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New methods of varicose veins treatment

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Abstract

Chronic venous disease may affect even 60% of the population. Manifestation of this condition may vary from no symptoms to an active venous ulcer. The treatment of this disease may improve patient's quality of life. A large number of new studies have been carried out since the guidelines publication of the Society for Vascular Surgery, American Venous Forum and European Society for Vascular Surgery considering chronic venous disease treatment. There is also available a 2 year follow-up of the study described in the guidelines. New non- thermal techniques like Mechanochemical ablation (MOCA) and Cyanoacrylate closure (CAC) are very effective, less painful and safe. The use of endovenous non- thermal ablation techniques doesn't require tumescent anaesthesia which works as a heat sink protecting surrounding tissues from damage in thermal techniques. This eliminates the risk of bleeding and pain associated with multiple needle injections along the vein section to be treated. New studies show that MOCA and CAC techniques have high closure rates directly after the procedure and in the follow-up periods.

Background

Chronic venous disease is a widespread medical condition. It occurs even in 60% of the population in developed countries. The manifestations of this disease are varicose veins, which

are dilated veins (3mm or more in the upright position). Symptoms of this condition cause a significant worsening of the quality of patients' lives. Patients with varicose veins of the lower limbs feel leg heaviness, fatigue, itching, night-time contractions and leg pain exacerbated by prolonged standing. The symptoms are intensified by heat and resting or lifting legs brings relief. The disease usually affects great saphenous vein (GSV) and short saphenous vein (SSV) [1, 2].

The classification used for the evaluation of chronic venous insufficiency is Clinical Etiological Anatomical Pathophysiological classification (CEAP). This scale takes into account clinical (C), etiological (E), anatomical (A) and pathophysiological (P) aspects of disease. Considering the clinical symptoms, we can assign the patient to C0-C6, where C0 is when there are no visible or palpable signs of venous disease and C6 is the presence of the active venous ulcer [2].

The most important tool used in diagnostic is Duplex ultrasound (DUS). DUS examination can easy detect valvular incompetence. It has a highest recommendation as a diagnostic test of the 1st choice [1, 2].

Treatment

Guidelines considering chronic venous disease of the Society for Vascular Surgery, American Venous Forum were published in 2011 and guidelines of the European Society for Vascular Surgery were published in 2015. Since then, there were reported many new studies. In both guidelines beside old surgery treatment there are described mainly endovenous thermal ablation techniques and there is lack of information about new endovenous non-thermal ablation techniques: mechanochemical ablation (MOCA) and injection of cyanoacrylate glue [1, 2].

Sclerotherapy is a non-thermal percutaneous technique involving injection of chemical agents like glycerin, hypertonic saline, polidocanol, sodium tetradecyl sulphate (STS) or morrhuate sodium to damage the endothelium and ablate veins. The disadvantage of this technique is large number of varicose vein recurrence and potential dangerous side effects like skin necrosis, allergic reactions to chemicals and pulmonary or cerebral embolism [1, 2]. In randomized clinical trial published by *Rasmussen* et al. foam sclerotherapy was associated the most with the recurrent varicose veins (16.3%). It was significantly more than after laser (5.8%), radiofrequency (4.8%) and surgery treatment (4.8%) [3]. The guidelines do not recommend sclerotherapy as a first choice treatment [1, 2].

Endovenous thermal ablation (EVTA) such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are recommended in preference to surgery or foam sclerotherapy. The use of endovenous thermal ablation techniques requires tumescent anaesthesia. Injected liquid in addition to anaesthetic effect, works as a heat sink protecting surrounding tissues from damage [1, 2]. However tumescent anaesthesia carries a risk of bleeding and pain and requires also multiple needle injections along the vein section to be treated. Despite its use, there may be side effects associated with heat release. These include skin burns, prolonged pain or neuralgia [4]. Patients treated with EVTA have less pain than those who were treated with surgery. The wound infection also occurs much rare in EVTA group than in surgery (0% vs. 2-6%). Endovenously treated patients recover much quicker and are able faster go back to work than those who were treated with surgery [2]. Endovenous laser ablation is performed with the percutaneously placed laser fiber. Laser cause a heat injury to the vessel endothelia, resulting in vein occlusion. Laser also does thermal destruction of the blood in the vessel. Older, lower laser wavelengths (810, 940 and 980 nm) target hemoglobin with unequal energy delivery. Higher wavelengths lasers (1320, 1470 and 1500 nm) aim water and are much more specific [1, 2]. New EVLA devices containing radial-tip fibers (RTFs) are operating at up to 1470 nm wavelengths and are less traumatic than the old ones [5].

RFA technique operates on a similar basis. The percutaneous device heats and destroys vessels wall throughout the thermal energy delivered by radiofrequency. Studies show that patients treated with RFA feel less pain than those treated with EVLA [1, 2].

Cyanoacrylate glue

Cyanoacrylate closure (CAC) is a new non-thermal technique of treating varicose veins. The strength of the technique is that no heat is used, which eliminates the risk of complications such as burns or neuralgia. It also doesn't require tumescent anaesthesia. There is no need for many needle punctures, which reduces the pain felt by the patient [2].

Guidelines of the Society for Vascular Surgery, American Venous Forum contain no citation regarding use of cyanoacrylate ablation and guidelines of the European Society for Vascular Surgery contain only one citation concerning first human use of cyanoacrylate glue for treatment of great saphenous vein incompetence [1, 2]. Currently there is available a 2 year follow-up of the same study. After 24 months post treatment occlusion rate of the great saphenous veins was 92.0% and technique was described as safe and effective [6].

In study published in 2016 by *Bozkurt* et al. 310 patients were divided into 2 groups. One was treated with cyanoacrylate ablation and second was treated with endovenous laser ablation. The procedure time was shorter (15 ± 2.5 vs. 33.2 ± 5.7, $p<0.001$) and closure rates at 12 months were higher (95.8% vs. 92.2%) in cyanoacrylate group. Also periprocedural pain reported by patients was less in the same group [7]. In study published in 2018 among 50 patients who were treated with cyanoacrylate glue, no signs of recanalization were observed in 47 patients (94%) after one year [8]. In 2017 *Lam* et al. published an expert review on the cyanoacrylate glue. They considered this technique as safe and efficacious [9]. Other review published in 2018 by *Bissacco* et al. analysed 7 studies with total of 1000 limbs treated with cyanoacrylate glue (Variclose® system). This technique was safe and effective in treatment of GSV incompetence. The occlusion rates were 97.3% at six months, 96.8% at one year and 94.1% at 30 months [10]. Another study published by *Yasim* et al. involved 180 patients with saphenous vein insufficiency. Cyanoacrylate glue ablation with VariClose device was effective. During the follow-up (mean time of 5.5 months) no signs of recanalization were observed [11]. In other multi-centre study, in which 180 patients took part, the total occlusion rate six months after treatment with the same device was 97.2% [12].

In 2018 scientists from Charm Vein Center in Korea reported successful treatment of recurrent varicose veins of 2.84 cm in diameter of great saphenous vein (GSV) using cyanoacrylate glue (VenaSeal system). This was reported first time use of this system to treat varicose vein with a diameter of more than 2 cm [13]. Cyanoacrylate ablation technique is also easy to learn for doctors. Studies show that cyanoacrylate closure is related to a short learning period for physician [14].

Mechanochemical ablation

Mechanochemical ablation (MOCA) is cited twice in the European Society for Vascular Surgery guidelines and not once in the Society for Vascular Surgery, American Venous Forum guidelines [1, 2]. This technique combines mechanical destruction of vessel endothelia by rotating tip of the catheter and chemical embolization with a liquid sclerosant drug [4]. It is also non-thermal treatment which eliminates the need for tumescent anaesthesia. MOCA is much more efficient than liquid sclerotherapy alone. The penetration of drug is increased and the level of endothelium damage is higher [15]. Studies show that mechanochemical ablation is less

painful than the radiofrequency ablation therapy. In the number scale of 0-10, median pain described by patients was 2 (0.5-4) in MOCA group vs. 3 (2-5) in RFA group, p=0.004) [16, 17].

In 2017 *Tang* et al. published early results of the study using mechanochemical endovenous ablation for treatment of varicose veins. This technique was safe and effective in the therapy of saphenous varices. Total occlusion rates were 97% (322/333) after GSV ablation and 100% (60/60) after SSV ablation [4]. Another study showed the importance of the chemical dose in mechano-chemical ablation. Anatomical success rate was significantly less when scientists performed mechano-chemical ablation with 1% Polidocanol liquid, than with 2% Polidocanol liquid (30.4% and 88.0% respectively, $p < 0.001$) [18]. A total of 121 Asian patients were followed up in study published in 2018 by *Hhor* et al. Three months after the treatment occlusion rates of great saphenous vein and short saphenous vein were 90.8% and 96.0% and after 1 year 84.8% and 94.3% respectively [19].

Meta-analysis, published in 2017 by *Vos* et al. included 15 articles up to year 2016. Overall results show that success of the treatment for MOCA was 94.7% at 6 months and 94.1% at 1 year [20]. In other meta-analysis, published in 2017, with total of 1521 veins, success rates of MOCA technique was 92% (95% CI 88–95%) after 6 months and 91% (95% CI 86–94%) after 12 months. After 2 and 3 years total occlusion rates were 91% (95% CI 85–95%) and 87% (95% CI 75–94%) respectively [21].

Conclusions

Chronic venous disease is a widespread medical condition. Appropriate treatment can improve the quality of life of patients. New studies maintain that endovenous techniques are better than surgery. Newer non- thermal techniques Cyanoacrylate closure (CAC) and Mechanochemical ablation (MOCA) are effective in therapy of varicose veins. These techniques do not produce heat, which eliminates the need for tumescent anaesthesia which is associated with pain reduction caused by multiple needle injections.

Studies show that patients treated with Cyanoacrylate closure feel less periprocedural pain that those treated with endovenous laser ablation. This technique is considered as safe and total occlusion rates are high. Moreover it is related to a short learning period for doctors.

Mechanochemical ablation technique combines mechanical destruction of vessel endothelia by rotating tip of the catheter and chemical embolization with a liquid sclerosant drug. MOCA is much more efficient than liquid sclerotherapy alone. This technique is less painful in comparing to radiofrequency ablation therapy. Studies also show high success of the treatment of this technique.

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