

## A prospective study of venous hemodynamics and quality of life at least five years after varicose vein stripping<sup>1</sup>

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### ABSTRACT

**PURPOSE:** To assess venous hemodynamics and quality of life at least five years after varicose vein stripping.

**METHODS:** We conducted a prospective study with 39 patients (63 limbs) with primary lower limbs varicose veins. Preoperatively, all patients were subjected to clinical evaluation, duplex ultrasound, air plethysmography (APG), and CIVIQ questionnaire of quality of life. By APG, venous filling index (VFI), ejection fraction (EF), and residual volume fraction (RVF) were determined. CIVIQ addresses four domains in course of 20 questions, including states of physical, social, and psychological well-being, and pain level. Varicose veins were treated by standard venous stripping. At least five years after surgery ( $77.9 \pm 10.9$  months), patients were reassessed and had clinical examination, duplex ultrasound, APG, and CIVIQ repeated. No late follow-up data was available for 24 patients.

**RESULTS:** Preoperative and late postoperative VFI levels were similar, whereas EF ( $P=0.05$ ) and RVF ( $P=0.01$ ), as hemodynamic variables, significantly improved following surgery. In the late postoperative period, overall CIVIQ scores were significantly lower ( $P=0.005$ ), as were scores in all four domains: pain ( $P=0.001$ ), physical ( $P=0.007$ ), social ( $P=0.008$ ), and psychological ( $P=0.05$ ).

**CONCLUSION:** In a small prospective cohort, improvements in venous hemodynamics and in quality of life of patients submitted to standard varicose veins stripping were maintained five years after the procedure.

**Key words:** Varicose Veins. Stripping. Plethysmography. Quality of Life. Surgery.

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## **Introduction**

Varicose veins (VV) are a disabling condition, representing a critical public health problem with economic and social consequences<sup>1-4</sup>. Prevalence is high, being about 20% to 73% in females and 15% to 56% in males<sup>5-6</sup>. Elastic compression stockings are the initial treatment. Venoactive drugs can bring some relief in symptoms. Surgical stripping or endovascular ablation are typically the treatments of choice.

Once untreated, VV usually affect many aspects of daily living, harming quality of life (QOL). QOL may be defined as the patient's overall perception of his/her disease, including its functional ramifications and responses to related therapy. Launois *et al.*<sup>7</sup> are credited with elaboration and validation of the Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ), used to assess disease-specific QOL in the setting of venous disease.

Knowledge of treatment outcomes in VV is mandatory for determining the most effective therapy. Accordingly, this study was designed to assess venous hemodynamics and late QOL at least five years after varicose vein stripping.

## **Methods**

The study was approved by the Institutional Ethics Committee and also each patient signed an informed consent (n. 13353/2008). We followed patients from a previous study at Division of Vascular and Endovascular Surgery of the University Hospital of the Faculty of Medicine of Ribeirão Preto, University of Sao Paulo<sup>17</sup>.

We selected 39 patients (63 lower limbs) with primary lower limbs VV with CEAP clinical classification<sup>8</sup> ranging from C2 to C6 complaining of pain, discomfort and edema. Patients with prior varicose vein surgery; deep venous reflux and obstruction, confirmed by duplex ultrasound; congenital malformations; diabetes mellitus; heart disease; arterial and lymphatic vasculopathies; collagenoses; myopathies; osteopathies; arthropathies (alone or as comorbidity); and other lower limb surgeries during the study period were all excluded.

### *Preoperative evaluation*

All patients were subjected to standard clinical examination. Duplex ultrasound was performed to rule out deep venous reflux and obstruction<sup>9</sup>, and also to diagnose superficial venous reflux (great saphenous vein, small saphenous vein or perforator insufficiency). Examinations were performed by the

same independent examiner, and all results were communicated to the senior investigator. Venous hemodynamics was assessed by air plethysmography (APG). APG was performed in the Laboratory of Noninvasive Vascular Investigation during evening hours. Testing began after a procedural demonstration, assuring complete patient understanding of the process. The functionality of calf muscular pump was studied by APG, using an SDV 3000 Angiotec<sup>®</sup> device (Belo Horizonte, Brazil) with computer automated calibration. The technique described and standardized by Christopoulos *et al.*<sup>10</sup> was applied to evaluate venous filling index (VFI), ejection fraction (EF), and residual volume fraction (RVF).

Disease-specific QOL was assessed by the CIVIQ questionnaire. The CIVIQ was designed expressly for evaluating QOL in patients with venous disease. This 20-question inquiry is aimed at four key areas, including states of social (three questions), physical (four questions), and psychological (nine questions) well-being and pain level (four questions). As such, it is marked by strong internal consistency and reproducibility, as well as high response capacity and longitudinal clinical validity<sup>7</sup>.

All preoperative data was defined with the prefix Pre.

### *Varicose veins stripping*

Patients were submitted to surgical stripping in order to eliminate the VV and eliminate the superficial venous reflux. The choice of each procedure was based on findings of clinical examination and of duplex ultrasound. Ankle-to-groin great saphenous vein stripping and simultaneous phlebectomy were performed in 55 lower limbs. The same procedure with simultaneous perforating veins ligation was performed in the eight remaining. As no small saphenous vein reflux was diagnosed, no small saphenous vein stripping was performed. The same surgeon (TM) performed all operations from January 2001 to December 2004.

### *Follow-up*

Postoperatively, every patient was closely followed until one year after surgery. No complications such as hematoma, wound problems, infection or nerve injuries were observed. At least five years after the procedure, patients were contacted by telephone and were asked to return to the hospital for reassessment of clinical examination, duplex ultrasound, APG, and CIVIQ. No late follow-up data was available for 24 patients. We attempted contact by telephone and mail with these patients, with no success. Postoperative data was defined with the prefix Post.

Statistical analysis

For comparing preoperative and postoperative data (APG and CIVIQ), the nonparametric two-tailed Wilcoxon test was utilized. Statistical evaluations were performed using the program Graph Pad Prism 4.0 (Graph Pad Software Inc., San Diego, CA, USA). Data was considered to be statistically significant at *P* values less than .05.

Results

From the 39 initial patients, 15 (22 lower limbs) were evaluated in the late postoperative period. Median age was 56 years (25 to 68 years). These patients were submitted to ankle-to-groin great saphenous vein stripping and phlebectomy (18 limbs) and the same procedure with simultaneous perforating veins ligation (four limbs). Mean follow-up was 77.9 ± 10.9 months.

Figure 1 describes the distribution of pre and late postoperative CEAP clinical classification (C). In the long-term, clinical classification was unchanged for 59.1% (13/22 limbs), whereas 40.9% (9/22 limbs) worsened relative to preoperative CEAP status.

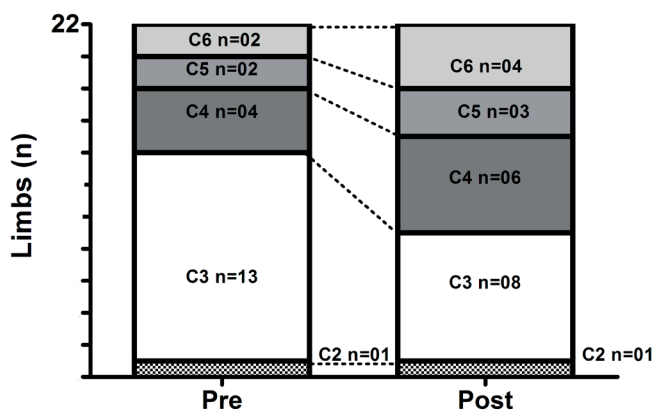


FIGURE 1 - Distribution of pre and late postoperative CEAP clinical classification (C). n-number of limbs.

Late postoperative duplex ultrasound detected reflux in superficial (6/22 limbs; 27.3%) and deep (3/22 limbs; 13.6%) venous systems, as well as in perforators (4/22 limbs; 18.2%).

Regarding venous hemodynamics, VFI remained stable throughout the duration of study, showing no change from baseline to late postoperative values. On the other hand, there was a significant increase in Post EF and a fall in Post RVF, when compared with preoperative levels, representing improved venous hemodynamics in the late postoperative period (Table 1).

TABLE 1 – Analysis of the variables VFI, EF and RVF during the preoperative and late postoperative period in 15 operated patients.

VARIABLES		MEDIAN	IQR	Z	<i>P</i> value
VFI	Pre	4.12	2.6-5.0	0.93	0.36
	Post	2.72	1.8-4.4		
EF	Pre	38.80	30.0-61.2	2.74	0.006
	Post	66.35	47.3-76.7		
RVF	Pre	37.15	24.7-45.2	2.48	0.01
	Post	23.85	13.1-36.9		

VFI = Venous filling index  
 EF = Ejection fraction  
 RVF = Residual volume fraction  
 IQR=Interquartile range

Analysis of overall CIVIQ answers indicated improved QOL in 66.7% (10/15 patients), no change in 26.7% (4/15 patients), and worsening in 6.6% (1/15 patients). These scores declined significantly in the late postoperative period, signaling enhanced QOL after surgical intervention for VV (Table 2). All four domains of the CIVIQ (pain, physical, social, and psychological) scored significantly better in late postoperative period, compared with preoperative assessments (Table 3).

TABLE 2 – Analysis of quality of life (QOL) of 15 patients during the preoperative and late postoperative period based on the CIVIQ.

CIVIQ	Median	IQR
PRE	51.00	43.0-64.0
POST	32.00	25.0-37.5

Z = 2.79; *P* = 0.005; IQR = Interquartile range

TABLE 3 – Analysis of the median values of the CIVIQ domains during the preoperative and late postoperative period of 15 patients.

DOMAINS	PRE		POST		Z	<i>P</i> * value
	Median	IQR	Median	IQR		
Pain	13.0	14.5-12	5.0	8.0-4.0	3.42	0.001
Physical	11.0	15.0-8.5	6.0	7.0-4.0	2.70	0.007
Social	8.0	10.0-5.0	4.0	5.0-3.0	2.63	0.008
Psychological	23.0	25.5-16.5	15.0	17.5-12.0	1.96	0.05

\**p*<0.05 was considered statistically significant; IQR = Interquartile range

The 24 patients (41 limbs) which were unavailable for late follow-up had median age of 48.5 years (40-64 years). They presented the following CEAP preoperative clinical values: C-2 (n=1); C-3 (n=12); C-4 (n=7); C-5 (n=3); and C-6 (n=1).

## **Discussion**

This study was designed as a prospective evaluation of long-term patient outcomes following VV stripping. Both hemodynamic and QOL parameters were assessed before surgery and in the late postoperative period. Repeated attempts to quantify venous reflux based on APG have established that the results do correlate well with clinical stages of venous disease. This approach is also useful for monitoring patient status following various surgical procedures<sup>10-17</sup>. Although improved venous hemodynamics have been reported in most immediate postoperative periods<sup>10,11,16-19</sup>, few sources have documented long-term results.

Dezzotti *et al.*<sup>17</sup> using APG to study changes in venous hemodynamics 30-45 days after surgery for lower limb VV, found postoperative improvement by virtue of a reduction in VFI and RVF and an increase of EF (39 patients). A decline in VFI was observed in our 39 patient 30-45 days after surgery, but the degree of change did not persist long-term (five years) after surgery in the 15 patients who completed the study. This suggests that the postsurgical VFI reverts as the disease evolves, thus explaining a worsening in clinical CEAP classification in 40.9% (9/22) of limbs. An alternate possibility is that the clinical evolution of venous disease results from local or microcirculatory factors and not from the hemodynamics of major veins<sup>20-22</sup>.

QOL analysis reflects patient perceptions of life in a number of ways, and is not merely an index of overall health<sup>23</sup>. Hence, QOL is considered a critical determinant of treatment success<sup>24</sup>, particularly in terms of disease progression. In chronic conditions such as venous disease, QOL assessments provide insight into patient complaints, which may not readily translate through traditional methods of morbidity and mortality determinations<sup>25</sup>. However, it is still unclear whether or not CEAP status, focused largely on physical changes, reflects the patient's self-perception of disease severity. Few studies have investigated this aspect<sup>26</sup>.

Kakkos *et al.*<sup>27</sup> studied 45 patients (48 legs) undergoing superficial venous surgery for primary varicose veins. Venous ultrasound, clinical examination, and a QOL questionnaire were used preoperatively and at six weeks and six months postoperatively. Severity of venous symptoms was subsequently correlated with CEAP class and CEAP score (scores of disease

severity standardized by means of CEAP status). The authors found that scores derived from venous symptoms rose significantly in advanced CVD, correlating with the extent of anatomic involvement. Thus, they viewed scores of clinical severity and CEAP scores as more sensitive indices of responses to surgical treatment in this setting, as opposed to CEAP classification alone.

Blomgren *et al.*<sup>28</sup> assessed the impact of preoperative duplex mapping on the QOL (via SF-36 questionnaire) of patients after surgery for lower limb varicosities. Despite improving the surgical result by reducing residual veins and recurrences, at no time did the exam impact patient QOL. The follow-up period was two years and the initial patient sampling of 293 was reduced to 237 (81%) by end of study.

In an international cohort study, Kahn *et al.*<sup>26</sup> evaluated 1531 patients, attempting to correlate CEAP status with severity of venous symptoms. The patients were distributed proportionately by ascending CEAP class as follows: 3.8%, 13.3%, 24.1%, 12.8%, 36.4%, 7.3% and 2.3%. Ultimately, declining QOL scores corresponded with increasing CEAP class, indicating that clinical status, based on the CEAP clinical classification, is predictive of QOL and the severity of venous disease. The generally impaired QOL of patients with chronic venous insufficiency has been further confirmed in the literature by comparative studies with other chronic disease such as rheumatoid arthritis, lumbar pain, menorrhagia, and suspected peptic ulcer<sup>29</sup>.

Much of the difficulty we encountered was in maintaining patient participation. The extended period (at least 5 years) of monitoring after surgery culminated in immense loss of follow-up. Only 38.4% of the initial patients were available for late follow-up assessment. Patients who lost follow-up were similar to those who completed the study, regarding median age and CEAP clinical classification. Baker *et al.*<sup>30</sup> also faced this problem when comparing postoperative QOL (at 30 days and six months) and baseline status of treated lower limb VV using the SF-36 questionnaire. Only 59% of patients responded to the questionnaire within this brief evaluation period. Smith *et al.*<sup>25</sup> managed an 80% follow-up rate within 6 months after treatment, losing 20% of patients in follow-up due to changes in address or telephone number.

In our study, overall CIVIQ scores improved significantly in the postoperative period compared with preoperative scores. Statistical analysis revealed improvement in 66.7% of the sampling, no change in 26.7%, and worsening in only 6.6%. Similar gains were noted for all four CIVIQ domains (pain, physical, social and psychological), underscoring the long-term benefits of surgical intervention in lower limb VV.

The strength of this study was limited by the number of patients enrolled, coupled with socioeconomic restrictions. Among the 39 patients agreeing to participate initially, only 15 patients completed the study, conducted during a period of at least 5 years. A lack of a non-surgical control group was also a limitation.

### Conclusion

In a small prospective cohort, improvements in venous hemodynamics and in quality of life of patients submitted to standard varicose veins stripping were maintained five years after the procedure.

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