







ENDOVENOUS TREATMENT OF THE VARICES OF THE LOWER LIMBS. THERMAL ENDOABLATION BY RADIO FREQUENCY AND ENDOLUMINAL CLOSURE BY CYANOACRYLATE.

Spanish full text

Introduction: Chronic venous disease (CVD) is defined as any functional or morphological disorder of the venous system of long duration that manifests with symptoms and/or signs. The clinical presentation of CVD is variable, characterised by a variety of symptoms such as heaviness, tiredness, itchy skin, night cramps, palpitations and lower limb pain. These symptoms often interfere with activities of daily living and work, reducing patients' quality of life. The CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification developed by the American Venous Forum (AVF) includes, under the term chronic venous disease (CVD), various disorders ranging from telangiectasias to venous ulcers. The risk of CVD increases with age in both men and women, although in the latter the number of cases is always higher at any age. Thus, in Western European countries, the probability of CVD in the 18-34 age group was 38.4% in women and 14.3% in men, reaching 84.0% and 66.0% respectively in patients >65 years. Therapeutic management of CVD includes the use of appropriate medical treatment, intravenous therapies and surgical procedures, employed in this order when the previous measure is ineffective. Firstly, medical treatment, including overnight elevation, skin and wound care, topical emollients and compression stockings, aims to relieve symptoms and prevent disease progression. Endovenous techniques, where the most frequently used are endoluminal closure with cyanoacrylate (CA) and thermal endovenous ablation with radiofrequency (RFA) or laser (LA), produce ablation of the affected vein, through the induction of a thrombo-inflammatory reaction that eventually causes fibrosis and obliteration of the vein to be treated. The main difference between them is the use of tumescent anaesthesia in the latter two techniques in order to minimise the risk of damage to the saphenous nerve, given that they are thermal techniques. Finally, the most common surgical technique is conventional surgery consisting of ablation and ligation of the varicose vein, which may or may not be removed (stripping). This is performed under general anaesthesia and requires compression of the treated limb after the intervention.

Aims:

- To assess the safety and efficacy of radiofrequency thermal endovenous ablation in the treatment of varicose veins compared to other endovenous techniques or surgery.

- To assess the safety and efficacy of endoluminal closure with cyanoacrylate in the treatment of varicose veins compared to other endovenous techniques or surgery.

- To analyse patient perspectives and preferences for the endoluminal techniques covered in this report.

Methods: Specific search strategies were designed to identify studies assessing the efficacy and safety of endoluminal sealing with CA and endovenous thermal ablation with RFA, as well as patient









perspectives and preferences. These searches were carried out in August 2020 in the principal biomedical databases. The main characteristics and results of the included studies were summarised in evidence tables. Studyspecific tools were used to assess the risk of bias of the studies. Both the data extraction from the studies and the synthesis and assessment of the evidence were performed by two investigators independently and blindly.

Results and discussion: From the various literature searches, 14 assessment reports, 28 systematic reviews, 26 primary studies and 21 ongoing studies were identified. After reading the full text, 2 systematic reviews, 13 primary studies on safety and/or efficacy and 4 ongoing studies were included. Regarding the systematic reviews, one of them evaluates the clinical efficacy of endoluminal closure using CA, while the other one focuses on the evaluation of endovenous ablation using RFA. Of the included primary studies, 2 evaluate CA versus endovenous ablation by LA, RFA or surgery (with or without stripping) and 9 compare RFA versus LA or surgery (with or without stripping). As for the ongoing studies located, one of them aims to evaluate the efficacy of CA versus surgery (with or without stripping), while the other compares RFA versus surgery (with or without stripping). Of the various updates carried out up to the date of publication of this report, one systematic review has been located which, after reading the full text, has been discarded as it did not meet the inclusion criteria. Finally, 63 studies including evaluation reports, systematic reviews and/or metaanalyses and primary studies have been excluded. The main reasons for exclusion were due to the comparator used or because they were studies without a comparator group and/or not randomised. Based on the evidence reviewed, the main clinical outcomes of the endoluminal techniques evaluated are summarised below:

- Both CA sealing and endovenous ablation with RFA had an occlusion rate (60-90%) and survival free from renacalisation (90%), evaluated in the long term (36-60 months) no lower than the comparison techniques (RFA or LA in the first case and LA or surgery in the second).

- No significant differences in clinical severity and quality of life were reported in patients treated with CA or RFA compared to the comparator group (RFA or LA and LA or surgery respectively) (up to 60 months), with both groups showing an improvement over baseline values.

- Based on published evidence, CA sealing or endovenous ablation with RFA does not appear to be associated with an increased rate of major adverse events (pulmonary thromboembolism or deep vein thrombosis) or minor adverse events (pain, phlebitis, ecchymosis, cyst, scarring, etc.). A higher rate of paraesthesia in patients treated with AC compared to LA in the first week of treatment was only reported in one ECA (this difference disappeared after 3 months). Other events such as pain, induration or ecchymosis were more frequent in patients treated with LA compared to CA, but these differences were perioperative (1 week) and disappeared by 3 months of follow-up. Finally, only one ECA observed a lower rate of lacerations in patients treated with RFA compared to surgery, and another observed a marginally significant difference in the frequency of thigh bruising in favour of RFA. In addition, the studies reviewed showed that the procedure time of CA sealing was shorter than that of thermal endovenous ablation techniques (RFA or LA), while the recovery and return to daily activities/work of the patient treated with CA was similar to the group treated with EVA, but shorter than the group treated with LA. Furthermore, no differences were found between RFA or LA with respect to the









aforementioned variables. However, the evidence seems to suggest that endovenous ablation by RFA has a shorter intervention and patient recovery time than varicose vein surgery.

- Three of the RCTs reviewed found that the level of satisfaction of patients treated with CA or RFA was between 80-99%, with most patients expressing a willingness to undergo reintervention if necessary.

Conclusions: The published evidence on efficacy and safety seems to suggest that both CA sealing and endovenous ablation via RFA are not inferior to their comparators, i.e. thermal techniques (RFA or LA) in the first case, and LA or surgery in the second. However, it should be noted that the lack of systematic collection of adverse events associated with their use may have biased the results shown in the studies, thereby reducing their consistency. The duration of CA intervention was shorter than thermal endovenous ablation techniques (RFA or LA), and the recovery time was similar to RFA, but shorter than LA. Furthermore, no differences were found between RFA or LA endovenous ablation with respect to these variables. Compared to varicose vein surgery, the evidence seems to suggest that RFA

