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Original Research

Day surgery versus Outpatient setting for endovenous laser ablation treatment. A prospective cohort study

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ABSTRACT

Objectives: The traditional surgical approach to the treatment of the superficial venous insufficiency requires at least 12 h of post-operative monitoring and this often means the necessity of an overnight hospitalization. The introduction of new, less invasive techniques (i.e endovenous laser ablation) reduces the hospitalization stay in a Day Surgery setting. However, the increasing skills of the operators and the patient's selection, allows to propose endovenous laser ablation in an Outpatient setting. The aim of this study is to evaluate the activity of a single high-volume center.

Method: We enrolled 112 consecutive patients with great sapehous vein insufficiency and indication to endothermal laser ablation, 57 operations (51%) were performed in Day Surgery setting and 55 (49%) in Outpatient setting according to endovascular laser ablation's criteria. Past medical history, CEAP classification, VCSS score, type of symptoms and intervention's data were collected. Post-operative results (success and complications rates, patient's functional and aesthetic satisfaction) were evaluated at 7 and 30 days after intervention. A QoL questionnaire (CIVIQ) was submitted to the patients 30 days after surgery.

Results: We did not observe a statistically significant difference between the two groups concerning treatment results and complications onset. The QoL assessment did not differed significantly, except for over 65-year old patients undergoing outpatient treatment that showed a better QoL compared to those undergoing the same treatment in Day Surgery (p 0.05).

Conclusions: The endothermal laser ablation technique allows a safe, comfortable and faster management of the venous disease in Outpatient setting. This would further reduce the costs of the treatment while preserving the functional and aesthetic results and the low complication rate of the Day Surgery setting.

1. Introduction

Chronic venous insufficiency and varicose veins of the lower limbs represent a pathology with a great impact on the patient's quality of life (QoL) with a broad range of symptoms as discomfort, pain and disability [1,2]. Considering the high incidence in worker population, the disease carries also a not negligible socio-economic impact.

In the last years, traditional surgery has been broadly replaced by endovenous techniques like endothermal laser or radiofrequency ablation which allow a lower invasiveness (i.e. the possibility to perform percutaneous access under local anesthesia) and pain and complications reductions with a consequent faster recovery time. NICE and the SIF-SICVE 2016 guidelines lately confirmed that the endothermal ablation with laser or radiofrequency is, when suitable, to be preferred to the traditional surgery [3,4]. The principle of endothermal laser ablation (ELA) is explained with the convertion of 1470 nm laser energy into heat with water vaporization and consequent collapse and obliteration of the inner vessel wall [5]. This technique is extremely safe and reliable and data from literature confirm a success rate of 88–100% [6]. Moreover ELA has been recently extended to the treatment of the small saphenous vein (SSV) [7].

Another important advantage of ELA is the possibility to perform the entire intervention through a percutaneous access under local ultrasound-guided tumescence anesthesia. This peculiarity reduces the post-operative hospitalization stay and allows a faster and safe recovery of the patient that could be managed in a Day Surgery or even Outpatient setting.

The aim of this prospective study is to compare the impact of Day Surgery versus Outpatient setting after ELA.

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2. Material and methods

Between October 2015 and July 2016 we enrolled 112 patients with great saphenous vein insufficiency and indication for ELA. They were randomly divided into two groups: 57 (51%) who underwent the operation in Day Surgery setting; 55 (49%) who underwent the operation in Outpatient setting.

Primary endpoints were: the technical success (GSV obliteration at 30 days) and patient's quality of life (through the Chronic Venous Insufficiency quality of life -CIVIQ-questionnaire) [8] between the two groups. Secondary endpoints were: the post-operative complications (haematoma and ecchymosis, swelling, pain, paresthesia) between the two groups.

Inclusion criteria were: CEAP (Clinical, Etiological, Anatomical, Pathophysiological) class > C1 (presence of varicose veins involving superficial venous system), GSV reflux, not tortuous vessel, GSV's calibre between 5 and 12 mm (horizontal posture). Exclusion criteria were double GSV or crosse's abnormalities, pregnancy/lactation, blood coagulation disorders or venous thrombosis, superficial GSV course (less than 4 mm). The work has been approved by the Ethic Committee and reported in line with the STROCSS criteria.

All the patients underwent a pre-operative evaluation with an accurate interview and history taking and a Doppler Ultrasound to confirm the GSV dilatation and exclude an eccessive tortuosity of the vessel. ELA was performed in a sterile setting (operating theatre for Day Surgery, specialized ambulatory for Outpatient setting) with Eufoton 1470 nm diode laser fiber. After a Seldinger's cannulation of the GSV, the tip of the laser catheter is placed proximately to the origin of the epigastric vein. An US guided tumescence anesthesia is performed all along the saphenous eye (500 ml of 5 °C physiological solution with 30 ml 2% lidocaine and 5 ml 1,4% sodium bicarbonate). The ablation is obtained with an energy supply of 80 J/cm for the first 2 cm and then 40 J/cm with a power of 4–7 Watt.

Post-operative follow-up consisted in a clinical (presence/absence of pain, swelling, ecchymosis, resumed daily activities) and ultrasonographic (presence/absence of DVT, GSV obliteration) controls at 7 and 30 days. The CIVIQ-20 QoL questionnaire was submitted to all the patients 30 days after surgery. It consists of 20 questions evaluating pain, sleep quality and the ability of doing everyday activities. Scores for each question ranges from 1 (no pain, no trouble) to 5 (severe pain, severe trouble). Questionnaire score ranges from 20 (best post-operative QoL) to 100 (worst post-operative QoL).

2.1. Statistical analysis

All the data were collected and stored for statistical analysis. Continuous variables were expressed as mean and standard deviation and compared through nonparametric test of Student. Categorical variables were expressed as scores or as percentages. For their comparison were built contingency tables or matrices of cross-correlation RXC. Chi-square (with Yates correction test for 2 × 2 tables) were used. For all variables, the statistical significance was conventionally set at $p < 0.05$. Through the use of the Student *t*-test for independent samples a correlation (statistically significant) between the outcome of the procedure in the two groups was sought.

3. Results

The prospective study is based on 112 consecutive patients treated with ELA with a mean age of 62 ± 13,2 and predominantly of female gender (79/112; 70%). They were randomly assigned to Day Surgery (57/112; 51%) or Outpatient (55/112; 49%) setting. Pre-operative characteristics of the general population and of the two subgroups are shown in Table 1. No difference between the two groups was highlighted for GSV length, joules delivered and post-operative complications rate nor for the time needed for a complete recovery (work, walk, drive as before the operation) as reported in Table 2. The 30-days follow-up confirmed the efficacy of the technique with an incomplete GSV occlusion reported in only 3 (2%) of cases (Table 2). Patient's satisfaction was evaluated both in aesthetic and functional results: in group A 87% of patients were fully satisfied while the remaining patients (13%) were only functionally satisfied; in group B 88% of patients were overall satisfied, 7% were functionally but not esthetically satisfied and 5% were esthetically but not functionally satisfied. The 30-days CIVIQ questionnaire revealed a medium score in Day Surgery group of 20,45 ± 0,94 while in Outpatients group-B was 20,5 ± 0,93 (p 0,1). However, there was a statistical different perception of QoL in patients over 65 years: for this subgroup of patients there was a better perception of QoL for Outpatient setting compare to Day Surgery (p. 0,05).

4. Discussion

The first endovenous treatment of an incompetent GSV reported in literature was performed by Boné in 1998 [9]. Since then we assisted to a progressive widespread of this minimal invasive, but equally efficient, way to manage patients suffering from chronic vein insufficiency. In particular, ELA has proved to be comparable to the traditional stripping in terms of effectiveness and showed superiority in terms of complication rates and impact on the QoL [10,11].

This is partially related to the percutaneous access and the tumescence anesthesia (that guarantee a faster recovery and the absence of important wounds to heal) and partially related to the improvement of the diode laser systems and probes. In fact, in early years, diode laser systems had a wavelength ranging from 810 to 980 nm with a targeted action on the molecules of haemoglobin [12,13]. For this reason, the effect of the ablation was dependent to the presence and the amount of red blood cells. Moreover, the first-generation probes had the drawback of an inhomogeneous delivery of energy along the vessel walls provoking quite frequently spots of venous injury with consequent ecchymosis and pain for the patient [14].

The latest developments in laser technology however, increased the wavelength to 1470 nm acting on water molecules as a specific target and this improved the efficacy of obtaining durable endogenous ablation of the GSV without increasing the joules delivered [4,10,15,16].

The probes as well were ameliorated with the introduction of a double ring system for a circumferential delivery of energy into the vein lumen that guarantee a reduction of joules needed to obtain thrombosis and a reduction of pain and discomfort to the patients [17,18].

The reduced invasiveness of the procedure permitted to offer ELA in Outpatient Setting, as advocated in the latest NICE Guidelines, where non-thermal and non-tumescent venous ablation (i.e sclerotherapy) is already performed [3].

Another important aspect of this new technique is the reduction of the economical impact of the disease not only for the shortening of hospital stay (Day Surgery versus overnight stay) but also in terms of working days lost [3]. In the last years, the excellent technical results confirmed in Literature and the increasing knowledge and operator's skills, permitted to propose ELA in Outpatient setting [16,19–22].

According to our perspective randomized study we found no difference in terms of clinical success and peri-post operative complications, among patients treated in Day Surgery versus Outpatient setting. However, a slightly but significant difference was highlighted in terms of QoL: patients with more than 65 years preferred Outpatient Setting compared to Day Surgery setting. We did not find similar data in Literature to compare with but this could probably be explained with the lower emotional stress and less impact on the resumption of everyday life and a better patient's compliance in Outpatient Setting.

One of the limits of this work is the relative small population size but, according to the perspective structure of the study, the ongoing collection of patients and data will probably allow us to better define the cohort of population that advantages most from one hospitalization

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