International Union of Angiology, London, 3-7 April 1995.
- 1 Fortbildungswoche für Phlebologie, Deutsche Gesellschaft für Phlebologie, Deutsche Gesellschaft für Gefäßchirurgie, Berlin, 19-30 Juni 1995.
- Jahrestagung 1996 der Schweizerischen Gesellschaft für Phlebologie « Neus in der Phlebologie » Lenzerheide, 25-27 Jan. 1996.
- XXX^e Congrès du Collège Français de Pathologie Vasculaire, Paris 14 Mars 1996.

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RÉSUMÉ :

Chirurgie à visée réparatoire des valvules dans le traitement de l'insuffisance veineuse superficielle. Valvuloplastie par bandage externe versus crossectomie. Une étude prospective multicentrique.

Objectif. Une étude prospective a été réalisée dans le but de comparer les résultats obtenus dans le traitement des varices primaires, débutantes et limitées par deux traitements différents :

- la valvuloplastie endoluminale ;
- la ligature haute ou déconnection de la jonction saphéno-fémorale.

Matériel et méthodes. Cent seize jambes (113 malades) ont été sélectionnées. Cinquante-sept avec des cuspidés normales dans les valvules dilatées ont eu une valvuloplastie en silicone sous contrôle Doppler (angioscopie peropératoire dans 16 cas) ; 59 jambes ont eu une ligature haute ou déconnection de la jonction.

Des examens écho-Doppler et photopléthysmographiques ont été réalisés avant et après l'intervention chirurgicale chez tous les malades. Les pressions veineuses ont été mesurées par le Doppler pour 36 jambes et de façon invasive pour 40. Les malades ont été suivis en postopératoire tous les 4 mois pendant 12 mois.

Résultats. Les indications thérapeutiques pour une valvuloplastie représentent 8,2 % de l'ensemble des cas et 66,3 % des varices débutantes.

Les résultats cliniques ont été légèrement supérieurs dans le groupe de chirurgie restauratrice. L'occlusion par thrombose de la partie proximale de la veine saphène interne a été significativement plus fréquente dans le groupe ayant subi une ligature ou une déconnection.

Les résultats de la photopléthysmographie et des mesures de la pression veineuse ont montré que les deux opérations ont été également efficaces pour éliminer le reflux de la crosse.

Normal flow was restored in the long saphenous vein by valvuloplasty, while a reverse flow was observed in all the patent veins after ligation or disconnection.

Conclusions. Salvaging the sapheno-femoral junction is more physiological and advisable than anatomical elimination.

External valvuloplasty can be a preferable alternative to ligation or disconnection in selected patients. (*J Mal Vasc* 1997 ; 22 : pages 128-136).

Key-words : Varicose veins. Venous valves. Venous insufficiency. Venous banding.

La circulation normale a été restaurée dans la veine saphène interne après la valvuloplastie, tandis qu'un reflux a été observé dans toutes les veines restant perméables après ligature ou déconnection.

Conclusions. La préservation de la crosse saphéno-fémorale est physiologiquement préférable à l'élimination anatomique. La valvuloplastie endoluminale peut être une meilleure alternative à la ligature ou à la déconnection chez des malades sélectionnés. (*J Mal Vasc* 1997 ; 22 : pages 128-136).

Mots-clés : Veines variqueuses. Valvules veineuses. Insuffisance veineuse. Bandage.

INTRODUCTION

International reports indicate that vein wall dilatation is the main cause of primary venous valve incompetence and that tissue alterations of valve leaflets occur in the latest stages of the disease (11, 15, 18, 21, 26, 37). A number of external valvuloplasties (EV) for treating primary valvular insufficiency of deep veins were performed on these basis and satisfactory results have been published (9, 27, 30, 31, 32, 47).

The rationale of the EV procedure is to restore valvular function by reducing the valvular anulus caliber with external banding which brings the valve cusps back to their correct position and enables them to be competent again.

The same concept and techniques were taken into consideration for the treatment of early insufficiency of the sapheno-femoral junction (SFJ) and of the proximal long saphenous vein (LSV).

The terminal LSV valve, corresponding to the SFJ and/or the subterminal valve of the proximal LSV were circled by synthetic or autologous grafts using different materials and methods (11, 13, 15, 18, 20, 24, 34, 55).

Our experience covered a total of 79 EV of the SFJ performed over 6 years. Good clinical results were obtained in 84 % of cases and the procedure appeared to be electable in selected cases (12, 13, 14, 20).

Both we and other Authors raised questions about the choice of the ideal EV technique and mainly about performing this apparently more difficult and expensive surgical procedure instead of simple and traditional high ligation or disconnection (HL-D) of the SFJ.

One of the answers came from the observation that patients waiting 20 months for surgical treatment of their varicose disease develop 18 % further sites of reflux (45). This leads to the conclusion that it is more advisable to proceed with early treatment rather than to delay it.

A second answer came from the high tendency to sapheno-femoral reconnection observed after HL-D, which seems to represent one of the main causes of varicose veins of the lower limb (VVLL) recurrence (10, 46). This also indicates that the HL-D operation does not give such safe and stable results as many Authors affirm.

A third reason for preferring a conservative method in the treatment of SFJ insufficiency is to obtain the highest

rate of postoperative patency of the LSV, if necessary for future grafting. Although this indication merits separate discussion, it has to be said that about 30 % of LSV thromboses occur after HL-D (19, 44) while previous clinical experience demonstrated a lower tendency of the EV to lead to postoperative thrombotic occlusion of the proximal LSV (11-15, 18, 20, 24, 55). A further answer to the latter question can be based on the concept that a physiological reparative procedure should always give better results than a demolitive one. This logical opinion however has not yet been supported by scientific demonstration.

For this reason 116 limbs of a randomized group of 113 patients out of a total number of 906 varicose patients (930 limbs) observed in four Italian Centres in a 6 month period were subjected to the different surgical procedures : one group of 57 limbs underwent EV and the second group of 59 limbs, HL-D of the SFJ.

The principle of both operations is the elimination of reflux in the SFJ.

Patients were followed up every four months for one year. Clinical, morphologic and hemodynamic results obtained in the two different groups of limbs were compared.

The purpose of this study is to answer the following questions :

- is the EV of the SFJ an advantageous procedure to be performed in selected cases instead of HL-D and when should it be performed ?
- which is the more advisable prosthetic material to be used ?

MATERIALS AND METHODS

One hundred-sixteen early varicose limbs were selected for the study out of a number of 930 limbs suffering from primary uncomplicated VVLL belonging to the LSV district observed over 6 months at the four Centres.

116 limbs were selected on the basis of the following protocol for admission to the study :

- early and/or limited VVLL ;
- symptoms of venous insufficiency ;
- reflux in the SFJ detected by Doppler and duplex investigations ;
- no anatomical variables or venous aneurysm in the proximal LSV ;

TABLE I. – Protocol for admission to the study.
Protocole d'inclusion.

N. 116 limbs
<ul style="list-style-type: none"> • Early and/or limited VVLL • Symptoms from venous insufficiency • Reflux in the SFJ (Doppler-Duplex) • No anatomical variables or V. aneurysm • No thrombotic risk • No deep V. pathology • No major pathology

- no thrombotic risk ;
- no major pathology ;
- no deep venous pathology (*table 1*).

More than 0,5 sec. time of reflux in the SFJ in standing position was considered pathological (23, 49).

All patients were considered suitable for the HL-D procedure and the EV was performed on the basis of patient consent and of valve cusp trophism and mobility. This latter parameter had never before been taken into consideration in surgery of VVLL.

Morphologic and functional examinations of the valvular apparatus in the proximal LSV and in the SFJ were performed with high resolution echography using from 7 to 13 Mhz probes (38, 39) (*Fig. 1*).

Anatomical structures and reflux in the LSV and in the common femoral vein, distribution of the tributary veins in the ovalis fossa, valvular anulus caliber and profile, thickness, length and cusp mobility in the terminal and subterminal valve were investigated.

At this stage of the study cusp trophism and mobility became differentiation parameters. For this reason the limbs included in the study may be considered as composing a non-random subgroup : in 57 limbs (49,1 %) valve cusps in the terminal and subterminal LSV valve were certainly trophic, patients gave their consent to the procedure and the EV was performed.

Fifty-nine limbs (50,8 %) underwent HL-D of the SFJ : in 39 of these (33,6 %) cusp trophism was uncertain, while in 20 limbs (17,2 %) valve conditions were good, but patients refused the EV. In all the cases photoplethysmographic post-exercise-refilling time (ERT) was investigated before and after operation. The mean preoperative ERT was slightly shorter in the HL-D group (*Table II*).

The clinical features of patients, as summarized in *table III*, overlapped with a prevalence of females. The mean age of patients and disease was slightly higher in the HL-D group.

In one participating Research Centre superficial and deep venous pressures (VP) were measured preoperatively and postoperatively in 36 limbs with the Doppler method in standing position and after 10 tiptoeing exercises. A flat 8 Mhz probe was taped to the leg surface. Superficial VP measurements were performed by applying the probe to the LSV at the ankle ; deep VPs were measured by applying the probe to the posterior tibial vein region, and the internal surface of the ankle after having located the posterior tibial artery.

TABLE II. – Preoperative parameters.
Paramètres préopératoires.

P.	57 EV (49,1 %)	59 HL-D (50,8 %)
– Reflux-Duplex (N.)	57	59
– Trophic cusps-echo (N.)	57	20 (17,2 %)
– Uncertain Cusps-echo (N.)	0	39 (33,6 %)
– Mean preop. PPG ERT (sec.)	14,7	11,5
Overlapping		

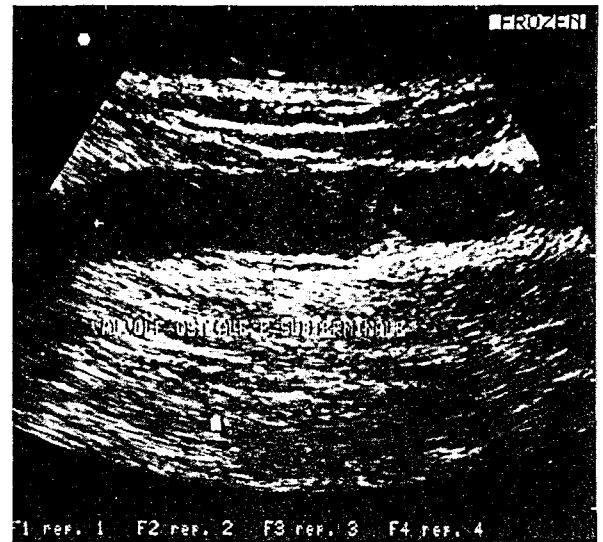


FIG. 1. – Preoperative High Resolution Echography of an early and mildly incompetent proximal LSV. Arrows indicate the terminal and subterminal valves. Mild dilatation of the subterminal valve. Subterminal valve cusps in closing position are clearly evident. Agger and leaflets thickness, length and mobility (real time observation) appear to be normal. Valve is suitable for the EV procedure.

Echographie préopératoire à haute résolution de varices proximales débutantes et limitées. Les flèches indiquent les valvules terminales et sous-terminales. Légère dilatation de la valvule sous-terminale. Mise en évidence des feuillets des valvules sous-terminales en position fermée. L'épaisseur, la longueur et la mobilité des feuillets sont dans les limites de la normale. Indication d'une valvuloplastie externe.

A rubber cuff, applied a few centimeters above the site of the Doppler probe, was inflated up to a maximum of 140 mm. of Hg and rapidly deflated. The onset of venous sound was recorded in the standing position and immediately after exercise.

This method has not yet been widely accepted, although it has been sufficiently experimented and the comparison between invasive and non invasive examinations performed on the same patients could demonstrate its reliability (1-6, 22, 25, 36).

The difference between preoperative and postoperative VP observed in the LSV and PTV district in each limb were calculated and the mean VP decreases obtained in the two groups of limbs were compared.

TABLE III. – Patients characteristics.
Caractéristiques des patients.

F.	57 EV (49,1 %)	59 HL-D (50,8 %)
– Sex	F. 43-M.14	F. 51-M. 8
– Side	L. 26-R. 31	L. 34-R. 25
– Mean body W. (kg)	62,8	63,6
– Mean age of patients (y.)	41,0	47,2
– Mean age of disease (y.)	8,4	13,2
– Symptoms from V.I. (number)	57	59
Overlapping		

In another Centre invasive VP measurements were performed in 20 limbs subjected to EV and in the 20 with HL-D according to well experimented and accepted techniques (29, 35, 40, 41). The same comparison was performed.

In all the cases studied the ERT, expressed in seconds, was measured with photoplethysmography (PPG), every 4 months, up to one year after surgery. This is considered a reliable method for the hemodynamic evaluation of venous disorders of the lower limbs (23, 48).

Patients were examined in the standing position and ERT evaluation was performed after 10 tiptoeing exercises.

The mean increases of the ERT obtained in the two groups of operated limbs were compared.

EV was performed by applying Dacron-reinforced Silicone prostheses (9, 30-32, 47) separately circling the terminal and/or subterminal valve by using a stapler device or by manual suture.

Two types of prosthesis were used: linear and right or left notched. The latter is used for savaging of tributaries or circling the anterior common femoral vein wall when comprising the terminal valve (fig. 2).

Applications were all monitored by intraoperative Doppler. In 16 cases, where preoperative echographic visualization of valve cusps was unclear, angiography (7, 16, 33, 52, 54) was performed in order to control cusps morphology and function before and after calibration of prosthesis.

In 26 cases over 57 (45,6 %) EV's were performed on the terminal valve, which appears to be the main structure responsible for SFJ competence. The elimination of reflux in this valve was sufficient to restore a normal flow in the junction and in the proximal LSV.

In 6 cases (10,5 %) the terminal valve was competent and reflux was observed below the subterminal valve, involving the proximal LSV in the hemodynamic disorder. In these cases only the subterminal valve was surgically treated.

In 25 limbs (43,8 %) EV of both valves was necessary (table IV).

In two other cases, previously selected for EV, angiography demonstrated some morphologic alterations of the valve cusps, such as retraction or asymmetry of borders, and they underwent HL-D of the SFJ (fig. 3).

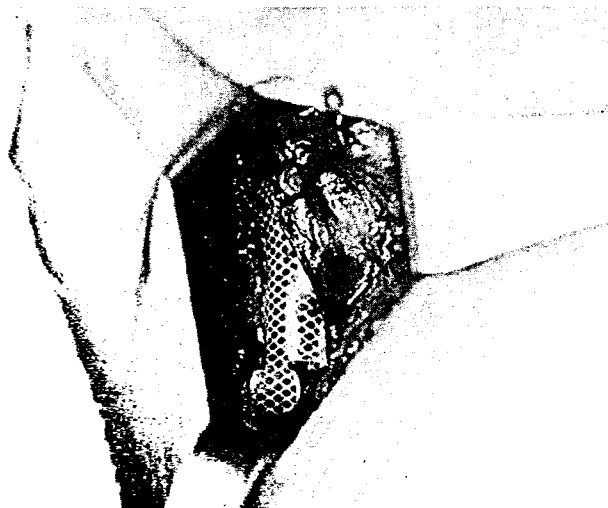


Fig. 2. – Intraoperative photograph. Major tributaries were ligated and sectioned. A Dacron reinforced Silicone notched prosthesis has been applied on the terminal valve under Doppler control surrounding the LSV wall and the anterior surface of the common femoral vein.

Les collatérales sont ligaturées et sectionnées. Une prothèse en Dacron siliconée est appliquée au niveau de la valvule terminale sous contrôle Doppler.

TABLE IV. – EV surgical technique.

Technique chirurgicale de la valvuloplastie externe.

- Surgical preparation of the proximal LSV and SFJ
- Salvaging of major competent tributaries
- EV of the Terminal valve : 26 (1 prosthesis) (45,6 %)
- EV of the Subterminal valve : 6 (1 prosthesis) (10,5 %)
- EV of both valves : 25 (2 prostheses) (43,8 %)
- Intraop. Doppler in all EV procedures
- Intraop. angiography in 16 EV procedures

TABLE V. – Clinical-instrumental results.

Résultats cliniques et instrumentaux.

12 months follow-up	57 EV	59 HL-D
– Disapp. of symptoms	52 (91,2 %)	46 (77,9 %)
– Recurr.-res. symptoms	5 (8,7 %)	13 (22 %)
– Disapp. of reflux-SFJ	48 (84,2 %)	59 (100 %)
– Reduction of reflux-SFJ	5	–
– Residual reflux-SFJ	4	–
– Reverse flow-LSV	4 (7 %)	51 (86,4 %)*

* P = 0,00001.

Intraoperative instrumental controls were not necessary in the 59 HL-D procedures.

HL-D was carried out according to the traditional technique: flush ligation and/or section of the SFJ.

In both procedures major competent tributaries, intraoperatively monitored by Doppler in 14 cases, were left *in situ* (55).

Combined operations consisting of perforating vein ligations and/or peripheral varicectomies were performed on 29 limbs subjected to EV and on 28 limbs subjected to HL-D.

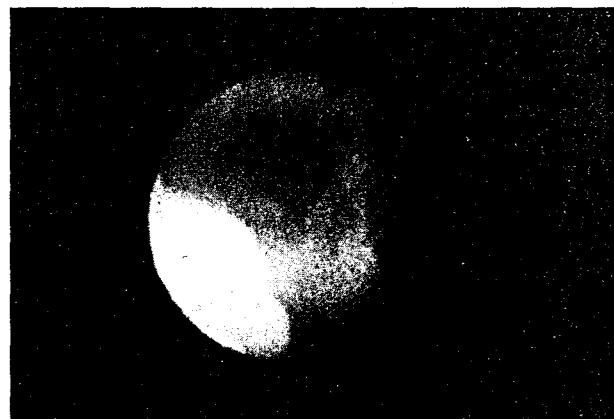


Fig.3. – Intraoperative angiographic observation of the proximal LSV. The angioscope has been inserted into the LSV at the knee level and observation is being performed from below the subterminal valve. Only one cusp of this valve is visible while the other is atrophic. Remarkable dilatation of one terminal valve commissure with hypotrophy and retraction of both cusps. Valves are not suitable for the EV procedure.

Angioscopie peropératoire d'une varice proximale située au niveau du genou. Vue inférieure de la valvule sous-terminale. Seul un feuillet est visualisé, l'autre étant atrophique. Noter la dilatation commissurale avec hypotrophie et rétraction des feuillets. La valvuloplastie externe n'est pas indiquée.

The treatment of all venous insufficiencies detected in the limbs led to a complete functional and clinical cure in all cases without influencing the hemodynamic postoperative result obtained with EV or HL-D in the LSV district.

The patients in both groups were given prophylactic drug therapy: intraoperative local antibiotics, Ca Heparin (0,2 ml every 12 hours) for 5 days and Defibrotide (400 mg every 12 hours-oral administration) for 15 days.

All the patients underwent clinical and instrumental postoperative controls every four months for one year. Doppler, duplex, and PPG ERT (VPs in two Centres).

The χ square test was used for the following statistical analysis:

- comparison between findings of reverse flow in the LSV after EV and HL-D (table V);

- comparison between LSV thrombosis and, consequently, between LSV patency observed after EV and HL-D (table VI).

The Mann-Whitney test was used for preoperative and postoperative comparisons of PPG ERT (fig. 4) invasive VP measurements of 40 limbs (fig. 5) Doppler VP measurements of 36 limbs (fig. 6, 7).

TABLE VI. - LSV thrombosis.
Thrombose au niveau d'une varice.

12 months follow-up	57 EV	59 HL-D
- Extensive occlusive	0	4 (6,7 %)
- Proximal occlusive	1 (1,7 %)	8 (13,5 %)
- Total	1 (1,7 %)	12 (20,2 %)*
- Patency LSV	56 (98,2 %)	47 (79,6 %)*
- Proximal recanalized	1	0
- Surgical error (Pr. calibration)	3	-

* P = 0,0054.

RESULTS

Fifty-seven limbs of the first group and 20 of the second had trophic valve cusps. The 20 of the second refused the EV procedure and underwent the HL-D procedure. During this study only 57 limbs (49,1 % of limbs observed) were subjected to surgical repair and 59 (50,8 %) to the HL-D procedure (table II). However 77 of the 116 early varicose limbs studied (= 66,3 %) met the criteria for the EV procedure (77/930 phlebopatic limbs observed = 8,27 %).

In the majority of the limbs subjected to the EV, the terminal valve was totally (45,6 %) or partially (43,8 %) responsible for SFJ insufficiency (Total=89,4 %). Subterminal valve incompetence was surgically treated in a lower percentage of cases (43,8 %) and appeared to be the only cause of LSV reflux in 6 cases (10,5 %) (table IV).

At the end of the one year follow-up clinical results nearly overlapped in the two groups, although symptoms of venous insufficiency were solved in 52 cases subjected to EV and in 46 subjected to HL-D.

Reflux in the SFJ disappeared in all the limbs subjected to the HL-D procedure and in 48 (84,2 %) limbs in the EV group. In 5 cases this procedure was followed by reduction of reflux (time of reflux ranging from 0,5 to

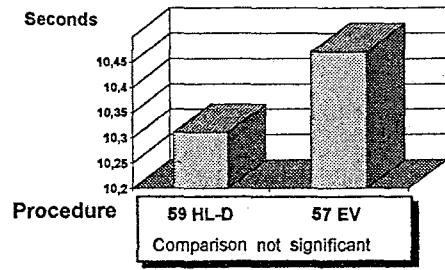


FIG. 4. - Invasive AVP. Measurements postoperative mean decrease Superficial-LSV (40 limbs).
Mesures postopératoires. LSV (40 membres).

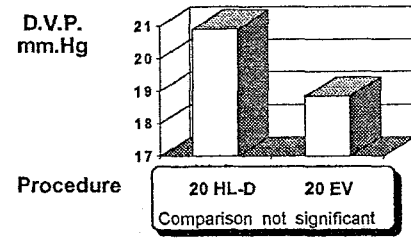


FIG. 5. - Doppler VP. Measurements postoperative mean decrease Superficial-LSV (6 limbs).
Doppler postopératoire. LSV (6 membres.)

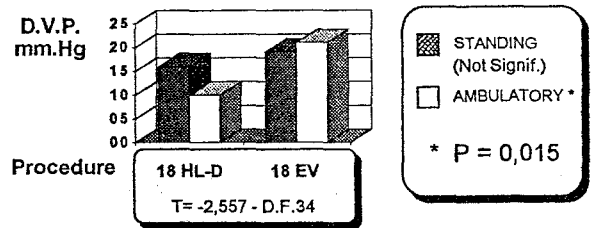


FIG. 6. - Doppler VP. Measurements postoperative mean decrease Deep-PTV (36 limbs).
Doppler postopératoire. PTV (36 membres).

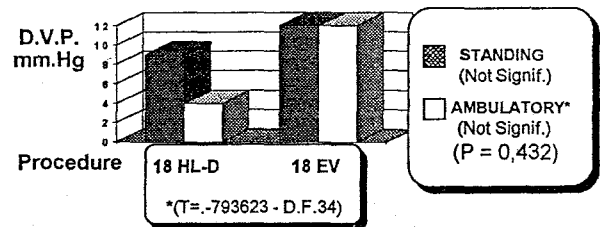


FIG. 7. - Minor complications.
Complications mineures.

1,5 seconds) and residual or recurrent reflux (> 1,5 sec.) was detected in 4 cases.

Recurrent symptoms were observed in 5 cases (8.7 %).

No residual or recurrent reflux was detected after the functional and anatomical elimination of the SFJ by HL-D, however recurrent or residual symptoms were observed in 13 of these limbs (22 %).

On the other hand the postoperative duplex investigation of the interrupted LSVs revealed reverse flow in 51 (86,4 %) out of 59 venous stumps, while this phenomenon was observed in only 4 (7 %) cases subjected to EV (P = 0,00001) (table V).

No major complications were observed in any of the cases.

Minor transitory complications, summarized in table VII, were observed in a low number of limbs subjected to either procedures.

Postoperative lymphedema that occurred in two legs was probably due to the extensive removal of peripheral varices and not to the procedure performed on the SFJ.

It is important to note that a foreign body reaction, which sometimes occurred with the use of different materials (12, 14, 20), was never observed with the use of Silicone prostheses (fig. 8). Postoperative high resolution echography did not reveal images that could be correlated with perivascular fibrosis nor did any inflammatory phenomena develop in the groin.

Postoperative thrombotic obstruction of the proximal stump of the LSV was observed in 12 cases (20,2 %) of the HL-D group between the first week and the 8th month. At the 12th month follow-up they were all stabilized. The extent of the thrombotic occlusion comprised from 3 to 7 cm in 8 limbs and occupied the entire length of the LSV in the thigh in 4. Only 2 of these 4 patients reported any pain in the lower limb. In all other cases postoperative LSV thrombosis was asymptomatic. None of them recanalized.

A short thrombus was observed beneath the prosthesis after one week in two LSVs subjected to EV. The patients were promptly given drug therapy and the thrombus recanalized in few days in one case with the SFJ remaining partially competent (time of reflux < 3 sec.). In the second limb the thrombus stabilized. The comparison of the postoperative thromboses in the two groups was statistically significant (P = 0,0054) (table VI).

The mean ERT increases obtained in the operated limbs were nearly identical in the EV group (10,47 sec.s) and in the HL-D group (10,31 sec.s)

Invasive VP measurements performed in 40 limbs in one Centre demonstrated a slight and not significant difference in the mean postoperative decrease (expressed in mm.Hg) between the two groups : 18,84 after EV and 20,91 after HL-D (fig. 5).

Results of non invasive VP measurements performed on 36 limbs in one Centre were the following.

The postoperative VP mean decrease in the LSV at the ankle in the HL-D group was 15,83 mm.Hg in standing position and 10 mm.Hg after exercise (ambulatory). A lower mean decrease was observed in the deep venous

TABLE VII. – Minor complications.
Complications mineures.

12 months follow-up	57 EV	59 HL-D
– Pain	2	1
– Hematoma	0	1
– Wound infection	0	1
– Skin anesthesia (leg)	0	1
– Lymphedema	1	1
– Foreign body reaction	0	–

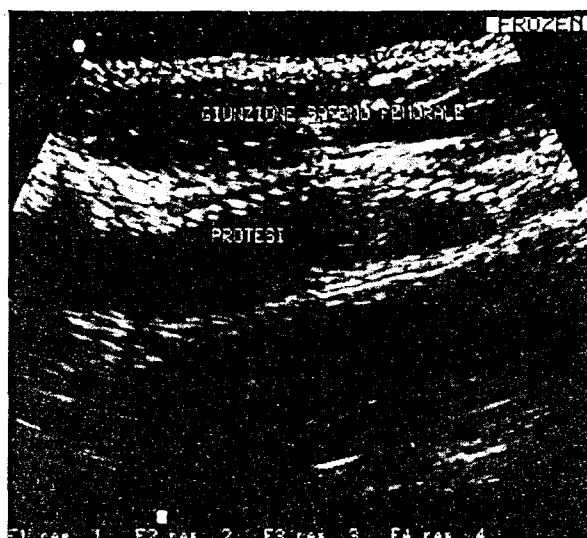


FIG. 8. – Postoperative (30 days) High Resolution Echography of a proximal LSV subjected to the EV procedure. Prosthesis surrounding the subterminal valve is visible and free from perivascular and periprosthetic fibrosis. Vein lumen is patent and competent (Duplex examination).

Echographie postopératoire à haute résolution 30 jours après valvuloplastie externe pour varice proximale. La prothèse est visible autour de la valvule sous-terminale. Pas de fibrose périprothésique ou périvasculaire. La lumière veineuse est perméable.

system (PTV) : 8,89 mm.Hg (standing) and 3,89 mm.Hg (ambulatory).

Higher differences in the EV group were observed : 18,89 mm.Hg (LSV-standing), 21,11 mm.Hg (LSV-ambulatory) and 12,22 mm.Hg (PTV-standing and ambulatory).

The comparison of ambulatory LSV VPs mean decreases observed in the two groups was statistically significant ; the comparison of the mean decreases of the ambulatory PTV pressure was not significant (fig. 6, 7).

DISCUSSION

At this point in phlebologic experience there is a new aspect in diagnostics for superficial venous surgery that has never been taken into consideration before. None of

the Authors who have published articles on demolitive procedures, disconnections or simple ligations of the SFJ for the treatment of VVLL have been obliged to face the problem of morphological and functional conditions of the venous valves.

The topic has gained interest with the more recent proposals of performing the EV on deep and superficial veins on the basis of classical theories of venous valve pathology. (9, 21, 24, 26-28, 30-32, 34, 37, 47, 55).

Clinical results of the previous experience using EV for the treatment of VVLL (11-15,18,20), some echographic observations of SFJ and LSV proximal valves (38, 39), the use of angioscopy and histopathological observations of venous valves (7, 8, 16, 17, 33, 42, 43, 50-52, 54), which are still in progress, seem to indicate that there are two pathophysiologic theories that can explain the development of venous valve incompetence. One is based on the principle of primary vein wall dilatation and the second on primary cusp tissue alterations. Recent experiences and observations seem to lead to the conclusion that the two mechanisms can overlap in the development of valvular incompetence in some cases and that cusp alterations can be found in some early VVLL so well.

For these reasons there is no doubt that the selection of patients for the EV requires more attention and more time especially during the preoperative examination of valve cusp morphology and mobility.

The EV surgical procedure is slightly more expensive and difficult than the HL-D if the operation is simply performed by applying a proper Silicone prosthesis to the venous wall.

The encouraging results observed after a large number of EVs (11-15, 18, 20, 24, 27, 32, 54, 55) were sometimes superior to those obtained using traditional surgical treatment in similar patients (10, 19, 44, 46).

This phenomenon can probably be explained by the hemodynamic observations of this study.

Patient characteristics (table III) include the mean age of patients and of the varicose disease. In our previous studies (12, 13, 16, 37) no relationship was observed between postoperative clinical results and patient age, although a tendency to poor results after EV was observed in subjects with a more advanced disease.

Body weight was also included because, in some of the patients studied, weight increases observed during the follow-up, were accompanied by progressive deterioration of clinical and hemodynamic results.

Modest differences in the preoperative parameters of the two groups of patients (table II) were observed, but only the variations of post-surgery values after surgery were considered and investigated.

No relevant clinical differences emerged at the end of the follow-up. (table V).

Reflux and SFJ were simultaneously eliminated in the 59 limbs of the HL-D group (100 %) while the SFJ became completely or partially competent again after 48 (84,2 %) EVs and a normally directed flow was detected in the LSV.

On the other hand in the 47 LSVs which remained patent and in 4 with short proximal thrombotic obstruction after HL-D, a reverse flow in the thigh (45 cases)

and down to the leg (6 cases) was observed (tables V and VI).

The comparison of the preoperative and postoperative PPG measurement in the two groups of limbs indicated that mean increase of ERT was a fraction of a second higher in the EV group and the difference was not statistically significant (fig. 4).

This indicates that the two operations are equally effective in eliminating the effects of valvular incompetence in the SFJ and in the proximal LSV.

The mean postoperative reduction of VP studied in 40 limbs using invasive measurements was more evident in the HL-D than in the EV group (2 mm.Hg difference). However, this comparison was not statistically significant. Both procedures can lead to a VP decrease ranging from approximately 19 to 21 mm.Hg (fig. 5). This confirms the previous photoplethysmographic observation.

Figures 6 and 7 show the postoperative changes in superficial and deep VPs observed before and after the surgical procedures in the 36 limbs subjected to non invasive measurements before and after exercise.

Some difference was observed in the VPs measured in the two groups before exercise. Mean VP decrease values were slightly higher in the EV group but no statistical significance was found.

A considerable difference was observed in the comparison of the ambulatory VP measurements between the two groups. The mean postoperative decrease in the EV group was more than 10 mm.Hg higher in superficial veins (comparison significant: $P = 0,015$) and about 8 mm.Hg in the deep ones (comparison not significant: $P = 0,432$).

This observation seems to indicate higher hemodynamic efficacy in the maintenance of flow in the SFJ which has to be considered a very important pathway in the whole venous emptying mechanism of the lower limb and that the superficial venous incompetence may have some influence on the deep circulation. The elimination of superficial venous incompetence seems to improve deep venous hemodynamics (1, 17, 53).

CONCLUSION

The percentages obtained from our patients indicate that varicose illness in the early stage is usually observed in not more than the 13 % of clinical cases and that only 8-9 % appear to be suitable for the EV procedure. However a large number of early varicose limbs affected with SFJ insufficiency (66,3 %) can be subjected to valvular repair and achieve satisfactory clinical and hemodynamic results.

The terminal valve seems to be the major cause of SFJ and LSV reflux. However the subterminal valve is often incompetent too, but quite rarely it represents the only cause of LSV reflux.

Hemodynamic investigations and echographic observations performed in the two groups of limbs treated with the two different surgical procedures led to the conclu-

sion that maintenance of physiological flow in the LSV is possible, postoperative thrombosis is less frequent, the patency rate is higher with EV and the hemodynamic efficacy of the operation is satisfactory in eliminating reflux and LSV incompetence.

The EV is an advantageous procedure to be implemented after a careful clinical and instrumental selection of cases with early, limited and uncomplicated VVLL. Limbs which do not meet these criteria will undergo more improvement with the HL-D.

Full attention to valve cusp function and morphology is required and intraoperative Doppler control is essential before the conclusion of the surgical procedure.

Intraoperative angioscopy is a difficult and time consuming procedure, although it may be necessary in a low number of cases as it appeared to be extremely useful in veins with uncertain preoperative visualization of valve cusps in the proximal LSV in order to perform the most correct surgical procedure.

Silicone prostheses have proved to be excellently tolerated in perivascular tissue up to now.

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