


# Mini-invasive high-tie by clip apposition versus crosssectomy by ligation: Long-term outcomes and review of the available therapeutic options

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## Abstract

**Objective:** The aim of the present study is to compare a mini-invasive (smaller than 2-cm incision) sapheno-femoral high-tie by clip apposition (HT group) with a traditional high-ligation by ligation (HL group).

**Methods:** One hundred fifty chronic venous disease patients were included in group HT and compared with 150 cases constituting the group HL. The main outcome was the sonographic detection of saphenous trunk recurrences. Procedural pain, esthetic satisfaction, and disease specific quality of life were assessed.

**Results:** At  $4.5 \pm 2.4$  years follow-up, 8 cases (5.3%) of Great Saphenous Vein reflux reappearance were reported in group HT vs. 19 cases (12.6%) (odds ratio: 2.6; 95% confidence interval: 1.1–6.1;  $P = 0.04$ ) of group HL. Esthetic satisfaction was scored as high and very high in group HT and HL, respectively ( $P < .0001$ ).

**Conclusions:** Proper high-ligation technique provides satisfying outcomes both in terms of recurrence rate and patient esthetic satisfaction. The different outcomes obtained by the two groups encourage further investigations regarding recurrence pathogenesis.

## Keywords

Chronic venous insufficiency, great saphenous vein, ligation, saphenofemoral junction, surgery

## Introduction

Endovenous procedures have become a mainstay in the treatment of saphenous reflux.<sup>1</sup> In particular, radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) have gathered enough evidence to be recommended as the best treatment options with a grade up to 1B.<sup>2</sup> These techniques are currently preferred over surgery, because they are safe and minimally invasive.<sup>2</sup> Such promising features of endovenous procedures have led some authors to consider conventional surgery as an apoptotic discipline in the phlebology field.<sup>3</sup>

However, according to the most recent reviews, RFA and EVLA are not improving the post-operative recurrence rate.<sup>4</sup> Additionally, a meta-analysis this year highlighted a higher recurrence risk following EVLA rather than surgery.<sup>5</sup> More than 50% of varicose vein recurrences involve the sapheno-femoral junction (SFJ), making the control of this reflux source a main goal of the procedure.<sup>6,7</sup> According to the literature, a traditional high ligation for Great Saphenous

Vein (GSV) stripping requires a 3 to 7 cm long groin incision, an extended dissection through the superficial fascia, a ligation of the SFJ tributaries and a ligation and division of the GSV flush to the femoral vein, between ligatures of 2/0 multifilament.<sup>8</sup>

The aim of the present study is to evaluate the performance of a minimally invasive SFJ high-tie by titanium clip apposition (HT) compared with a traditional high-ligation by ligatures (HL). The rationale of the investigation is to evaluate the actual appeal of a specific saphenous sparing varicose vein surgery procedure in an age in which endovenous and percutaneous techniques seem to represent the leading therapeutic option.

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## Methods

This is a retrospective study analyzing historical cases in a period ranging from 2007 to 2014. One hundred fifty chronic venous disease (CVD) patients (M/F 1/1; age:  $59 \pm 9$ ; BMI:  $24.1 \pm 1.8$ ) who underwent HL were compared with 150 who underwent HT (M/F 1/1; age:  $58 \pm 9$ ; BMI:  $23.8 \pm 2.0$ ) by sonographic evaluation of GSV reflux reappearance (Table 1).

Inclusion criteria were:

- 18–70 years old
- C3EpAsPr
- Venous Clinical Severity Score (VCSS) from 6 to 8
- External iliac vein competence above the inguinal line
- History of not more than two pregnancies, as potential risk factor for pelvic refluxes<sup>9</sup>
- Clinical and sonographic follow-up accomplished

Exclusion criteria were:

- pregnancy and lactation
- pelvic venous reflux
- use of anticoagulants
- previous varicose vein surgery
- history of thrombosis
- diabetes
- neurological, muscular, or orthopedic disorders

All patients signed an informed consent allowing the anonymous use of their data for future studies. All clinical and sonographic assessments were performed by the same certified and highly experienced sonographer who was not blinded because of the echogenic appearance of the titanium clip in the HT group. In case of GSV reflux reappearance, a distinction was made among direct stump reconnection, pelvic venous network involvement, neoangiogenesis, or newly incompetent tributaries along the leg.

**Table 1.** Patient population characteristics.

	Group HL, n = 150	Group HT, n = 150	P
Gender ratio (M/F)	75/75	75/75	<1.0 <sup>a</sup>
Age (years), mean $\pm$ st.dev	$59 \pm 9$	$58 \pm 9$	<0.2 <sup>b</sup>
BMI, mean $\pm$ st.dev	$24.1 \pm 1.8$	$23.8 \pm 2.0$	<0.1 <sup>b</sup>

<sup>a</sup>Differences in gender have been calculated by chi-square test.

<sup>b</sup>Differences in age and body mass index (BMI) have been calculated by Mann–Whitney test.

Two weeks after the procedure, a 100 mm visual analogue scale was used for assessing the inguinal scar esthetics (A-VAS) both by the same patient and by a blinded assessor (0 = worst possible scar; >60 mm = esthetically satisfying; 100 mm = not visible scar).<sup>10</sup> A 100-mm visual analogue scale was also used to assess procedural pain (P-VAS) and pain during the first post-procedural week (PP-VAS) (0 = no pain; 10–30 mm mild pain; 40–60 mm moderate pain; 70–90 mm severe pain; 90–100 mm = unbearable pain). Procedural pain was defined as the amount of pain patients experienced during the procedure.<sup>11</sup> In both cases, either patient or assessor were invited to rate using an appropriate graded ruler.

Prior to and 6 weeks after the procedure, patients were asked to complete the Aberdeen Varicose Vein Questionnaire (AVVQ) to observe the disease-specific quality of life.<sup>12</sup>

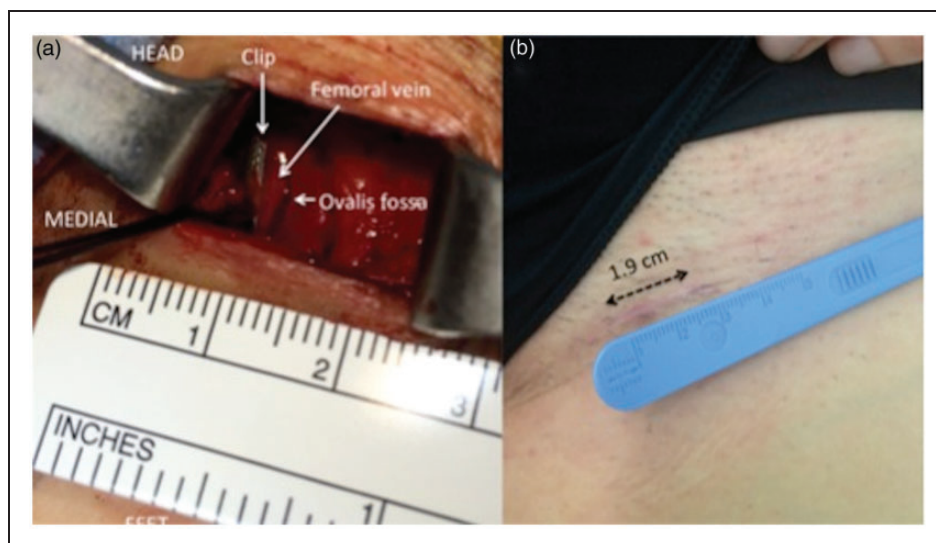
### Surgical technical notes

All of the HL group patients underwent the following surgical procedure:

- 3- to 5-cm long incision on the inguinal crease, centered on the pre-operative echo-guided skin marking
- Opening of the superficial fascia by sharp dissection and use of three medium size retractors
- GSV identification, sharp dissection, and encircling on a vessel loop
- GSV ligation (2-0 multifilament absorbable thread) and section before its entrance inside the oval fossa
- Dissection of the remaining GSV tract toward the confluence with the femoral vein
- Ligation and division of all the junctional tributaries (3-0 or 4-0 depending on the vessel caliber)
- Clamping of the GSV flush on the femoral vein by a right angle
- Ligation of the GSV flush to the femoral vein, by one ligature (2-0 multifilament absorbable thread)

All of the HT group patients underwent the following surgical procedure:

- 2-cm long incision on the inguinal crease, centered on the pre-operative echo-guided skin marking
- Opening of the superficial fascia by sharp dissection and use of two small size retractors
- GSV identification, sharp dissection, and encircling on a vessel loop
- Dissection of the remaining GSV tract toward the confluence with the femoral vein
- Ligation and division of all the junctional tributaries (3-0 or 4-0 depending on the vessel caliber)



**Figure 1.** (a) Titanium clip application on the femoral side of the SFJ. Femoral vein was clearly identified, together with the fossa ovalis boundary. (b) 1.9-cm long incisional scar at 2-week follow-up.

- Ligation of the GSV (2-0 multifilament absorbable thread) distal to the pre-terminal valve
- Ligation of the GSV (2-0 multifilament absorbable thread) flush on the femoral vein confluence
- GSV division in between the two ligatures
- Titanium application by a 90° applier (Horizon®, large size) flush on the femoral stump, below the previous ligature (Figure 1).

Both HL and HT were performed in an office-based setting, under local anesthesia and by the same experienced surgeon, always reporting the procedural times and the groin incision length at the end of the surgical act. All ovalis fossa were closed by two single stitches (3-0 multifilament absorbable thread). All skin closures were by 4-0 transparent mono-filament subcuticular running suture. In both groups, incompetent tributaries that were previously identified along the leg at the sonographic scanning were flush ligated and divided by the GSV between ligatures of 3-0 multifilaments. GSV was never stripped or ablated, since the applied strategy was saphenous sparing.<sup>13</sup> No adjunctive sclerotherapy was performed.

### Statistical analysis

InStat GraphPad (GraphPad Software, Inc., La Jolla, CA, USA) was used for statistical analysis. The data were expressed as mean ± standard deviation. Kolmogorov–Smirnov test was used to assess the data distribution. Demographic, clinical, and sonographic differences were tested by Mann–Whitney test and by Chi-square test as appropriate. The two-tailed Fisher’s exact

**Table 2.** Baseline clinical and sonographic assessment.

	Group HL, n = 150	Group HT, n = 150	P
SFJ diameter, mean ± st.dev	9.4 ± 1.5	9.3 ± 1.5	<0.7
Reflux time, mean ± st.dev	3.2 ± 0.4	3.3 ± 0.6	<0.4
VCSS, mean ± st.dev	6.7 ± 0.8	6.8 ± 0.8	<0.3

SFJ diameter, reflux time, and VCSS differences have been calculated by Mann–Whitney test.

test followed by odds ratios (ORs) and 95% confidence intervals (CIs) was used to assess the risk of GSV recurrence. Statistical significance was defined as  $P < 0.05$ .

### Results

The two groups were homogeneous in SFJ diameter (HL:  $9.4 \pm 1.5$  mm (min: 7 mm, max: 14.5 mm); HT  $9.3 \pm 1.5$  mm (min: 6.9 mm; max: 14.8 mm), reflux time (HL:  $3.2 \pm 0.5$  s (min: 1.8 s; max: 4.8 s); HT:  $3.3 \pm 0.6$  s (min: 1.7 s; max: 4.6 s), and presence of a GSV trunk re-entry perforator (Table 2). At  $4.5 \pm 2.4$  years mean follow-up, both groups’ CEAP class decreased to C1, with the exception of 19 (12.6%) in the HL group and 8 (5.3%) C2 cases in the HT group. Post-procedural VCSS was  $2.4 \pm 1.3$  in HL group and  $1.9 \pm 1.3$  in HT group ( $P < .0006$ ). Nineteen cases of GSV reflux reappearance were reported in HL group (12.6%) versus 8 cases (5.3%) in the HT group (OR: 2.6; 95% CI: 1.1–6.1;  $P = .04$ ).

In the HT population, a direct stump reconnection was never detected, while pelvic congestion was

sonographically demonstrated in two cases (25%). GSV recurrences in the HL group were attributed to SFJ direct stump reconnection in four cases (21%), to pelvic sources in three (15.8%) cases, to neovascularization in another three cases (15.8%) and new lower limb tributary incompetence in the remaining nine cases (47.4%). In the remaining six cases (75%), the GSV reflux was fed by an incompetent tributary along the leg, without any neovascularization at the junction. The mean length of the HL skin incision was  $3.9 \pm 0.7$  vs.  $2.0 \pm 0.2$  cm in the HT group ( $P < .0001$ ). The mean procedural time from the inguinal incision to its skin suture was  $25 \pm 2$  in the HL group vs.  $27 \pm 3$  min in the HT group ( $P < .0001$ ).

According to patients' evaluation in the HL group, inguinal scar esthetic A-VAS was  $76 \pm 7$  and  $85 \pm 6$  in the HT group ( $P < .0001$ ). The blinded assessor scored a A-VAS of  $78 \pm 5$  in the HL group and  $87 \pm 5$  mm in the HT group ( $P < .0001$ ). The mean P-VAS was  $16 \pm 6$  mm for the HL group and  $15 \pm 3$  mm for the HT group ( $P = ns$ ) on the 0- to 100-mm VAS. One-week post procedure, the mean PP-VAS was  $4 \pm 2$  mm for the HL group and  $3 \pm 2$  mm for the HT group ( $P = ns$ ). No need for analgesics was reported in both groups.

Six weeks after treatment, the AVVQ improved significantly in both groups, from  $17.5 \pm 4.6$  to  $4.1 \pm 2.8$  in the HL group ( $P < .0001$ ) and from  $17.1 \pm 5$  to  $4.2 \pm 2.4$  in the HT group ( $P < .0001$ ). The difference in AVVQ change between the groups was not statistically significant ( $P = ns$ ). A case of self-solving lymphocele at the groin was detected in the HT group, whereas in the HL group, one mild temporary paresthesia and one mild wound infection occurred at the inguinal incision. The latter was successfully treated after 1 week of oral antibiotics. Major complications were not reported in either of the two groups.

## Discussion

Modern phlebology is characterized by a continuous advancement in devices that are designed to treat saphenous reflux. Since the early 2000s, traditional varicose vein surgery has progressively declined in favor of EVLA and RFA. Innovative technical options are constantly brought into market, leaving progressively behind the surgical option: steam,<sup>14</sup> mechanochemical ablation,<sup>15-17</sup> polidocanol endovenous microfoam,<sup>18</sup> holmium laser-assisted,<sup>19</sup> cyanoacrylate adhesive,<sup>20</sup> or long catheter-assisted foam sclerotherapy.<sup>21</sup> Nevertheless, this technological advancement is not followed by a correspondent improvement in terms of recurrence rate whenever compared with traditional ablative surgery.<sup>22-24</sup>

According to the most recent reviews on GSV recurrences, ablative surgery (stripping), RFA, and EVLA

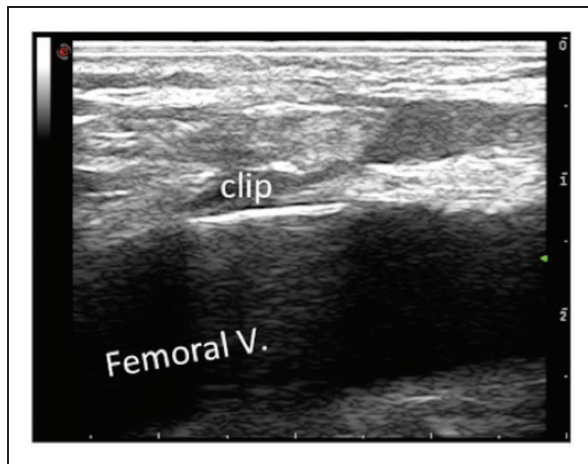
demonstrated overlapping results in the 3-year occlusion rate, ranging from 6.5% to 7%.<sup>4</sup> In 2015, a Cochrane investigation demonstrated a varicose vein recurrence reduction following a saphenous sparing surgical strategy rather than a traditional ablative one.<sup>25</sup> The herein presented data demonstrate the still existing competitiveness of saphenous sparing varicose vein surgery in terms of safety and recurrence rate, in particular for the herein described HT option (5.3% at 5 years).

Moreover, the factors increasing the appeal of modern devices showed a satisfying performance in the HT group: side effects, mini-invasiveness, pain, procedural times, day case feasibility, and ease of use. Both the assessor and the patients' esthetic satisfaction scores regarding the incisional scar were extremely high at 2 weeks. The HT procedural time was comparable to that which is required by most of the modern techniques, as was the possibility of performing the procedure in an office-based setting. A mainstay of the surgical technique for SFJ disconnection is not leaving long femoral stumps of the GSV: a multi-center study identified this technical mistake in more than 2/3 of symptomatic recurrences.<sup>26</sup>

However, previous investigations have reported no significant difference in the recurrence rates related to the surgeon's experience.<sup>6</sup> To perform a technically and strategically adequate saphenous-sparing surgery, as well as to avoid biased outcomes, the surgeon must have both adequate average surgical training and sonographic skills.<sup>27</sup> If correctly performed, HT demonstrated its efficacy also in pain management, producing scores overlapping those of the modern techniques. The significantly lower recurrence rate in the HT vs. HL group generates questions about the importance of incisional length and of the materials used to perform a SFJ disconnection.

Titanium clips are magnetic resonance imaging compatible and clearly visible on sonographic assessment: a feature that allows an accurate post-operative check of the clip positioning (Figure 2). Moreover, because of the use of a 90° applier, the clip use facilitates the femoral stump closure in small accesses like the one herein described in the HT group, so significantly limiting the dissection extent and thus the potential trigger for neovascularization.<sup>28</sup>

The use of different sutures and SFJ disconnection techniques remains a debated topic. Previous studies demonstrated not significant differences among oversewing with polypropylene sutures and standard transfixion with absorbable sutures.<sup>29</sup> There was also no difference in recurrence rate when comparing standard SFJ ligation with a running inverting suture on the femoral venotomy,<sup>30</sup> while a contradictory outcome was reported by Frings demonstrating a decreased recurrence rate by closing the endothelial stump by a running oversewing.<sup>31</sup>



**Figure 2.** Longitudinal scanning of the femoral vein (Femoral V.) with a titanium clip application on the sapheno-femoral junction after a high tie procedure.

The present investigation opens new questions about the potential role of the titanium clip as a physical barrier for recanalization. Alternative techniques have been described to suppress SFJ reflux in a saphenous sparing strategy. Among these, external valvuloplasty was shown to be effective but adequate just for selected cases.<sup>32</sup> Investigations aimed at combining the mini-invasiveness of modern endovenous devices with the efficacy of a saphenous sparing strategy were reported but just by preliminary data.<sup>33,34</sup> An interesting strategic option has been recently proposed by Okazaki through a small skin incision and an echo-guided GSV ligation during endovenous ablation procedures. However, the ligation is performed 2 cm from the SFJ so not representing the same proper high ligation flush on the femoral.<sup>35</sup>

Even if titanium clip application for high ligation has been in use for many years now, to the best of our knowledge, the present investigation represents the first report about their use on the SFJ femoral stump, moreover providing comparison data with a traditional high ligation by ligature. Both the HL and the HT group were shown to be painless procedures leading not only to effective reflux control (recurrence rate 5.3% vs. 12.6%, in HT vs. HL group, respectively; OR: 2.6; 95% CI: 1.1–6.1;  $P=0.04$ ) but also to a satisfying clinical CEAP and VCS outcome. These data open the discussion about the appropriateness of the modern trend in abandoning varicose vein surgery in favor of just endoluminal techniques.<sup>36</sup>

A previous dogma regarding GSV caliber size for RFA and EVLA feasibility has been challenged by recent articles.<sup>37</sup> Omitting further considerations on the endoluminal treatments for large GSVs, a hemodynamic surgery performed with a minimally invasive approach results to be not yet to be abandoned. Recurrence rates and clinical outcomes of this

therapeutic strategy were reported to be competitive whenever compared with endovenous techniques.<sup>4</sup> In the same way, safety profiles, mini-invasiveness, procedural times, and settings of the herein reported surgical strategy are to be considered totally satisfying.

Moreover, technical limitations can arise with endovenous devices during access and catheterization, limiting the feasibility of these procedures for tortuous vessels.<sup>38</sup> Traditional surgery and modern endovenous techniques may overlap in safety and efficacy; however, the cost-effectiveness of each procedure must also be considered.<sup>39</sup> The present investigation encourages further investigations to determine the real efficacy and cost-effectiveness of a mini-invasive surgery, to be tailored to the individual patient's reflux pattern and performed with adequate materials, techniques, and strategy.

Until now, the significant technologic advancement in GSV reflux treatment has led to a consistent improvement in mini-invasiveness and post-operative quality of life, but without impacting a recurrence rate that has remained invariable, in accordance with the unchanged strategy. A mini-invasive surgery can be esthetically satisfying and safely performed in an office-based setting, while also yielding competitive recurrence rates. Deeper analyses are required to identify the main triggers of SFJ recurrence, in particular regarding the dissection extent and the used materials: randomized controlled trials are encouraged on this topic. Further investigations are needed before considering varicose vein surgery an obsolete therapeutic option.

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### Author's contributions

SG conceived and designed the study, researched literature and collected data and wrote the first draft of the manuscript.

EM and AMM were involved in manuscript preparation, data analysis and statistical analysis. SO was involved in data collection and critical review of the manuscript. PZ was involved in protocol development, patient recruitment and data analysis, manuscript critical review and preparation. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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