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Rivaroxaban for thromboprophylaxis after venous ablation with radiofrequency in the saphenous femoral and saphenous popliteal junction

Rivaroxaban para tromboprofilaxis después de ablación venosa con radiofrecuencia en la unión safenofemoral y safenopoplítea

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Abstract

Objective: *The objective of the study was to compare the prevalence of endovenous heat-induced thrombosis (EHIT) in thromboprophylaxis with rivaroxaban versus none thromboprophylaxis in ablation with radiofrequency (RF) ablation.* **Methods:** *A retrospective, observational design of cases and controls of patients with chronic venous insufficiency was reviewed after the procedure of truncal ablation with RF. Group 1 did not receive thromboprophylaxis after the surgery. Group 2 received 10 mg of rivaroxaban every 24 h for a 2-week period. The presence of EHIT was evaluated during the 3rd and 7th days of post-surgery.* **Results:** *Between January 2013 and December 2017, a total of 113 patients were evaluated with 132 procedures. As a result, we found a significant difference in the total of procedures in favor of thromboprophylaxis with rivaroxaban decreasing the EHIT by p ≤ 0.0031 and odds ratio 8.5 with a confidence interval of 95% (2.10-39.9).* **Conclusion:** *The use of rivaroxaban was effective in the thromboprophylaxis of EHIT in the venous ablation with RF.*

Key words: *Endovenous heat-induced thrombosis. Radiofrequency. Rivaroxaban. Thromboprophylaxis. Venous ablation.*

Resumen

Objetivo: *Comparar la prevalencia de trombosis endovenosa inducida por calor (EHIT, por su siglas en inglés) en la tromboprofilaxis con rivaroxaban en comparación a la no tromboprofilaxis en la ablación con radiofrecuencia.* **Métodos:** *Se realizó un diseño retrospectivo, observacional de casos y controles en pacientes con insuficiencia venosa crónica después del procedimiento de ablación troncal con radiofrecuencia. El grupo 1 no recibió tromboprofilaxis después de la cirugía. El grupo 2 recibió 10 mg de rivaroxaban cada 24 horas por un periodo de 2 semanas. Se evaluó la presencia de EHIT durante el 3. y 7. días del postoperatorio.* **Resultados:** *Entre enero de 2013 y diciembre del 2017, se evaluaron un total de 113 pacientes con 132 procedimientos. Como resultado, encontramos una diferencia significativa en el total de procedimientos en favor de la tromboprofilaxis con rivaroxaban, con una disminución de la EHIT, con una p = 0.0031 y una OR de 8.5, con un IC del 95% (21.0-39.9).* **Conclusión:** *El uso de rivaroxaban fue efectivo en la tromboprofilaxis de la EHIT en la ablación venosa con radiofrecuencia.*

Palabras clave: *EHIT. Radiofrecuencia. Rivaroxaban. Tromboprofilaxis. Ablación venosa.*

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Introduction

Since 1999, the venous ablation using radiofrequency (RF) has been a safe procedure in the treatment of superficial venous disease, even with the presence of venous ulcers. The advantages to this procedure are less pain, faster recovery, and a superior procedure than a conventional saphenectomy[1-3], and the occlusion of the greater saphenous vein (GSV) small saphenous vein (SSV) and the anterior accessory saphenous vein (aASV) happens. These results are due to the thermal destruction of the intima and the collagenous decomposition in the media. This procedure is not free of complications. The principal complication is the deep venous thrombosis induced by endovenous heat (endovenous heat-induced thrombosis [EHIT]) followed by thrombophlebitis or superficial venous thrombosis with a frequency of up to 16%[3,4]. In the case of EHIT, using an accepted classification of the thrombosis disseminates through the superficial venous system until the deep venous system requires treatment as thrombolysis and thrombectomy[5,6]. In addition, there is an increase in morbidity and there are been cases of lung thromboembolism (TEP) that can be dangerous for the patient[7,8]. As other authors affirmed, there is not a current standard of thromboprophylaxis for the endoluminal venous procedures[9] despite the evidence of TVP and TEP as complications. To compare the prevalence of EHIT with thromboprophylaxis with rivaroxaban versus no thromboprophylaxis in ablation with RF, the results motive this publication.

Methods

After a retrospective observational study using a case-control design performed on patients at one site (San Luca Vascular Medical Center located in Queretaro, Qro, Mexico). The patients received medical attention in the period between January 1, 2013, and December 31, 2017. The clinical classification clinical, etiologic, anatomic, and pathophysiologic (CEAP)[10] was used for the patients. The patients excluded from the study were patients < 18 years old; patients with previous history of thrombophilia, or history of anticoagulation and a serum creatinine > 2 mg/dl. In addition, patients without a detailed report of the saphenous-femoral junction (SFJ) or saphenous-popliteal junction (SPJ) on the post-operatory progress were excluded from the study.

All patients included in the study were classified between C2 and C6 according to CEAP. All patients were treated with ambulation, avoidance of prolonged periods of standing position, and stocking compression of 15-20 mm/Hg or compression bandages within 1 month before the procedure, with the exception of patients that bleed from the rupture of a varicose vein and treated immediately. The pre-operatory evaluation, the intraoperative monitoring, and the post-operatory follow-up were performed with Doppler color (Sonosite M–Turbo Bothell, WA, USA). Moreover, the saphenous vein refluxes were evaluated with the Valsalva maneuver, and manual calf compressions considering vein refluxes were positive when vein reflux had duration > 500 ms.

The surgical procedure was performed with an RF dispositive and catheter of RF ClosureFast (Venous Technologies San Jose, Calif, USA) 7 Fr. The Seldinger technique was used for catheter introduction at the level of the distal thigh or knee, in the case of GSV; 1 cm below the gastrocnemius muscles, in the case of SSV; and the third distal or thigh medium in the case of aASV. In all the cases, a catheter was placed close to SFJ below the epigastric vein or close to SPJ. The Fowler position was used to congest the venous bed and facilitate the puncture access needle. The Trendelenburg position was used after the procedure, to empty the venous system to get a superior vein collapse in preparation for ablation[3]. Tumescent anesthesia was used with a prepared solution with 1000 ml of saline solution, lidocaine 50 ml with 2% epinephrine, and sodium bicarbonate diluted in the saline solution used for endogenous sedation. The ablation was performed in segments of 7 cm and finished 3 cm over the puncture zone with a stable temperature of 120 grades C. All the procedures were performed by only one vascular surgeon (R.G). The ablation was performed in one, two, and three of the different truncal veins (GSV, SSV, and aASV); all the procedures were unilateral. In some cases, the procedure performed was distal mini-phlebectomies.

Postoperatively, the patients were treated with compression socks of 15-20 mm/Hg and asked to walk routinely at least for 3 months after the procedure.

Group 1 was included in the study in January 2013 and did not receive thromboprophylaxis. Group 2 was included in the study in October 2014 and received 10 mg of rivaroxaban (Bayer, Leverkusen, Germany) each 24 h for the duration of 2 weeks starting immediately after surgery. All patients received physical examinations looking for possible complications related to the use of an anticoagulant such as minor bleeding, bruises, hematomas, or the need for compression in the puncture area for more than 10 min[11], and major bleeding defined as a drop of > 2 g hemoglobin/dl or a

need of transfusion[12]. In addition, the patients were evaluated by ultrasonography.

For publication, the EHIT classification was reported in accordance with the recommendation provided by Kabnick et al.[5], which refers EHIT as a classification of 1-4. EHIT 1 is defined as the thrombus extending to the (SFJ). EHIT 2 is the thrombus propagation into the deep venous system with a cross-sectional area of obstruction of < 50%. EHIT 3 is defined as thrombus spreading inside of deep vein system > 50% cross-sectional area obstruction. EHIT 4 is total occlusion of the femoral vein. An EHIT Class 2 was considered clinically relevant because anticoagulant treatment and weekly follow-up with ultrasonography was needed for 4 weeks.

The statistical analysis was tested using bivariate analysis with Chi-square for p-value with the Fisher exact test and determination of odds ratio (OR) confidence interval (IC) 95% using the Epi Info program version 7.2.2.6.

Results

Total subjects enrolled in this study were 113, 84 were females and 29 males. A total of 132 interventions with ablation using RF performed in greater and minor saphenous, or accessory anterior saphenous vein. Group 1 the control did not receive previous prophylaxis. Group 2 (case group) o treatment group received rivaroxaban.

Group 1 received a total of 68 procedures, with 49 (72.1%) to the GSV and aASV and 19 (27.9%) to SSV. EHIT was present in 20 procedures (75% EHIT 1, 15% EHIT 2, 10% EHIT 3, and 0% EHIT 4). Group 2 received a total of 64 procedures with 51 (79.6%) to GSV and aASV and 13 (20.4%) SSV and the EHIT was present in 7 procedures (85% EHIT1, 15% EHIT 2, 0% EHIT 3, and 0% EHIT 4). The results provided a significant difference in the total of the procedures in favor of the prophylaxis with rivaroxaban, reducing EHIT with p = 0.0031 and OR 8.5 with IC 95% (2.10-39.9). Significant differences were not found between other variables as gender, age, obesity, and chronic degenerative diseases, nor any secondary side effects, for example, bleeding and bruising post-surgery. No secondary side effects were found that required the suspension of treatment with rivaroxaban. All the patients with EHIT 2 and 3 obtained total thrombus remission at the end of the anticoagulation treatment.

Discussion

This study reports on the efficacy and safety of rivaroxaban comparing one group without prophylaxis post-surgery for thrombosis and another similar group with thromboprophylaxis with rivaroxaban prescribed the same day of the surgery. Both groups received endovenous ablation with RF. The treatment with rivaroxaban was effective as thromboprophylaxis of EHIT in the SFJ. Several studies confirmed the use of rivaroxaban as an excellent therapeutic measure in EHIT[13] while other studies reported the utility of rivaroxaban in cases of thromboprophylaxis[9,14]. The most relevant results of the prophylaxis were reflected in the EHIT Class 1 that has not an impact as a complication but is included in an already established complication that impacts this type of EHIT. There are no standards known for the initial and lasting of thromboprophylaxis. Of great importance experience is that this study is one of the first investigations of thromboprophylaxis for endoluminal ablation using RF that it can be fundamental to establish criteria for the prevention of this complication that involves other ablation techniques. There have been many efforts to investigate if factors such as the vein diameter, the RF catheter, and placing distance with respect to the (SFJ or SPJ) are determinants for the presence of EHIT. One study reported one diameter > 8 mm from the GSV is significant for the EHIT formation Class 2[15], while other studies did not acknowledge the statistically significant. Neither studies found differences in the placement of the catheter tip to the level of (SFJ)[16].

We consider that our study is one of the first studies comparing a group of subjects to establish with certain the effectiveness of treatment with rivaroxaban for venous thromboprophylaxis and the EHIT prevention.

Conclusion

This research study demonstrates the efficacy and effectiveness of rivaroxaban in the EHIT thromboprophylaxis ablation with RF. This study supports the use of rivaroxaban for EHIT prophylaxis; our results presented in this study defend the hypothesis that 10 mg of rivaroxaban1 is effective and safe in patients with EHIT. However, we agree that there is a strong need for more clinical studies to authenticate this investigation.

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Conflicts of interest

The authors declare do not have conflicts of interest.

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Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

References

1. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVeS Study). J Vasc Surg. 2003;38:207-14.
2. Rautio T, Ohinmaa A, Perälä J, Ohtonen P, Heikkinen T, Wiik H, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. J Vasc Surg. 2002;35:958-65.
3. Vasquez MA, Wang J, Mahathanaruk M, Buczkowski G, Sprehe E, Dosluoglu HH. The utility of the venous clinical severity score in 682 limbs treated by radiofrequency saphenous vein ablation. J Vasc Surg. 2007;45:1008-14.
4. Hingorani AP, Ascher E, Markevich N, Schutzer RW, Kallakuri S, Hou A, et al. Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: a word of caution. J Vasc Surg. 2004;40:500-4.
5. Kabnick L, Ombrellino M, Hea A. Endovenous Heat Induced Thrombus (EHIT) at the superficial-deep venous junction: a new post-treatment clinical entity, classification and Potential Treatment Strategies. Miami, FL: Presented at the 18th Annual Meeting of American Venous Forum; 2006.
6. Kwak JH, Min SI, Kim SY, Han A, Choi C, Ahn S, et al. Delayed presentation of endovenous heat-induced thrombosis treated by thrombolysis and subsequent open thrombectomy. Vasc Specialist Int. 2016;32:72-6.
7. Marsh P, Price BA, Holdstock J, Harrison C, Whiteley MS. Deep vein thrombosis (DVT) after venous thermoablation techniques: rates of endovenous heat-induced thrombosis (EHIT) and classical DVT after radiofrequency and endovenous laser ablation in a single centre. Eur J Vasc Endovasc Surg. 2010;40:521-7.
8. Sufian S, Arnez A, Lakhanpal S. Case of the disappearing heat-induced thrombus causing pulmonary embolism during ultrasound evaluation. J Vasc Surg. 2012;55:529-31.
9. Keo HH, Baumann F, Diehm N, Regli C, Staub D. Rivaroxaban versus fondaparinux for thromboprophylaxis after endovenous laser ablation. J Vasc Surg Venous Lymphat Disord. 2017;5:817-23.
10. Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, et al. Revision of the CEAP classification for chronic venous disorders: consensus statement. J Vasc Surg. 2004;40:1248-52.
11. Sharifi M, Mehdipour M, Bay C, Emrani F, Sharifi J. Effect of anticoagulation on endothermal ablation of the great saphenous vein. J Vasc Surg. 2011;53:147-9.
12. Sharifi M, Mehdipour M, Bay C, Smith G, Sharifi J. Endovenous therapy for deep venous thrombosis: the TORPEDO trial. Catheter Cardiovasc Interv. 2010;76:316-25.
13. Fokin AA, Borsuk DA, Kazachkov EL. Efficacy of using rivaroxaban for treatment of heat-induced thrombosis after endovenous laser ablation. Angiol Sosud Khir. 2016;22:97-101.
14. Uthoff H, Holtz D, Broz P, Staub D, Spinedi L. Rivaroxaban for thrombosis prophylaxis in endovenous laser ablation with and without phlebectomy. J Vasc Surg Venous Lymphat Disord. 2017;5:515-23.
15. Lawrence PF, Chandra A, Wu M, Rigberg D, DeRubertis B, Gelabert H, et al. Classification of proximal endovenous closure levels and treatment algorithm. J Vasc Surg. 2010;52:388-93.
16. Haqqani OP, Vasiliu C, O'Donnell TF, Iafrati MD. Great saphenous vein patency and endovenous heat-induced thrombosis after endovenous thermal ablation with modified catheter tip positioning. J Vasc Surg. 2011;54:10S-7.