

## External Venous Valve Plasty (EVVP) in Patients with Primary Chronic Venous Insufficiency (PCVI)

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**Objectives.** To evaluate the patency of EVVP and its effect in symptom relief, ulcer healing and ulcer-free period in patients with PCVI.

**Methods.** Between 1993 and 2004, 1800 patients with CVI were evaluated and seventeen with PCVI were selected for EVVP. They were all investigated with ambulatory venous pressure measurement (AVP), colour duplex ultrasound (CDU), ascending venography and descending video venography. The CEAP classification was used to group the patients. Six patients were C4, four C5 and seven C6. All had deep reflux and high levels of AVP.

**Results.** All procedures were technically successful. The ulcer healing rate was 4/7 (57%) within 3 months. All C4 patients experienced symptom improvement postoperatively and had a median recurrence free period of 72 (range 60–122) months. The C5 group had a median ulcer free period of 61 months (12–72) and the C6 of median 48 (12–72) months. Single valve plasties (4) reached a median competence period of 48 months (12–72), 12 multiple valve plasties at the same level show a median 78 months (63–122) and 10 multilevel repairs median 54 months (12–96). Multiple valve plasties at the same level (multi-station plasties) performed on the C4 group seemed to yield the longest durability with a median of 103 months (84–122).

**Conclusion.** EVVP with an ulcer healing rate of 57% and satisfactory symptom improvement seems to be an alternative of surgical treatment for selected patients with PCVI. The durability of this technique seems to be related to clinical severity and the multiplicity of repairs.

**Keywords:** Venous insufficiency; Valve plasty; Clinical and functional outcome; Venous pressure measurements; Venous reflux.

### Introduction

Patients with chronic venous insufficiency (CVI) and leg ulceration constitute a serious medical and social problem. The prevalence of venous leg ulcers is reported to be 0.1 to 1.0.<sup>1–3</sup> The total direct annual cost of treatment of venous leg ulcers in Sweden has been estimated at 73 million Euro based on a prevalence of 0.3 percent and 45 percent venous ulcers.<sup>4</sup> In the UK the cost is between 400–600 million pounds per year.<sup>5</sup>

Patients may suffer *primary* venous incompetence of unknown cause in which familial predisposition plays a role in the aetiology of their disease. The defective venous valves in this group of patients often

are amenable to surgical repair. In *secondary* venous incompetence valve leaflets have often been damaged by an episode of deep venous thrombo-embolism (DVT), making surgical repair impossible. In the majority of cases adequate compression and local treatment of leg ulceration has been the main stay of *symptomatic* treatment. A great challenge has been finding an effective *causal* therapy, i.e. repairing incompetent valves that are causing reflux. Reflux is one of the main pathophysiological factors in CVI that can be surgically corrected.

Superficial and perforator reflux is abolished by excision or ligation of the affected veins, while deep venous reflux represents a major challenge since it requires either repairing or replacing the valve structure for it to regain competence. Since the introduction of the open valveplasty in 1968 by Kistner, a series of antireflux procedures have been described, including the external venous valve plasty (EVVP).<sup>6–7</sup> In patients with PCVI it is possible to find valves amenable to repair with this particular technique.

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The aim of this study is to evaluate the effect of EVVP on patient symptoms, ulcer healing rate, ulcer-free period and period of competence following repair in patients with severe PCVI.

### Material and Methods

Between 1993 and 2004, 1800 patients with CVI were referred for consideration of reconstructive deep venous surgery (RDVS). They were initially evaluated at our vein clinic and vascular laboratory by colour duplex ultrasound (CDU) and ambulatory venous pressure measurement (AVP). PCVI was diagnosed in only one third of the patients and the rest had a secondary CVI. Among those with PCVI about half had superficial and perforator vein incompetence with a normal deep venous system. Forty percent had a combined deep, superficial and perforator incompetence that responded to treatment without reconstructive deep venous surgery (RDVS). From the remaining 10% of patients with PCVI seventeen were selected for EVVP. All these patients had a long history of disabling venous insufficiency with skin changes and/or ulceration.

The median age of patients was 52 years (range 28–75) with a male predominance (M: 11, F: 6). This selected group was further investigated with ascending venography and descending video venography.<sup>8</sup> 5 patients were considered to be grade III and 12 patients grade IV according to the Kistner classification of reflux. The CEAP classification was used to group the patients (Table 1).<sup>9</sup>

Patients presenting with concomitant superficial and/or perforator insufficiency were first treated with partial stripping of the long saphenous vein, resection of the short saphenous vein and/or conventional perforator ligation. Patients were treated for a period of six months with class 2 compression stockings before considering (RDVS). Failure to heal an ulcer (11) or improve symptoms of venous disease (6) after this regimen was an indication to perform RDVS. Impaired venous-muscle pump function due to ankle arthrodesis and calf muscle atrophy, constituted a major contraindication for treatment by RDVS.

Patients were followed-up at 3 months and then every 6 months by clinical examination, CDU and AVP.

### Investigations

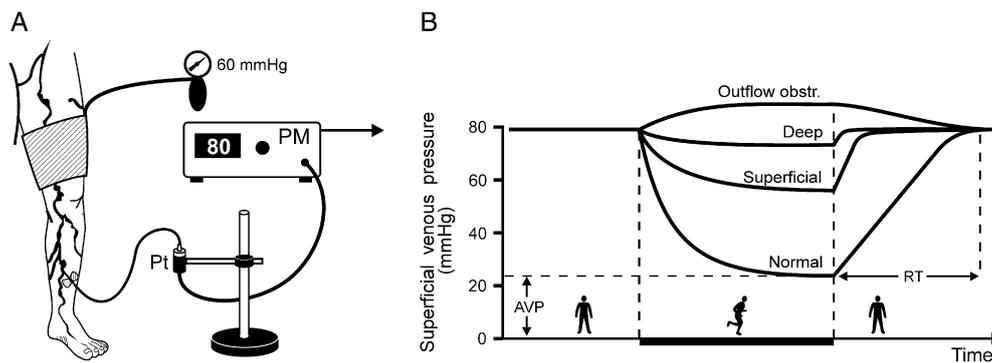
*Ambulatory venous pressure (AVP)* measurement is still considered the reference standard in the assessment of global reflux, function of the veno-muscular pump and the severity of venous hypertension. A 21-gauge "butterfly" needle was inserted into a vein in the leg and connected to a pressure transducer, a pressure monitor and a recorder (Fig. 1). Canulation of dorsal foot veins should be avoided due to the possibility of falsely normal values caused by functioning valves at the ankle level.<sup>10</sup> At upright position the patients were supported by a frame. At rest, the distance between the heart level and the canulation site determines the recorded venous pressure. The patients then performed a standardised "walking on the spot" exercise. The mean venous pressure recorded when the curve flattens at the end of this exercise indicates the ambulatory venous pressure (AVP). Normally the pressure drops to below 30 mmHg. The measurement is then repeated after selective occlusion of the superficial veins. A 30 cm wide pneumatic tourniquet is placed around the thigh and inflated to 60 mmHg to occlude the long saphenous and other superficial thigh veins. The short saphenous vein may be occluded with a rubber tourniquet. By selectively occluding the superficial segments it is possible to identify the incompetent venous system (i.e. either the great or small superficial saphenous veins or the deep system) (Fig. 1).

AVP measurement provides the following information: pressure drop during exercise, ambulatory pressure and recovery time, which is the time taken from cessation of the step test until the resting pressure level is reached.

*Colour duplex ultrasound (CDU)* was used to evaluate axial reflux in the different anatomical segments of each venous system. The examination was performed with the patient standing, weight-bearing primarily on the contralateral limb. A 12 cm wide pneumatic cuff is placed distally to the segment to be examined, and connected to a venous compression unit which

**Table 1. Comparison of groups C4 (skin changes), C5 (healed ulcer) and C6 (manifest ulcer) with regard to pre-operative, functional findings and number of EVVP performed. The material according to the CEAP classification showing deep insufficiency and the number of reconstructions performed in the different clinical groups**

Clinical stage (CEAP)	N	Deep reflux	AVP (mmHg)	Single plasty	Multistation plasty	Multilevel plasty
C4	6	6	72	2	4	2
C5	4	4	80	1	3	2
C6	7	7	85	1	5	6



**Fig. 1.** A: Vein pressure recording setup. B: Typical superficial vein pressure curves at rest and during walking in subjects with no venous insufficiency (Normal), superficial- and deep venous insufficiency, and venous outflow obstruction. Note that dorsal foot vein is not cannulated.<sup>10</sup> Pt: Pressure transducer, PM: Pressure monitor, AVP: Ambulatory venous pressure.

enables very fast (<0.2 s) inflation and deflation (VenoPulse, E. Stranden). The inflation pressure is adjustable, and set at 150 mmHg. The venous compression unit ensures a standardized repeatable venous reflux procedure (inflation of the cuff, sustained for 3 s and then deflated), which in our opinion to a larger degree mimics venous reflux than the commonly used Valsalva manoeuvre. The latter method may miss distal venous incompetence which is masked by a competent proximal valve, and in some elderly patients the effort applied to the manoeuvre is reduced because of fear of incontinence.

5 and 10 MHz ultrasound probes were used to detect venous reflux (GE Vingmed System V, Horten, Norway). A valve closure time >0.5 s was defined as pathological.<sup>11</sup> Although there are recent reports in the literature suggesting that the peak reflux velocity correlates better with the severity of venous insufficiency, valve closure time is more widely used.<sup>12</sup>

*Descending video venography* is a dynamic imaging method of the venous valve leaflets that may be amenable to repair allowing classification of the severity of axial reflux. Contrast medium is injected through a femoral puncture which allows an obstruction in the ilio-caval segment can be excluded. The patient is then tilted 60 degrees, head upward, and dye injected during a Valsalva manoeuvre. The dye column is followed distally until it stops or the Valsalva manoeuvre is completed (Fig. 2)<sup>8</sup> and graded into 4 categories described by Kistner<sup>13</sup>: Grade I proximally in the thigh, grade II above the knee, grade III below the knee, and grade IV to the ankle.

#### *EVVP – surgical technique*

The feasibility of valve repair was established by pre-operative CDU and descending video venography

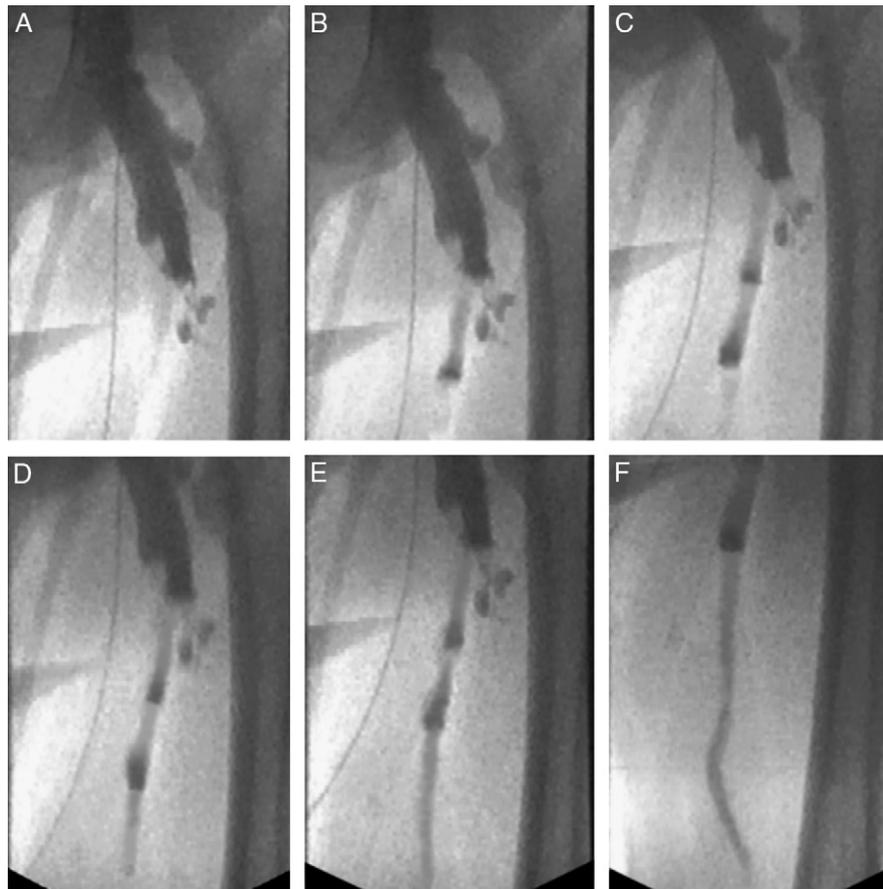
and in some cases with intra-operative angioscopy. A conventional approach was applied in the groin through a longitudinal incision and a posterior approach in the popliteal fossa by using an S-shape incision. Magnifying loupes were routinely used. The valve site and the commissural sites of the leaflets were identified by careful adventitial dissection. At this point angioscopy can be helpful in identifying the valve commissures, and testing valve function (Fig. 3).<sup>8,14,15</sup> A continuous suture line of 5–7 stitches with polypropylene 7–0 was started at the cranial end of the valve to tighten the leaflets. This procedure was performed at the site of both commissures. The repaired valve was then tested either by the “strip-test” or angioscopy (Figs. 3 and 4).

A 2.8 mm angioscope with a flushing channel connected to a pump and introduced through a side branch was used in the performance of EVVP in 5 patients. The valve was first tested for incompetence by flushing with saline solution. Closure of the repaired valve when injecting saline at a flow rate of 30 ml/min proves competence.

Single valvuloplasties can be performed at the femoral or popliteal level. *Multilevel* plasties can be performed at both levels in the same extremity. The term *multistation* plasties refers to repairing more than one valve at the femoral level (common, superficial and deep femoral vein).

Anticoagulation with low molecular weight heparin (dalteparin) was administered to all patients before, during and for three months after surgery. After that anticoagulants and platelet inhibitors were discontinued. This was a prophylactic measure since thrombosis after EVVP is reported by other authors.<sup>19</sup>

All patients treated by EVVP are advised to continue using elastic stockings, if possible of a lower compression class, for the rest of their lives. The great majority of patients complied with this advice because



**Fig. 2.** A sequence of 6 pictures from the descending video venography demonstrating venous reflux down to knee level (grade II). This exemplifies the advantage of video recording where the contrast medium can be followed dynamically at the desired speed to study venous valve function.

of the duration of symptoms and were motivated to help prevent recurrence of their symptoms. Supplementary elastic stockings will reduce some of the strain in the venous system and may influence the durability of EVVP.

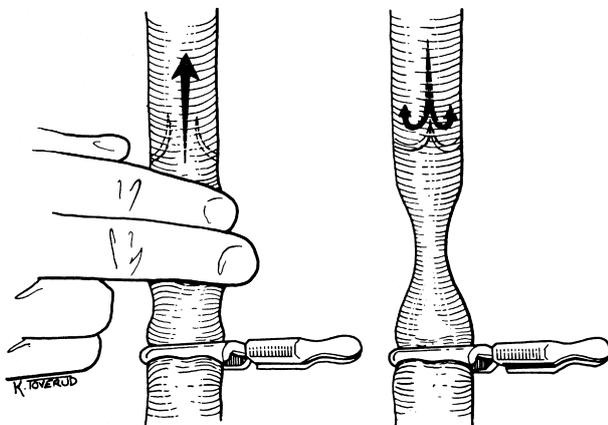
*Statistical methods*

Our strategy in the study was pragmatic. For discrete variables we used the Students t-test and for continuous variables the Mantel-Henzel test. For comparison of the different results we used Kaplan-Meier survival curves. We were aware of the lack of power in the study. All data are presented as median and range.

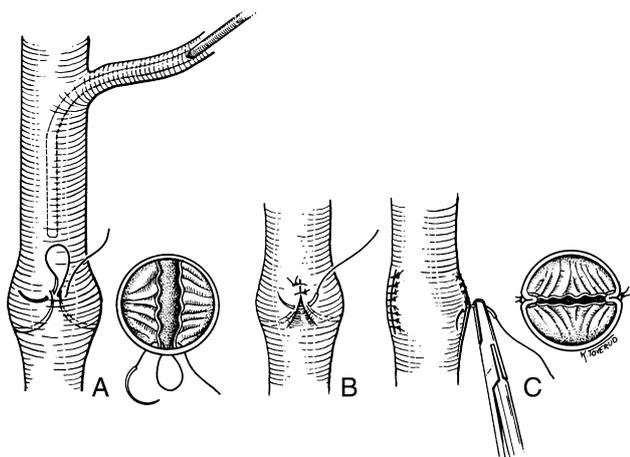
**Results**

All procedures were performed by the same surgeon and proved to be technically successful according to the strip test or angioscopic findings. *Multistation* repairs were performed in twelve patients: double repair in eight, triple plasties in four. *Multilevel* repairs were done in ten patients. In eight patients the popliteal vein valve was repaired alone or in combination with femoral repair.

The clinical and haemodynamic endpoints were ulcer or symptom recurrence, reflux and/or a high level of



**Fig. 3.** "Strip test" to confirm valve patency.



**Fig. 4.** The surgical technique of external venous valve plasty assisted by angioscopy: a view of incompetent valve cusps and the first external suture placed in a commissure (a), external sutures in both commissures (b) and the finished valve repair (c).

AVP. The clinical recurrence was related to reflux shown by CDU and high AVP in all cases. At 3 months follow-up all except one patient showed competent functioning valve plasties. The total follow-up period was 60 months (range 3–122). Single plasties had a patency of 48 months (12–72), multistation plasties 72 months (63–122) and multilevel repairs 36 months (12–96).

The healing ulcer rate was 4/7 (57%) within 3 months. All C4 patients (skin changes) experienced symptom relief postoperatively and had a recurrence free period (symptoms) of median 72 (60–122) months. The ulcer-free period in the C5 group (chronically recurrent ulcer, but presently healed) and the C6 group (manifest ulcer) was 61 months (12–72) and 48 months (12–72), respectively (Fig. 5).

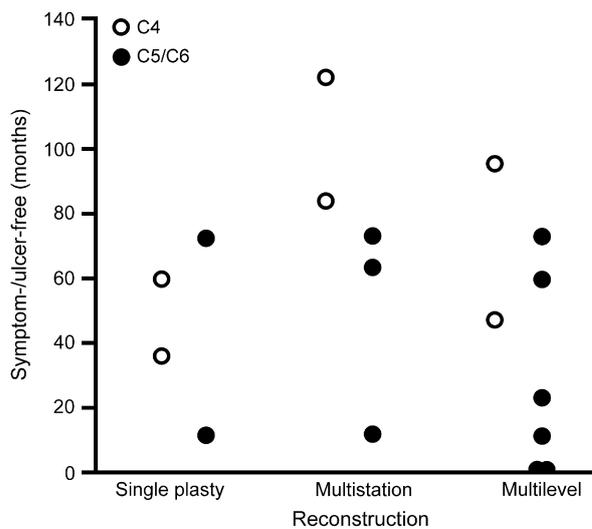
Postoperatively, the AVP reduction was greatest in the C6 group, median 35 mmHg (0–65) (Fig. 6). This reduction was maintained through the follow-up period until the valve plasty became incompetent.

Three patients did not experience any clinical improvement despite a patent EVVP at the follow-up (Fig. 7). This was probably due to an incompetent calf muscle-pump.

Our results did not reach statistical significance, largely due to the small size of the study group.

**Discussion**

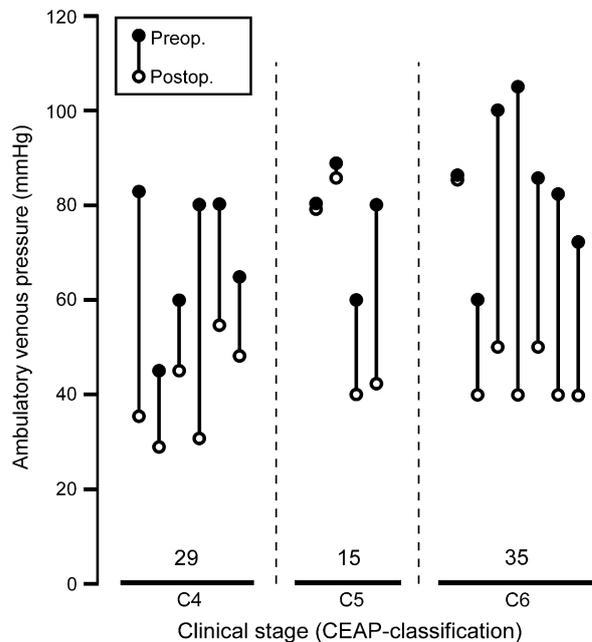
The aim of our study was to evaluate the clinical and haemodynamic effects of EVVP, as well as its durability in patients with PCVI. After treating concomitant superficial and/or perforator insufficiency; we added an observation period of six months with optimal



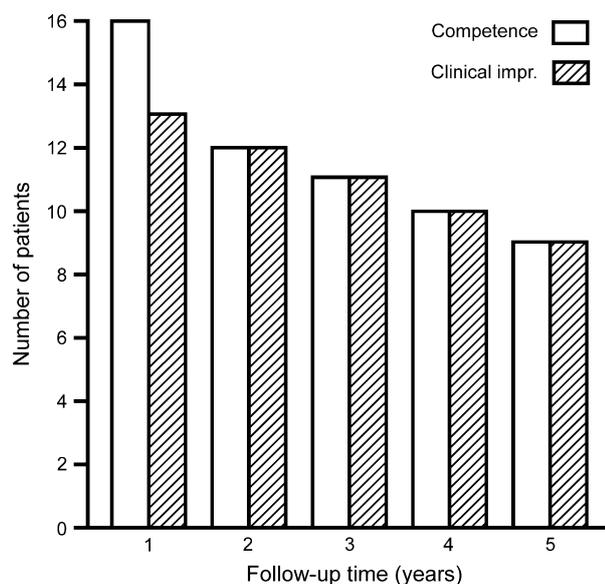
**Fig. 5.** Comparison of clinical outcome (symptoms-/ulcer free months) and number/level of reconstruction. There was no statistical significant difference between groups.

compression therapy enabling us to evaluate the results of the EVVP itself.

The recurrence-free period achieved in the C4 group was longer than the recurrence-free period in the C5 and C6 groups. Multistation repairs were performed in all groups, most frequently in the C4 group, and seemed to yield the longest durability (Fig. 5). The ulcer free period in C5 and C6 was longer among those



**Fig. 6.** The reduction in ambulatory venous pressure accomplished by external venous valve plasty in the CEAP groups 4, 5 and 6, respectively. The numbers refer to the median reduction in ambulatory venous pressure.



**Fig. 7.** Patency and clinical improvement were directly related in the follow-up period, except for three patients that did not experience clinical improvement despite a competent external venous valve plasty.

with multistation repairs. Even though statistical significance was not achieved probably due to the small sample, our results suggested that multistation repairs have more durable competence compared to single plasties, regardless of the clinical stage. The C4 group had better overall results, irrespective of the number of reconstructions. There was a direct correlation between symptom/ulcer recurrence and recurrence of reflux/high AVP during the follow-up period (Fig. 7).

The indication for RDVS in other reports was mainly C5 and C6 patients.<sup>16</sup> We have extended the indication to C4 patients with severe symptoms and a high AVP (>60 mmHg), since we may be able to avoid the development of an ulcer by intervening at this stage.

Our results compare favourably with the literature in this field. Raju *et al.*<sup>17</sup> reported cumulative competence period and ulcer-free interval of 63% after 30 months with a similar technique.<sup>17</sup> Tripathi *et al.*<sup>16</sup> showed an ulcer healing rate of 50% and a competence at the valve stations of 31% after 2 years.<sup>16</sup> Our 3 and 5 year competency after EVVP was 64% and 52%, respectively. These results provided an ulcer-free interval to C5 patients of median 61 months and C6 patients of median 48 months. C4 patients had a symptom recurrence-free interval of median 72 months. The clinical improvement and ulcer healing rate after this procedure seems to be better than that provided by traditional compression therapy.

Some investigators advocate the internal repair.<sup>18–20</sup> We preferred the EVVP, especially because it does not require a venotomy with the potential hazard of

damaging the valve cusps. In addition, several repairs can be performed during the same operation because EVVP is less time consuming.

Among patients with secondary CVI there is a limited group that has a combination of destroyed valves and incompetent but otherwise undamaged valves, where EVVP still is possible. But the largest group with valves amenable to EVVP is definitely among those with PCVI. The number of these patients in our group was rather small, perhaps for several reasons. These were patients with a complicated history and generally there was a favourable response to the initial superficial/perforator surgery and compression therapy.

In our opinion the measurement of AVP is still the reference standard when evaluating the overall venous function in the lower limb. The use of photoplethysmography instead of AVP has been suggested because it is a non-invasive test.<sup>21</sup> However, we prefer measuring AVP since this parameter is *directly* related to the patients' symptoms.

We used AVP pre-operatively as well as during the follow-up period. Combining the information from CDU and descending video-venography was an effective way to assess the degree of reflux and to identify incompetent valves which could be repaired. EVVP requires meticulous adventitial dissection and the use of magnifying loupes is necessary in order to identify the valve cusps. The use of an angioscope can make this part of the procedure easier.

The relatively small size of our group of patients treated by EVVP prevents us from drawing definite conclusions about the best method of valve repair. We have found that external venous valve plasty is an effective way of treating patients with primary chronic venous insufficiency. Careful selection of patients based on clinical findings and an extensive haemodynamic and imaging work-up is mandatory.

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Accepted 2 April 2006

Available online 21 August 2006