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Staged or simultaneous varicose vein treatment after saphenous vein ablation

Równoczasowe lub odroczone leczenie żylaków kończyn u pacjentów poddawanych ablacji żyły odpiszczelowej

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Abstract

Chronic venous disease (CVD) is a progressive condition that affects a significant percentage of the population. Clinical manifestation of CVD differs between the patients: from asymptomatic patients with esthetic problems only to the very severe stages (including venous leg ulcer) that significantly decrease the quality of life (QoI). Although the varicose vein patients can be asymptomatic and they decide for treatment only for cosmetic reasons, many of them present the symptoms and/or signs of CVD, including pain, heaviness, itching, cramps, swelling, trophic changes or ulcerations. Therapeutic management of varicose veins includes surgery, minimally invasive procedures (involving saphenous ablation or sclerotherapy), compression therapy and pharmacological treatment. Traditional surgical treatment has been a leading method in invasive VV management for many years. Nonetheless, minimally invasive treatment thrived in the 21st century and overtook open surgery regarding VVS and more advanced stages of CVD. Another commonly used minimally invasive method in the treatment of VV is foam sclerotherapy. The efficacy of EVLA in the treatment of VV can be improved by performing adjunctive foam sclerotherapy (FS) of the tributaries. The combination of EVLA and FS is an effective method of reducing the rate of reinterventions in VV patients with saphenous vein incompetence. In the patients undergoing saphenous ablation, VV treatment (FS or mini phlebectomy) can be performed within the same procedure or as the delayed treatment. The argument for delayed treatment is the potential possibility of the VV regression (partial or complete) after saphenous vein ablation. On the other hand, saphenous ablation and varicose vein treatment within the same session result in fast and complete varicose vein removal without the need for additional procedures. Nevertheless, there is no consensus regarding the optimal timing of performing FS after EVLA of the GSV trunk and because of many diversified scientific reports there are still different approaches to this problem in phlebological centres around the world. Since the timing of adjunctive FS after EVLA procedure in the treatment of VV associated with GSV incompetence is a topic of open debate among surgeons, this study is a review that compares concomitant and staged treatments of VV.

Key words: saphenous ablation, varicose veins, phlebectomy, sclerotherapy, treatment

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Introduction

Chronic venous disease (CVD) is a progressive condition that affects a significant percentage of the population. The population prevalence of CVD is estimated as even 40–70% [1] in a general population of adults [2]. Clinical manifestation of CVD differs between the patients: from asymptomatic patients with esthetic problems only to the very severe stages (including venous leg ulcer)

that significantly decrease the quality of life (Qol) [3–6]. Teleangiectasies concern up to 60–80% of people [6]. Varicose veins (VVS) are enlarged peripheral veins that occur as the result of vein wall failure, vein valve failure or both [7, 8]. Approximately 70% of the lower leg VVS are imputed to the incompetence of saphenofemoral junction (SFJ) as well as with reflux of great saphenous vein (GSV). Aside from GSV, small saphenous veins (SSV), perforator veins (PV), pelvic veins as well as gonadal veins can be also incompetent [8, 9]. According to different sources, VV affects 16,4–40% of the adult population [10, 11]. Most reports indicate that there is female predominance regarding VVs [3, 12] but some authors state that this problem affects men more frequently [10]. The varicose vein patients can be asymptomatic, but in many patients, the symptoms and/or signs of CVD are present, including pain, heaviness, itching, cramps, swelling, trophic changes or ulcerations [4, 13, 14]. Nonetheless, a lot of patients remain asymptomatic and decide for treatment only for cosmetic reasons [15]. There are several known risk factors for VV development such as age, sex, obesity, pregnancy or hormonal treatment, history of deep vein thrombosis as well as genetic factors [16].

Current treatment of varicose veins

Therapeutic management of varicose veins includes surgery, minimally invasive procedures (involving saphenous ablation or sclerotherapy), compression therapy and pharmacological treatment [17]. In the REACTIV study, conservative VV management and surgical treatment were compared. This showed the superiority of surgical treatment over conservative one regarding QoL, symptomatic relief, anatomical extent, patient satisfaction and cost-effectiveness as well [18]. Traditional surgical treatment has been a leading method in invasive VV management for many years. Nonetheless, minimally invasive treatment thrived in the 21st century and overtook open surgery regarding VV and more advanced stages of CVD [6]. First, inhuman, endovenous laser ablation (EVLA) was performed by Carlos Bone in 1999 [19]. Since then, endovenous thermal ablation (EVTA) has developed significantly and become the first-choice treatment of GSV incompetence [6, 20]. EVLA provides energy straight into the vein lumen and leads to a thermal injury that directly damages the vein endothelium and deeper layers of the vein wall. That result in non-thrombotic occlusion of the vein by collagen degeneration, fibrosis and narrowing of the lumen. Moreover, venous contraction and the direct effect of the laser fibre are additionally intensified by tumescent anaesthesia application [21, 22]. The effectiveness of EVLA in the treatment of VVs is very high in both, immediate postprocedure period as well as in the long-term observations [22–24]. However, up to now, none of the treatments used for VV removal is free from recurrence in the follow-up period. The progression of the disease and incompetence of the veins/branches in the region of the saphenofemoral and saphenopopliteal junctions as well as neovascularisation and vein recanalization are the main causes for venous hypertension and varicose vein recurrence. Despite some differences in the pathology leading to the VV recurrence, both, surgical as well as minimally invasive treatments, are not free from the recurrence [25]. In a systematic review and meta-analysis of randomised controlled trials, where, among others, effectiveness and outcomes of EVLA and open surgery were compared, conducted by Kheirelseid in 2017, the rate of the patients requiring reintervention at 5 years or more follow-up visit was 23.6% in the EVLA group and 18% in the group of the patients underwent surgical treatment [26].

Another commonly used minimally invasive method in the treatment of VV is foam sclerotherapy (FS). Sclerosing agent administration leads to the injury of the endothelium and vein wall that results in fibrosis of the vein. Both liquid and foam sclerotherapy are commonly used around the world as well as present in the current guidelines [27–29].

The efficacy of EVLA in the treatment of VV can be improved by performing adjunctive FS of the tributaries. The combination of EVLA and FS is an effective method of reducing the rate of reinterventions in VV patients with saphenous vein incompetence [30]. A randomized clinical trial conducted in the United Kingdom on 798 patients revealed that 31% of patients who underwent only saphenous vein trunk ablation by EVLA and 38% of patients who underwent FS only, requested secondary procedures focusing on residual varicose veins (RVV) at six weeks follow up [31]. In the patients undergoing saphenous ablation, VV treatment (FS or mini phlebectomy) can be performed within the same procedure or as the delayed treatment. The argument for delayed treatment is the potential possibility of the VV regression (partial or complete) after saphenous vein ablation. On the other hand, saphenous ablation and varicose vein treatment within the same session result in fast and complete varicose vein removal without the need for additional procedures. Wang et al. compared outcomes of simultaneous saphenous vein EVLA with concomitant sclerotherapy together with EVLA alone. At 6 months follow-up EVLA-FS group had a significantly lower percentage of visible RVV that required reintervention as well as a smaller diameter of RVV than the EVLA-alone group. In terms of QoL EVLA-FS group presented better results than the EVLA-alone group [32]. However, combining EVLA with FS went with a significantly higher postoperative pain score at 4 weeks after treatment along with complications after the procedure including persistent ecchymosis, pigmentation and induration at 4 weeks and 6 months follow-up [32]. Nevertheless, there is no consensus regarding the optimal timing of performing FS after EVLA of the GSV trunk and because of many diversified scientific reports there are still different approaches to this problem in phlebological centres around the world [33]. Since the timing of adjunctive FS after EVLA procedure in the treatment of VV associated with GSV incompetence is a topic of open debate among surgeons, this study is a review that compares concomitant and staged treatments of VV.

Simultaneous treatment (EVLA + varicose veins treatment within one session)

The main circumstance that supports the concomitant approach is that it significantly reduces the need for secondary interventions as well as improves Qol [34]. Additionally, patients always expect visible cosmetic effects after the first operation and they would rather want to have their incompetent veins occluded at a one-visit procedure than prolonged staged treatment [32]. Ylimaz et al. in a study involving 504 patients described some advantages of simultaneous treatment of VVs with the use of EVLA and ultrasound-guided foam sclerotherapy (USGFS). First of all, treating the incompetent vein and varicose tributaries at the same time decreases the total duration of the treatment and its costs, because sterile materials used for EVLA can be also used for the USGFS in the same session. Additionally, the amount of foam needed to perform USGFS is reduced due to the smaller diameter of varicose veins after tumescent anaesthesia application. Concomitant treatment also reduces the total time of required compression therapy in comparison with the staged approach, which is beneficial for patients [35]. The authors also mention the facts that RVV that are left untreated after EVLA can become clotted as a result of stasis of blood what may hinder further secondary interventions. Finally, repositioning of the foam from treated tributaries to ablated truncal vein escalates the effect of the ablation and makes it even more permanent [35]. Contrarily to the above, there are also concepts supporting deferred treatment of the tributaries after the first-stage procedure. Some authors suggest that staged treatment allows the regression of the VV and consequently reduce the range and need for secondary interventions [34].

In a randomized clinical trial conducted by Lane et al. 50 patients underwent EVLT with concomitant FS and 51 underwent EVLT and the FS was deferred [36]. Comparison of the outcomes of these two groups revealed significant improvement of venous clinical severity score (VCSS) in the group of simultaneous treatment at 6-weeks, 6-months and 1-year follow-up as well as a significant difference in Qol measured by Aberdeen Varicose Vein Questionnaire (AVVQ) at 6 months follow up in favour of the simultaneous treatment. The reintervention rate was only 2% after concomitant treatment vs. 36% after delayed procedure. Although both groups presented significant improvement in symptoms, it was explicitly greater in the concomitant one [36]. Mohamed et al. performed a prospective study that compared concomitant and staged treatment of VV with the use of endovenous mechanochemical ablation (MOCA) and phlebectomy. The main finding of this study is that although concomitant treatment of the tributaries relates with significantly higher peri-operative and postoperative pain scores, there is better alleviation regarding symptoms and a lower rate of complications than staged treatment. Moreover, the simultaneous treatment went with a significantly lower need for secondary interventions than the sequential approach (4% vs. 18%) [37]. Interestingly, the authors observed that in terms of Qol, patients who underwent staged treatment for GSV incompetence required up to one year to reach approximate AVVQ scores as those patients, who were treated simultaneously with MOCA and phlebectomy [37].

Obi et al. conducted an analysis involving 979 patients undergoing simultaneous or staged procedures including RFA and adjunctive phlebectomy due to VV and CVD. The VCSS and CEAP scores of the patients included in this study reflected a significantly advanced level of the disease. The most prominent improvement in VCSS was noted in the concomitant group in comparison to the group, in which RFA was performed alone ($p = 0.019$). The authors' observation implies that in patients with moderate to the severe status of the disease, concurrent clearance of symptomatic VV after GSV ablation leads to preferable alleviation of the disease reflected by VCSS [38]. Nonetheless, there was a small, but a significantly higher rate of post-procedural complications including hematomas and superficial venous thrombosis in patients, where phlebectomy were performed directly after RFA [38]. This slight, significantly higher rate of minor complications after the concomitant approach is also supported in other studies [33, 37]. Results of another study indicate that although at 4 weeks follow-up, the improvement in Qol in the group of patients undergoing concomitant EVLA and FS was worse than in the EVLA-alone group, general efficacy of simultaneous tributary FS was higher [32]. This worse Qol rate in the concomitant group is associated with the fact that FS leads to a higher incidence of postoperative complications in comparison to EVLT alone, such as skin hyperpigmentation, skin necrosis, phlebitis, transient lymphedema, which could be connected with increased pain scores [8, 31, 32]. Wang et al. observed that these complications of FS are a reason for decreased Qol at 4 weeks after the procedure in comparison to the EVLA-alone group. However, this predominance of EVLA-alone group regarding Qol lasted up to 6 months after the procedure, and then simultaneous treatment started to present better Qol improvement [32]. In a comparative study conducted by Brown et al. outcomes of truncal ablation of incompetent GSV with or without adjunctive phlebectomy were compared. This study involved 3375 patients with documented C2 disease assessed with CEAP classification. In a multivariable analysis for predictors of VCSS improvement, ablation combined with concomitant phlebectomy presented significantly higher odds of such improvement in comparison to ablation of GSV alone (OR 4,12; 95%CI, 296–5,75) [39]. Postprocedural complications including heaviness, achiness, swelling, throbbing, itching, pain and impact on work were significantly lower in patients who underwent ablation alone. However, total improvement in postprocedural symptoms was significantly lower in the ablation-only group in comparison to patients treated with ablation and phlebectomy concomitantly [39].

In the most recent meta-analysis and systematic review regarding concomitant vs staged treatment of VV conducted by Aherne et al., fifteen studies were included for analysis. In terms of reintervention, concomitant treatment was associated with a significantly lower rate of secondary procedures (6.3%) in comparison to the group of patients treated with staged approach (36.1%) [33]. In terms of QoI, this analysis revealed better results in the concomitant group early after the procedure but this superiority over staged treatment was lost by 3 months follow up [33, 36].

Staged treatment

Although there are a lot of circumstances favouring concomitant treatment of VV that are mentioned above, many authors and surgeons support deferred treatment of the tributaries after the initial procedure. This idea is supported by the fact that staged treatment allows residual tributaries to diminish after ablating GSV trunk without any adjunctive procedures after a primary intervention. Although the varicose regression is incomplete in at least 36.1% of patients undergoing staged treatment, this approach not only is more time effective regarding the initial procedure, which is approximately 20 minutes shorter than simultaneous treatment of tributaries but also reduces the range of required secondary interventions in the future [33].

Kawai et al. performed an analysis of 954 limbs where a group of patients that underwent simultaneous phlebectomy after EVLA was compared with patients that received EVLA-alone treatment. The authors observed no significant differences regarding the rate of required additional sclerotherapy after initial treatment between the phlebectomy and non-phlebectomy groups. According to these results, the authors suggest a strategy to avoid simultaneous treatment of the varicose tributaries during the default EVLA [40]. Interestingly, the results of logistic regression included in this study also showed that female sex is a significant factor of future required additional sclerotherapy after the initial procedure [40].

In a study conducted by Monahan, the author observed that treating GSV incompetence with EVTA only without adjunctive procedures resulted in 13% of complete VV resolution after RFA-alone, however, 88.7% of VV decreased in size. These results support the idea that elimination of the source of venous hypertension may lead to alleviation of the visible superficial varicosities and consequently decrease the need, cost and time regarding secondary intervention or even, in some cases eliminate the necessity of adjunctive treatment at all [41].

The same approach is also supported and recommended by Welch who reviewed retrospectively 184 initial RFA procedures. At a 9-month follow-up, he observed that 62.1% of patients who underwent treatment for GSV incompetence with RFA only did not require further treatment of VV. Owing to this result, the author suggests that as most of the patients present clinical improvement after primary treatment of incompetent GSV, it is reasonable to wait several months and reassess the need for secondary interventions after initial treatment of VV[42]. Likewise, Weiss et. Al. observed that some patients who presented VV and were treated with radiofrequency ablation (RFA) of the GSV without any adjunctive procedures of the tributaries, the endovenous occlusion method was highly successful with a 90% rate of complete disappearance of treated GSV as well as patients demonstrated reduced or minimal VV at 2-years follow-up. That vanishing of VV without any direct intervention may occur in non-severe cases as a result of the elimination of venous hypertension and reflux [43]. Onida et al. added an important argument to this debate suggesting that an influential number of patients that are treated with a concomitant approach are over-treated as their VV may regress. Moreover, both EVLA and RFA seem to save 30–40% of patients with VV and GSV incompetence from not necessarily adjunctive procedures [44]. Theicumvar et al. delivered important observations regarding concomitant and staged treatment of VV. In his study standard different treatment methods of GSV incompetence were compared including above-knee EVLA (group A), above and below-knee EVLA (group B) and above-knee EVLA with concomitant below-knee FS (group C) [45]. In terms of superficial venous reinterventions, there was a slight superiority of concomitant treatment over deferred approach when results of groups A and B were considered collectively as one group of patients undergoing staged treatment (36% vs. 39%) [33]. If all three groups were considered separately, however, additional sclerotherapy was required in 61% of patients in group A, 17% in group B and 36% in group C and these differences were highly significant. These results show that longer length EVLA of incompetent GSV from the lowest point of reflux to groin not only could be more effective than above-knee EVLA only but also more effective than above-knee EVLA combined with adjunctive sclerotherapy of the below-knee varicose tributaries [45]. In terms of QoI reflected by AVVQ at 6-weeks follow up, there was a significant improvement in all three groups in comparison to the score taken before the initial procedure with the highest percentage improvement in group B (84.2%) vs. 55.4% in group A and 72.8% in group C [45]. It is worth mentioning not a frequent but potentially dangerous complication of EVLT which is endovenous heat-induced thrombosis (EHIT). It may occur during endovenous ablation of the insufficient superficial vein when it comes to propagation into the deep venous system [46]. Hicks et al. compared the concomitant approach using RFA and phlebectomy with a deferred approach concerning EHIT occurrence after the procedure. The authors observed a significantly lower rate of EHIT in patients treated with RFA only as a primary treatment in comparison to patients undergoing simultaneous RFA and phlebectomy (5.8% vs 14.1%)

[46]. As for deep venous thrombosis (DVT) related to the concomitant and staged approach different studies suggest that the risk ratio favours the staged approach, however, there are no significant differences between these two groups so far [33, 47].

Recurrence of VV after initial treatment

Recurrent varicose veins are a common problem occurring in patients undergoing not only surgical treatment of CVD but also with endovenous techniques. Various constitutional risk factors may increase the probability of developing recurrent VV including female gender, obesity, numerous pregnancies and pregnancies following VV treatment, severe CVD (C4–C6) and comorbid deep vein incompetence [48]. El Sheikha et al. described clinical recurrence of VV at 5 years follow up in groups of patients treated with EVLA and concomitant phlebectomy or EVLA alone as an initial treatment. It came out that the most frequent reason for clinical recurrence of VV was the development of new reflux into superficial veins including mostly anterior accessory vein and also Giacomini vein and non-axial tributaries [34]. De Maeseneer emphasises the role of persistent incompetence of saphenofemoral junction after initial treatment which may cause propagation of the reflux into the anterior accessory vein and further down, resulting in RVV on the anterior thigh [48]. Recurrence of VV may also be associated with recanalisation of the ablated venous trunk. Van der Velden reported several independent predictors of GSV recanalisation after initial ablation such as sex, clinical class, SFJ reflux, GSV diameter, length of treated vein, type of the device used for treatment and amount of the energy delivered into the vein lumen [49]. It is also possible that neovascularisation involving multiple small vessels that may develop directly around the ablated GSV and penetrate the vein wall are responsible for recanalisation and recurrence after EVLT. Such a phenomenon occurred in 5% of ablated GSV trunks [50].

Conclusion

It seems that there is no obvious consensus on which approach, concomitant or staged, is definitively better in the treatment of VV. Although recent scientific reports suggest slight supremacy of concomitant treatment over the staged one, there are a lot of valid arguments in favour of staged treatment of VV including that a lot of patients are over-treated with a concomitant approach. It is wise to base the decision regarding the treatment method on individual patients' characteristics and risk factors predisposing them to VV recurrence. It may be reasonable to put an inquiry to this debate what groups of patients are most suitable for each approach and what factors could help to choose the most beneficial method and improve the long-term success rate of VV treatment.

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