Prospective Study of a Single Treatment Strategy for Local Tumescent Anesthesia in Muller Phlebectomy

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Background: Ambulatory Muller phlebectomy for varicose veins can be performed under local anesthesia. However, subcutaneous injection of local tumescent anesthetics may cause discomfort because of acidity of the solution. Addition of sodium bicarbonate lowers the acidity of anesthetic solutions, which might cause less pain. The objective of this study was to study whether alkalinization of the local anesthetic solution with sodium bicarbonate 1.4% decreases perioperative pain during Muller phlebectomies.

Methods: It is a double-blind single-center randomized controlled trial. In all, 101 patients scheduled for ambulatory Muller phlebectomy were randomized to receive either local anesthesia with alkalinized solution (lidocaine 1% and epinephrine in sodium bicarbonate 1.4%) or standard solution (lidocaine 1% and epinephrine in saline 0.9%). Primary outcome was pain during injection of local anesthetics with the use of the Visual Analogue Scale (VAS). Secondary outcomes were peroperative and postoperative pain, use of analgesics, patient satisfaction, return to function, and complications.

Results: Patients receiving subcutaneous injection of local anesthetics diluted in sodium bicarbonate 1.4% experienced significantly less pain during injection compared with patients treated with standard anesthetic solution (VAS, 1.75 ± 1.8 vs. 3.55 ± 2.2, $P < 0.00$). Peroperative and postoperative pain, complication rates, use of analgesics, patient satisfaction, return to function, and complications did not differ between the 2 groups ($P > 0.10$).

Conclusions: Alkalinization of local anesthetic solution with sodium bicarbonate 1.4% significantly improves patient comfort during injection of local tumescent anesthesia.

INTRODUCTION

Varicosis has a prevalence between 10% and 50% and is a common health problem in Western countries.[1–3] Known risk factors for developing varicose veins include age, sex, positive family history, and pregnancy. Patients may be asymptomatic or experiencing pain, tenderness over varicose veins, heavy legs, ankle edema, skin changes, or venous ulcers.[4] Varicosis has a large impact on society and therefore plays a major part in everyday practice of general practitioners and specialists treating venous disease.[5]

Possible treatments for varicosis differ from conservative compression therapy to minimal invasive surgery such as sclerotherapy, laser therapy, or

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phlebectomy. Because of the time-consuming nature of ambulant phlebectomy, physicians may prefer sclerotherapy as a standard therapy.[5] Nonetheless, according to de Roos et al.,[5] ambulant phlebectomy is the first choice of treatment because of lower recurrence rates, higher patient satisfaction, and probably higher cost-effectiveness.[5]

Muller phlebectomy consists of removing varicose veins through a 1−2-mm incision with a phlebectomy hook. Performing this in ambulatory setting requires local anesthetics. Social and economic advantages are accomplished because of the lack of sedation, making it possible to perform varicose surgery in external ambulatory surgery centers.[6] Drawback of this method is peroperative and postoperative pain, which is often not optimally controlled with standard local anesthetics.

Local tumescent anesthesia (LTA) is frequently used in plastic surgery and dermatology for ambulant phlebectomy and is proven effective for pain relief.[7,8] LTA is the preferred method for performing varicose vein surgery, especially Muller phlebectomy.[7] Routine LTA solution consists of epinephrine 1: 100.000 and lidocaine 1% diluted in saline solution 0.9%. It is hypothesized that epinephrine causes vasoconstriction resulting in a reduction of blood flow, which induces pain reduction.[8] Prolonged duration of anesthesia and delayed resorption are obtained; however, caution is needed because of a late plasma peak.[8] Lidocaine has a maximum dosage for safety reasons, preventing lidocaine overdose.[8]

In the authors' observation, pain is not routinely controlled during and after LTA. It is suggested that this poor pain control results from an increase in hydrogen ions in the local tissue environment. Because of acidity of lidocaine, nociceptors are activated, leading to higher pain sensation.[9] Diluting LTA in sodium bicarbonate in a low concentration is proposed to neutralize lidocaine acidity. Creton et al.[7] stated that adding sodium bicarbonate 1.4% to local anesthetics enables surgeons to use less lidocaine epinephrine. Moreover, it is supposed to cause less painful injections because of immediate and deeper anesthesia.[4,7] Using sodium bicarbonate for dilution facilitates surgery by eliminating onset time and using less amounts of lidocaine.[7] Furthermore, it has been hypothesized that application of large amounts of diluted LTA would result in sufficient anesthesia in subcutaneous tissues for local superficial surgery, subsequently, reducing peroperative and postoperative pain.[8]

The aim of this double-blind randomized controlled trial was to examine whether alkalization of local tumescent solution results in a significant reduction of peroperative and postoperative pain compared with standard LTA solution in patients undergoing ambulant Muller phlebectomy. Secondary outcomes are use of analgesics, complications, patient satisfaction, and time to full recovery of functionality. Our hypothesis is that addition of bicarbonate to LTA will reduce peroperative pain as measured by Visual Analogue Scale (VAS) by 50%.

METHODS

Patient Selection

In the period from March 1, 2013, to March 16, 2014, 101 patients were included in our outpatient clinic in the South of the Netherlands, based on the following inclusion criteria: aged older than 18 years and indication for ambulant Muller phlebectomy. CEAP classification: C (clinical classification), 3−4; E (etiological classification), all primary chronic venous insufficiency of undetermined cause, anatomical segment localization AS2−4 (great or small saphenous vein); and P (pathophysiological classification), reflux. Exclusion criteria were allergy for local anesthetics, acute diseases, chronic kidney or liver failure, analgesics treatment, treatment with monoamine oxidase inhibitors or tricyclic antidepressants, psychiatric illness according to the Diagnostic and Statistical Manual of Mental Disorders-IV classification criteria, and alcohol abuse. All patients were screened preoperatively with duplex of the superficial and deep venous system, excluding deep venous insufficiency or deep venous thrombosis. Furthermore, reflux or insufficiency of the greater saphenous vein and small saphenous vein was determined. The size of all treated varicose veins was >3 mm, none of the patients had recent deep venous thrombosis and none of the treated varicose veins had connection with insufficient perforator veins.

Study Design

The present study was approved by the Local Medical Ethics Committee Atrium-Orbis and is registered as trial NTR 4534. All interventions and analysis were performed at our teaching hospital in the South of the Netherlands. All patients who met the inclusion criteria received verbal and written information about the study. After informed consent, patients received a randomization number and were electronically randomized into 2 groups by a computer generated list: group 1 (intervention) LTA using lidocaine chlorohydrate 1% with epinephrine in sodium bicarbonate 1.4% (4 mL lidocaine chlorohydrate 10 mg/mL with epinephrine 5 μg/mL with