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Incidence and Risk Factors for Deep Vein Thrombosis after Radiofrequency and Laser Ablation of the Lower Extremity Veins

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Abstract

Introduction: The rates of thromboembolic complications such as deep venous thrombosis (DVT) after venous ablation procedures for symptomatic superficial venous insufficiency are controversial. We sought to describe the risk factors for, and incidence of DVT after radiofrequency ablation (RFA) and laser ablation (LA).

Methods: We queried the Truven Health Marketscan Database from 2007–16 for patients who underwent RFA or LA and had a follow-up duplex ultrasound within 30 days of the ablation procedure. The primary outcome was DVT at 7- and 30-days identified by ICD-9 and ICD-10 codes. Multivariable regression was used to evaluate the patient and procedural variables associated with a DVT at 30-days, expressed as odds ratios with a 95% confidence interval (OR 95% CI). Patients and procedures with a previous DVT diagnosis were excluded.

Results: A total of 256,999 patients underwent 433,286 ablation procedures: 192,195 (44.4%) RFA and 241,091 LA. Of these, 8,203 (1.9%) had a newly diagnosed DVT within 7-days and 13,347 (3.1%) within 30-days of the procedure. The incidence of DVT decreased over the study period. LA (2.8%) demonstrated a lower incidence of DVT at 30-days compared to RFA (3.4%), $p < 0.001$. On multivariable regression, LA (OR 0.82, 95% CI 0.80–0.85) was again associated with a decreased risk for 30-day DVT, as was female gender (OR 0.74, 95% CI 0.71–0.77) and sclerotherapy performed on the same day (OR 0.91, 95% CI 0.85–0.98). A diagnosis of peripheral artery disease (OR 1.23, 95% CI 1.16–1.31) and concomitant stab phlebectomy (OR 1.43, 95% CI 1.37–1.49) was associated with an increased risk of DVT within 30-days.

Conclusions: The incidence of newly diagnosed DVT within 30-days of an ablation procedure was 3.2%. The risk for DVT decreased in recent years and LA was associated with a 18% decreased risk compared to RFA.

Introduction:

Treatment for symptomatic superficial venous insufficiency with radiofrequency ablation (RFA) and laser ablation (LA) has greatly surpassed that of open surgical management.^{1,2}

Both RFA and LA have been shown to be as or more successful in varicose vein treatment as compared to open surgery,^{3–7} and appear to be more beneficial for the patient as they can be performed without general anesthesia, and are associated with decreased early disability and pain.^{5,7}

Despite the relative safety of these techniques, LA and RFA may cause endovenous heat-induced thrombosis (EHIT) which clot may extend or propagate leading to deep vein thrombosis (DVT).^{8–10} In rare cases LA and RFA procedures may also lead to pulmonary embolism (PE).^{3,4,11} The overall risk for thromboembolic complication after endovenous ablation is controversial, and estimates in the literature vary greatly, from less than 1% to 18%.^{3,4,11–16}

As RFA and LA are the most commonly performed surgical treatments for symptomatic superficial venous insufficiency, we sought to identify the risk factors for and the incidence of DVT after RFA and LA over time.

Methods:

Using the Truven Health Marketscan Database, a comprehensive national private insurance claims database, we identified patients from 2007–16 undergoing RFA or LA. We used Current Procedure Terminology (CPT) codes to identify RFA (36475 and 36476) and LA ablation (36478 and 36479). The primary outcome was DVT at 7-days and 30-days identified by ICD-9 and ICD-10 codes (Appendix A). This study is unable to distinguish DVT from EHIT as a specific ICD diagnosis code for EHIT is unavailable. The secondary outcome was PE at 7-days and 30-days of an ablation procedure identified by ICD-9 and ICD-10 codes (Appendix A).

Lower extremity ablation procedures were included if they had a follow-up duplex ultrasound (CPT 93970 and 93971) within 30 days of an ablation procedure. If patients had a previous DVT or PE documented by ICD-9 or ICD-10 code, procedures after this date were excluded. Patients with a previous open ligation or stripping procedure (CPT 37700, 37718, 37722, 37735, 37760, 37761, 37780) were excluded. If patients had both an RFA and LA procedure on the same day, these procedures were also excluded, see Figure 1.

Patient demographics were collected from the enrolment file, and co-morbidities were analyzed from the outpatient and inpatient claims files. The presence of lower extremity venous ulcers were also evaluated by ICD-9 and ICD-10 codes (Appendix A). A Charleston co-morbidity index was calculated as previously described.¹⁷ Concomitant sclerotherapy (CPT 36468, 36470, 36471) and stab phlebectomy procedures (CPT 37765, 37766, 37785) on the same day of the ablation were also evaluated, see Appendix B.

Descriptive statistics were used to characterize patient demographics and co-morbidities. Multivariable regression was used to evaluate patient and procedural variables to determine risk factors for new DVT development, expressed as odds ratios and 95% confidence interval (OR 95%CI). Linear trend of proportions were calculated to determine a significant change in DVT rates by year. Data collection was performed using SAS (Cary, NC) and data analysis was performed using Stata 14 (College Station, TX).

Results:

A total of 256,999 patients underwent 433,286 ablation procedures: 192,195 (44.4%) RFA and 241,091 LA. The average age (mean±SD) of the procedure was 49.2±9.97 and patients were predominately female (76.5%), see Table 1. Stab phlebectomy was performed on a total of 68,134 (15.7%) on the same day as an ablation procedure and was similar for LA 37,811 procedures (15.7%) and RFA 30,323 (15.8%), $P=.40$. Sclerotherapy was performed on a total of 29,743 (6.9%) on the same day as an ablation procedure and was higher for LA 18,897 (7.8%) compared to RFA, 10,846 (5.6%), $p<.001$.

In total, 8,203 (1.9%) procedures had a newly diagnosed DVT within 7-days of the ablation procedure and 13,347 (3.1%) had a DVT within 30-days of the procedure. On univariate analysis male gender, congestive heart failure, peripheral vascular disease, chronic pulmonary disease was higher for procedures that developed a DVT in 30-days (Table 1). Comparison of RFA and LA demonstrated a lower incidence of 30-day DVT for LA (2.8%) compared to RFA (3.4%), $P<.001$. The incidence of 30-day DVT trended downward 2009–16 for both procedures (Figure 2), $P<.01$. A total of 127 PEs (0.03%) were identified within 7-days of an ablation procedure: 56 (0.02%) for LA and 71 (0.04%) for RFA, $p=.009$. A total of 423 PEs (0.10%) were identified within 30-days of an ablation procedure: 205 (0.09%) for LA and 218 (0.11%) for RFA, $p=.003$.

On multivariable regression LA (OR 0.82, 95% CI 0.80–0.85), female gender (OR-0.74, 95%CI 0.71–0.77) and sclerotherapy (OR-0.91, 95%CI .85-.98) were associated with a decreased risk for 30-day DVT. A diagnosis of peripheral artery disease (OR-1.23, 95%CI 1.16–1.31) and concomitant stab phlebectomy (OR-1.43, 95%CI 1.37–1.49, $P<.001$) were associated with an increased risk of 30-day DVT, see Table 2.

Discussion:

In this study, we found that the overall rate for DVT within 7-days and 30-days of RFA or LA was 1.9% and 3.1%, respectively. The rates of DVT decreased over time, suggesting an improvement in overall procedural safety; however, LA demonstrated a considerable decreased risk for DVT when compared to RFA. Other variables associated with lower risk for DVT were female gender, and sclerotherapy. Higher risk for DVT at 30 days was associated with peripheral artery disease and concomitant stab phlebectomy.

The risk for DVT after varicose vein treatment is generally thought to be quite low, as many studies have reported rates less than 1%.^{3,4,12} Our results are more consistent with those of O'Donnell, et al., who found that 3.1–4.4% of patients had a DVT after RFA or LA.¹¹ Our study demonstrates DVT rates decreasing over time, which is likely due to published techniques that may reduce DVT rates such as increasing the catheter tip distance from the saphenofemoral junction and using compression postoperatively. Because RFA/LA do not require general anesthesia, many of these procedures are performed in a physician's office rather than in hospitals, thus studies based on inpatient data may be underestimating a large number of procedures.¹⁸

Interestingly, our results suggest that the timing postoperative screening might affect reports of thromboembolic complications. Currently, guidelines recommend routine duplex ultrasound within two to three days of surgery to screen for thromboembolic complications;^{5,19} others recommend screening within a week of surgery.²⁰ Ryer et al. identified 43 EHIT diagnoses that required anticoagulation at one week postoperatively, but only 20 of those had been found on an initial ultrasound at 24 hours postoperatively.²¹

Some have suggested that postoperative evaluation of DVT is unnecessary,²² arguing that ultrasound over diagnoses DVT, leading to overtreatment. However if postoperative ultrasound were reserved for only those with symptoms, a considerable number of DVT would be missed.^{9,16} Jones et al. also questioned the clinical significance of most forms of EHIT, however progression to PE has occurred in multiple studies.^{9,21,23,24} These occurrences are rare, but in the setting of what is generally thought to be an elective procedure, are unacceptable. It is unknown the true incidence of PE caused by EHIT; however, our findings suggest that 1.5% of DVTs lead to PE within 7-days 30-days of an ablation procedure. As we excluded procedures with previous PE this is concerning and further analysis of anticoagulation strategies that include dosing strength and duration are needed to prevent possibly life-threatening outcomes.

Concomitant stab phlebectomy is commonly performed with RFA and LA, however our study suggests that it increases the risk for thromboembolic complication with either endovenous treatment. Hicks et al. recently showed similar results with regard to RFA where RFA with concomitant stab phlebectomy had a significantly higher incidence of EHIT compared to RFA alone (14% vs 6%, $p=0.04$). As the risk for DVT appears to be lower for LA overall, the association between concomitant stab phlebectomy and LA for DVT is less pronounced in the literature. One study showed a trend between stab phlebectomy and LA, however they did not reach statistical significance,¹⁸ and another showed no increased risk.¹⁰ In the study where they found more risk, Hicks et al. theorized that phlebectomies may be associated with more postoperative pain than RFA alone, decreasing postoperative activity levels and thus increasing risk for DVT. It is also possible that the patients who received RFA with a concomitant stab phlebectomy had somewhat worse venous disease or a larger greater saphenous vein than those who received RFA alone, which possibly represented a selection bias.

This study is limited by the factors inherent to using a large insurance claims database, which limits our ability to obtain more detailed clinical factors for analysis. Specifically, we were unable to characterize the extent and location of DVT after ablation procedures, and we were unable to distinguish between DVT and EHIT. However, we excluded any procedures with a previous diagnosis of DVT, thus narrowing DVT to likely procedure related causes. In addition, administrative database codes to confirm a diagnosis of DVT may not always be reliable. Alotaibi et al. found that administrative data was 75.2% sensitive and 95.8% specific for DVT,²⁵ with other studies showing similar findings.^{26,27} The true incidence and clinical significance of DVT/ EHIT is unable to be determined without evaluating clinic notes and radiographic files which are unavailable in claims database. Furthermore, we assume the same laterality of DVT and RFA/ LA as ICD-9 codes which does not specific laterality is a majority of our analysis, and ICD-10 use, which notes laterality, began in

late 2015. Finally, this dataset only includes those who are insured, thus may actually be underestimating the risk for DVT in what is typically a healthier population than Medicare and inpatient databases. Conversely, this national database includes office-based procedures and allows more generalizability than smaller, single institution studies.

Conclusions:

The incidence of thromboembolic complications after RFA are decreasing in recent years, with a decreased risk using LA compared to RFA. Patients and providers should be aware of the incidence and risk factors of DVT after venous ablation; however, larger clinical studies are needed to evaluate the clinical significance of a positive DVT diagnosis after venous ablation on patient outcomes. Whether ultrasound screening should be required and/or extended to 30-days requires further investigation.

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Appendix A: Appendix Caption Missing

Diagnostic codes	ICD-9	ICD-10
Deep venous thrombosis (DVT)	45111, 45119, 4512, 45181, 45189, 4519, 4532, 45340, 45341, 45342, 45389, 4539 9961, 99670, 99674, 99779, 9992	I8010, I8011, I8012, I8013, I80201, I80202, I80203, I80209, I80211, I80212, I80213, I80219, I80221, I80222, I80223, I80229, I80291, I80292, I80293, I80299, I82220, I82401, I82402, I82403, I82409, I82411, I82412, I82413, I82419, I82421, I82422, I82423, I82429, I82431, I82432, I82433, I82439, I82491, I82492, I82493, I82499, I824Y1, I824Y2, I824Y3, I824Y9 I824Z1, I824Z2, I824Z3, I824Z9
Pulmonary embolism (PE)	41511, 41519, 41513, 4162, 4532, V1255	I2602, I2609, I2699, I82220, I82290, Z86711
Venous insufficiency/ulcer	4540, 4542 70710, 70711, 70712, 70713, 70714, 70715, 70719 8921, 8922, 8940, 8941, 8942	I87311, I87312, I87313, I87319, I87331, I87332, I87333, I87339, I87391, I87392, I87393, I87399, I83001, I83002, I83003, I83004, I83005, I83008, I83009, I83011, I83012, I83013, I83014, I83015, I83018, I83019, I83021, I83022, I83023, I83024, I83025, I83028, I83029, I83201, I83202, I83203, I83204, I83205, I83208, I83209, I83211, I83212, I83213, I83214, I83215, I83218, I83219, I83221, I83222, I83223, I83224, I83225, I83228, I83229

Appendix B: Appendix Caption Missing

Procedure	CPT	Description
Radiofrequency (RFA)	36475 36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging

Procedure	CPT	Description
		guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated
Laser ablation (LA)	36478 36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated
Sclerotherapy	36468 36470 36471	Injection of sclerosant; spider veins -single incompetent vein – multiple incompetent vein Injection of sclerosing solution; single vein Injection of Sclerosing solution; multiple veins, same leg
Open ligation	37700 37718 37722 37735 37760 37761 37780	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions. Ligation, division, and stripping, short saphenous vein. Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below. Ligation and division and complete stripping of long or short saphenous veins with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia Ligation of perforator vein(s), subfascial, radical (Linton type), including skin graft, open, 1 leg Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg Ligation and division of short saphenous vein at saphenopopliteal junction.
Stab phlebectomy	37765 37766 37785	Stab phlebectomy of varicose veins, 1 extremity; 10–20 stab incisions. Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions. Ligation, division, and/or excision of varicose vein cluster(s), 1 leg
Ultrasound	93970 93971	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study

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Fig. 1.
Study design and outcomes of DVT after RFA and LA.

Fig. 2.
Incidence of deep venous thrombosis (DVT) within 30 days of lower extremity venous ablation

Characteristic	Total (n=433,286)	No 30-day DVT (n=419,939)	30-day DVT (n=13,347)	P-value
Age	49.2±9.97	49.2±9.97	49.4±9.92	.0059
Female Gender	331,439 (76.49)	322,055 (76.7)	9,384 (70.3)	.001
Myocardial infarction	3,018 (.70)	2,920 (.70)	98 (.73)	.60
Congestive Heart Failure	8,613 (1.99)	8,305 (1.98)	308 (2.31)	.007
Peripheral Vascular Disease	35,139 (8.11)	33,796 (8.05)	1,343 (10.06)	<.001
Cerebrovascular disease	17,738 (4.09)	17,135 (4.08)	603 (4.52)	.012
Dementia	298 (0.07)	294 (0.07)	4 (0.03)	.082
Chronic Pulmonary Disease	58,226 (13.44)	56,306 (13.41)	1,920 (14.39)	.001
Rheumatologic Disease	12,254 (2.83)	11,853 (2.82)	401 (3.00)	.21
Peptic Ulcer Disease	4,411 (1.02)	4,297 (1.02)	132 (0.99)	.73
Mild Liver Disease	20,644 (4.76)	19,972 (4.76)	672 (5.03)	.136
Diabetes	47,265 (10.91)	45,689 (10.88)	1,576 (11.81)	.001
Diabetes with Chronic Complications	10,679 (2.46)	10,323 (2.46)	356 (2.67)	.12
Hemiplegia or paraplegia	984 (0.23)	950 (0.23)	34 (0.25)	.50
Renal Disease	5,894 (1.36)	5,709 (1.36)	185 (1.39)	.79
Any malignancy	19,790 (4.57)	19,163 (4.56)	627 (4.70)	.46
Moderate or severe liver disease	863 (0.20)	837 (0.20)	26 (0.19)	.91
Metastatic Solid Tumor	1,578 (0.36)	1,531 (0.36)	35 (0.26)	.81
AIDS	844 (0.19)	809 (0.19)	35 (0.26)	.07
Ulcer	36,796 (8.49)	35,350 (8.42)	1,446 (10.83)	<.001
Laser Ablation	241,091 (55.64)	6,593 (3.43)	6,754 (2.80)	<.001
Sclerotherapy	29,743 (6.86)	28,899 (6.88)	844 (6.32)	.012
Stab Phlebectomy	68,134 (15.72)	65,365 (15.57)	2,769 (20.75)	<.001

Characteristic	Odds-ratio	95% Confidence Interval	P-value
PAD	1.21	1.16–1.31	<.001
Laser	0.81	0.78–0.84	<.001
Female Gender	0.75	0.72–0.78	<.001
Stab phlebectomy	1.43	1.37–1.49	<.001
Sclerotherapy	0.91	0.85–0.98	.012
Lower extremity wound	1.21	1.14–1.28	<.001
Year (Every 1 year from 2007)	0.92	0.92–0.93	<.001