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Strategy to prevent nerve injury and deep vein thrombosis in radiofrequency segmental thermal ablation of the saphenous veins using a new objective pain scale

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Abstract

Objective: We evaluated the benefit of local anesthesia including tumescent anesthesia and active walking soon after surgery in preventing nerve injury and deep vein thrombosis caused during endovenous ablation.

Methods: Endovenous ablation was performed in 1334 consecutive patients. Varicectomy was performed using the stab avulsion technique. After surgery, patients were encouraged to walk 100–200 m inside the ward for 3–5 times/h. The pain was evaluated objectively using the Okamura pain scale and subjectively using the numerical rating scale.

Results: Stab avulsion was performed at 11.8 ± 8.0 sites and the mean operative time was 33.9 ± 15.2 min. The mean Okamura pain scale and numerical rating scale scores were 1.6 ± 1.3 and 3.0 ± 2.0, respectively. Deep vein thrombosis and pulmonary embolism were absent. The incidence of nerve injury was 0.3%.

Conclusions: Endovenous ablation should be performed with the patients under local anesthesia to prevent nerve injury and deep vein thrombosis.

Keywords

Varicose veins, endovenous ablation, nerve injury, deep vein thrombosis, objective pain scale

Introduction

Endovenous ablation (EA) is currently used as a treatment method for saphenous vein insufficiency. Most endothermal procedures have been developed to be performed under tumescent local anesthesia (TLA).[1] However, general anesthesia and peripheral nerve blocks with sedation pose risks such as post-procedural delay in discharge, prolonged immobilization, and deep vein thrombosis (DVT).[2] Appropriate treatment strategies are therefore needed to prevent nerve injury and DVT associated with EA. We perform all our surgical procedures on patients under local anesthesia including TLA and careful intraoperative pain management. We have studied the effectiveness of this strategy to avoid complications.

We also developed the Okamura pain scale (OPS)[3] to evaluate the effectiveness of pain relief. This scale makes it possible to objectively and semi-quantitatively evaluate pain related to medical procedures in real-time in a way that was not possible before. We also evaluated the usefulness of the OPS in varicose vein surgery as it allowed us to consider the causes of pain, take

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remedial measures swiftly, and also verify their effectiveness.[3] However, the study population appeared too small to evaluate rare complications such as nerve injury and DVT and pulmonary embolism (PE). The present study included a sample volume three-fold higher than the previous study and could therefore help evaluate rare complications. OPS is currently reported as a tool for the objective assessment of various types of pain associated with medical procedures in real-time.[4]

This study aimed to evaluate the merits of local anesthesia and active walking soon after surgery to prevent nerve injury and DVT. The presented findings may be of substantial interest for a range of physicians, including interventional cardiologists.[5]

Methods

Ethics statements

This study was performed in accordance with the principles of the Declaration of Helsinki. The experimental protocol of this study was approved by the Institutional Review Board of Okamura Memorial Hospital (approval number: A020-002). Additionally, informed consent, as well as publication consent, when applicable, was obtained.

Study population

We included a total of 1334 patients who underwent EA between December 2014 and August 2020. The inclusion criterion was a diagnosis of symptomatic primary varicose veins with Clinical-Etiology-Anatomy-Pathophysiology (CEAP) class 2–6, requiring correction of venous reflux (>0.5 s), assessed using venous duplex ultrasonography. The exclusion criteria were secondary varicose veins, a history of DVT, and the use of hormone medications.

Basic treatment methods at our institution

In principle, patients were admitted overnight to prepare for the risk of bleeding and to allow for ambulation under control, and in all cases, one leg was treated at a time under local anesthesia. If both lower limbs required treatment, the opposite side was treated approximately a month later. Patients were instructed to quit smoking for at least two months before surgery. A Closure Fast (Covidien, Tokyo, Japan) radiofrequency catheter system with a shaft diameter of 7 Fr and generator was used, and the standard methods were followed.[6] The great saphenous vein was not ablated on the peripheral two-thirds of the lower leg and was instead preserved. The small saphenous vein was ablated within from the back of the knee line to about one-half of the proximal side. The stab avulsion technique[7] was used for varicose vein resection, including for perforator vein insufficiency.[3] If patients regularly consumed anticoagulants or antiplatelet drugs and if withdrawal was not possible, stab avulsion was not performed. DVT prophylaxis adhered to the EA guidelines.[8]

The following measures were taken to alleviate intraoperative pain.

1. Hydroxyzine (Atarax P® 6.25–12.5 mg) was administered slowly via an intravenous drip for mild sedation. The patient wore two pairs of pants (disposable shorts and trunks) to reduce discomfort. The music and room temperature in the operating room were adjusted to help the patient relax, and the sound of the electrocardiography monitor was turned down.
2. Because the main trunk of the saphenous nerve is often in close proximity to the great saphenous vein (GSV) in the peripheral one-third of the lower leg, GSV was marked using echography preoperatively to avoid saphenous nerve injury. Sufficient TLA fluid (40 mL of 1% lidocaine with epinephrine and 500 mL of saline and prepared with 20 mL of sodium bicarbonate; adjusted to 0.1% lidocaine) was injected to avoid traction pain caused by varicectomy. Varicectomy was also performed carefully, distal to the marking. Varicectomy was not performed directly above the small saphenous vein along the course of the peroneal nerve and lateral to the lower leg and peripheral to the ankle joint.
3. Xylocaine jelly was applied twice to the site of the planned local anesthetic injection (approximately 5 g each while the patient lay in bed and after the surgeon performed disinfection).
4. A 32-gauge needle (React Systems, Osaka, Japan) was used to administer local anesthesia.
5. To avoid cold pain stimulation, 1% lidocaine for local anesthesia and TLA solution were heated in a warming cabinet set at 40°C before use.
6. TLA at the varicectomy sites was injected slowly in two different ways (first, along the blood vessels and second, three-dimensionally just before varicectomy).

Intraoperative pain was objectively assessed using the OPS (0, calm expression; 1, grimace; 2, body movement; 3, complaints of pain; 4, repeated complaints of pain; 5, continuation of the procedure is difficult or inhaled/intravenous anesthesia is added). The numerical rating scale (NRS)[9] score (0–10) was assessed postoperatively and compared with the objective pain rating. Each painful procedure was evaluated over time, with the highest value being the overall rating of the OPS. If an OPS score of 3 was present at two

or more locations, the overall rating was equivalent to a repeated pain complaint, an OPS score of 4.

In general, the intraoperative assessment of pain should be performed by nurses with adequate observation using OPS and recorded in the medical record. The patient's body movements and pain complaints can be recognized by the nurse and surgeon, and the cause of the pain should be examined. Once the cause of the pain is determined, pain should be managed. Postoperatively, the OPS and NRS scores should be compared, and improvements should be sought. By repeating this process, treatment procedures with less pain would become possible.

After surgery

The stab avulsion sites were covered with absorbent pads, elastic bandages, and stockings. A moderate pressure (30–40 mmHg) was applied over the bandages while paying attention to the development of peripheral nerve injury. If the operation (ablation and/or stab avulsions) were performed on the thigh, the area was lightly compressed with a elastic bandages and supporter only overnight.

Patients were encouraged to walk from the operating room back to the ward and continue to walk actively (100–200 m in the ward for approximately 3–5 times per hour) under observation by the medical staff and were advised to watch for bleeding after surgery. The patients were instructed to move their legs if they woke up during the night on the day of surgery, as they were at high risk of developing a PE in the morning on the first day after surgery.[10]

On postoperative day 1, the stab avulsion site was sealed using surgical tape and covered with a dressing (absorbent pads). The patient's leg was placed in elastic stockings below the knee and the patient was asked to walk for 300–500 m. Upon confirming the absence of bleeding, the patient was discharged from the hospital. The surgical tape was removed during the first outpatient visit after surgery, and oozing stab avulsion sites were once again sealed with surgical tape or covered with a hydrocolloid dressing.

Patients were asked to wear below-the-knee elastic stockings all day for one week postoperatively. Subsequently, they were worn only during the daytime for two weeks if edema occurred. This treatment continued until severe skin lesions, such as ulcers healed completely.

Primary endpoints were nerve injury and DVT. The patients were assessed routinely using clinical examination and venous duplex ultrasonography before the operation, at 1–5 days after the operation, and at 1 and 3 months after the operation.

Statistical analysis

Numbers are expressed as means ± standard deviations (minimum – maximum).

The correlation coefficient (Pearson) was used to relate the OPS and NRS. Medians were calculated using Microsoft Excel 2019, version 2005 (Microsoft, Redmond, WA).

Results

The patients' mean age was 66.6 ± 11.2 years (17–92 years), and there were 471 male and 863 female patients. The CEAP classifications were as follows: C2, 609 limbs; C3, 141 limbs; C4a, 418 limbs; C4b, 112 limbs; C5, 26 limbs; and C6, 28 limbs. The ablation sites were the GSV in 1,081 limbs, small saphenous vein (SSV) in 209 limbs, and GSV + SSV in 44 limbs.

The mean operative time for the 1,334 legs was 33.9 ± 15.2 (5–116) min. Stab avulsion was performed at a mean number of 11.8 ± 8.0 (0–54) sites. The mean ablation length was 27.9 ± 10.7 (3–59) cm, and the mean volume of the TLA solution used was 550.2 ± 164.8 (44–1160) mL. The only sedative was a preoperative dose of intravenous hydroxyzine 6.25–12.5 mg, and no additional medication was required. No additional inhalation or intravenous anesthesia was used.

The intraoperative pain scores on the OPS and NRS were 1.6 ± 1.3 (0–4) and 3.0 ± 2.0 (0–10), respectively. No patients had an OPS score of 5. Figure 1 shows a scatter plot. The correlation coefficient (Pearson) between the OPS and NRS was 0.4, which indicated a weak positive correlation. All patients were able to walk immediately after surgery. No additional sclerotherapy was given. No DVT or PE occurred. No postoperative anticoagulation was used except in one patient with class 3 endovenous heat-induced thrombosis (EHIT), who required a direct oral anticoagulant.

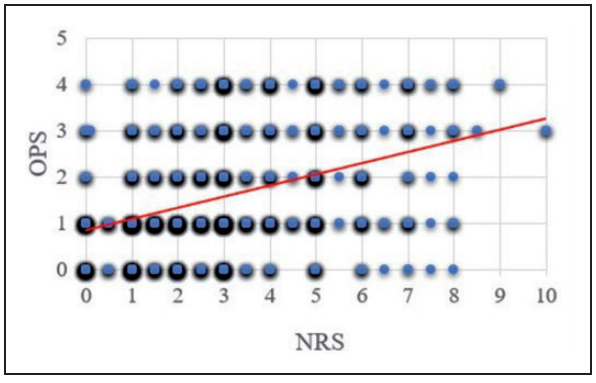

Figure 1. Correlation between the Okamura pain scale (OPS) and numerical rating scale (NRS). The correlation coefficient is 0.4. The results show a weak positive correlation on the scatter plot.

There were three cases of class 2 and none of class 4 EHIT. Four patients (0.3%) had sensory numbness in the distal part of the saphenous nerve (three cases) and around the incompetent perforating vein (one case). No sural nerve injury developed in this series after small saphenous vein ablation. After radiofrequency ablation, recanalization was noted in one patient (femoral, 3.5 cm of an incompetent perforator vein). No patient required hospitalization beyond a single night. However, several patients visited the outpatient department ahead of schedule because of bleeding; few of these patients even required suturing. In approximately one in 10–20 patients, there may be oozing to the outer sides of the elastic stockings after surgery, and in such cases, gauze may be applied from the outside to apply greater pressure. Fifteen patients (1.1%) used oral or intravenous antibiotics for suspected surgical site infection.

Discussion

In our retrospective analysis involving a total of 1334 patients who underwent EA under local anesthesia using the OPS, we did not observe any occurrences of DVT and PE. The incidence of nerve injury was 0.3%. These incident rates were lower than those reported previously.

DVT and PE associated with EA are rare complications, with the frequency of DVT and PE after EA in Europe and the United States being reported to be $< 0.5\%$ and approximately 0.1%, respectively.[11] However, with an increase in the number of cases, these complications are increasingly being reported,[12] with extremely rare incidences of fatalities.[10] The incidence of nerve injury is relatively high, ranging from 1 to 5%.[13] To prevent these serious complications such as nerve damage, it is important to operate the patients under local anesthesia. This helps avoid DVT by allowing them to walk immediately after surgery. However, effective intraoperative pain management is equally necessary.

Concerning anesthesia, propofol and dexmedetomidine are used as anesthetics; however, deep sedation can mask pain symptoms and inadvertently produce body movement. Intravenous anesthesia also involves problems related to respiration and circulatory depression. Small doses of fentanyl are difficult to administer because they are narcotic, and postoperative rest is necessary. Nerve blocks[14] are excellent for numbing pain, but immediate walking is difficult, and signs of nerve injury can be missed. In some hospitals with anesthesia departments, general anesthesia may be an option.

We used various pain management methods to complete the surgery in patients under local anesthesia. Hydroxyzine at 6.25–12.5 mg was used for light sedation. A double xylocaine jelly application method was devised. Xylocaine jelly was applied twice to the site of the planned local anesthetic injection. Local anesthesia was administered with reference to a recent report on dental anesthesia,[15] wherein xylocaine was heated, and an ultrafine 32-gauge needle (React Systems) was used. The TLA solution was heated to 40°C and removed from the warming chamber before starting the surgery.

The main trunk of the GSV in the peripheral one-third of the lower leg was marked. Varicectomy was performed carefully, distal to the marking, to preserve the saphenous nerve and prevent traction pain of branches from the main trunk of the GSV.

Because pain is a personal emotion,[16] adequate explanation during the outpatient and perioperative period is important for patients. It is also necessary for patients to relax, as anxiety, tension, and stress lower one's pain threshold.[17] In addition, talking to the patient, such as saying "You will receive a medication that will make you feel a little sleepy," "We will use the thinnest, gentlest needle," "We will use an anesthetic jelly to relieve the pain," and "Please relax your shoulders" can be helpful.

Various scales have been reported for the objective assessment of pain.[18] We devised a new OPS; OPS scores 0 (calm) and 1 (grimace) refer to the face scale. In the case of the painful stimulus, the body moves unconsciously with an escape reflex (OPS score 2). When the pain is intense, we say, "ouch!" (OPS score 3: complaints of pain). For unbearable pain, patients complained of repeated pain symptoms (OPS score 4). If patients complained of pain to the point of being unable to continue the surgery, additional inhalation or intravenous anesthesia was administered (OPS score 5). To compare with the subjective pain scale, patients were asked to rate their pain using the NRS postoperatively. The patients' mean OPS and NRS scores of 1.6 and 3.0, respectively, correlated positively but weakly, with a correlation coefficient of 0.4. An OPS score of 4 or higher should be considered as an indication of a possible nerve injury. Currently, the OPS has been reported in academia as a tool for the objective assessment of various types of pain associated with medical procedures in real-time.[4] We have previously used the OPS scoring system in other procedures as well (PCI, Pacemaker implants, etc.).

Intraoperative pain can be semi-quantified with the OPS and relayed to the surgeon for more accurate treatment. The pain can be due to anxiety, nervousness, injection of local anesthesia, TLA deficiency, or nerve traction. A less painful treatment is possible by assessing and treating the cause of pain.

Adequate ambulation immediately after surgery is effective for preventing DVT. Most patients will

remain in bed if not instructed to do so; thus, active ambulation should be encouraged, but under control. Simultaneous surgery on both lower extremities should be avoided because of the prolonged operation time and the possibility of postoperative gait restriction. There is also a possibility of xylocaine toxicity. Further, smoking cessation[19] is the first step of a medical procedure because smoking is an important risk factor for thromboembolism.[20]

This study has a few limitations. First, this was a single-center study, and therefore, might involve selection bias. Second, we did not compare the OPS to other objective pain scales. Thus, multicenter studies are needed to validate our findings.

Conclusion

To prevent nerve injury and DVT, it may be an option to assess patients' intraoperative pain over time with the OPS and perform surgery using local anesthesia, which allows for adequate ambulation during the immediate postoperative period.

Presentation information

This study was presented at the 49th annual meeting of the Japanese Society for Cardiovascular Surgery (July 2019, Okayama) as a panel discussion and at the 40th annual meeting of the Japanese Society of Phlebology (September 2020) on the web and as a symposium.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Informed consent

Informed consent, as well as publication consent, when applicable, was obtained.

Ethical approval

This study was performed in accordance with the principles of the Declaration of Helsinki. The experimental protocol of this study was approved by the Institutional Review Board of Okamura Memorial Hospital (approval number: A020-002).

Guarantor

KY takes the overall responsibility for the article.

Contributorship

KY and SM were responsible for study conception and design. KY, TY, SS, and MH collected the data. KY and SM performed the statistical analysis. KY, SK, and SE were responsible for analysis and interpretation of the data. KY and SM wrote the article. KY, SM, TY, SS, MH, SK, and SE together performed critical revision of the article. All authors reviewed and edited the manuscript and approved the final version of the manuscript. KY takes the overall responsibility for the article.

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