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Effect of Saphenous Vein Diameter on Closure Rate With ClosureFAST Radiofrequency Catheter

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Purpose: Radiofrequency ablation (RFA) of veins >12 mm in diameter has been a controversial subject since the first-generation device was submitted for Food and Drug Administration (FDA) approval. Veins >12 mm were excluded in the initial study. Many insurance carriers used >12 mm size as reason to not approve the procedure. As the concept of tumescent anesthesia was better communicated, RFA was used for large veins. The 12-mm size limit was not used in the studies for the newer ClosureFAST catheter approval, yet remains in force with some insurance companies. Our objective was to determine whether vein diameter >12 mm had effect on closure rates with the ClosureFAST catheter. *Methods*: ClosureFAST RFA was used to eliminate saphenous reflux in consecutive cases in 1 center. Retrospective analysis was performed on prospectively gathered data. Veins were divided into ≤12 mm diameter (group A) or >12 mm diameter (group B). Duplex scans were scheduled for 2 to 5 days and 6 months postprocedure. *Results*: A total of 338 great and small saphenous veins were treated, 246 saphenous veins in group A (mean 8 ± 2 mm) and 96 in group B (mean 17 ± 4 mm). Early duplex showed complete closure in 231 veins in group A (94%) and 92 veins in group B (96%; NS). The remaining veins showed partial closure with none showing retrograde flow. Six-month duplex scans were completed in 155 veins. Complete closure was seen in 110 veins in group A (98%) and 43 veins in group B (100%; NS). All veins partially open on early scan had closed by 6 months. The 2 veins open at 6 months in group A were closed on initial scan. *Conclusions*: Vein diameter >12 mm had no effect on closure rate with the ClosureFAST catheter.

Keywords: varicose veins; radiofrequency ablation; saphenous vein

Introduction

Radiofrequency ablation (RFA) of saphenous veins of more than 12 mm in diameter has been a controversial topic since the Food and Drug Administration (FDA) 501(k) clearance for the first-generation device in March 1999. The original device was a catheter which had extendable prongs which would make contact with the saphenous vein wall. In the fully deployed state, the larger of the 2 available devices was 12 mm in diameter. Thus, it was originally thought that maximum diameter of a treated vein should be 12 mm. Initially the clinical registry established in 1998 to monitor treatment outcomes and safety excluded veins of more than 12 mm.[1] For these reasons, many insurance carriers used vein diameter of more than 12 mm as an exclusion criterion for procedure approval.

Soon tumescent anesthesia became routine with RFA as reported by Manfrini et al.[2] Tumescent anesthesia, injected around the saphenous vein, compresses the vein against the catheter, thus ensuring contact of veins larger than maximum catheter diameter. The initial clinical registry soon abolished the greater than 12 mm exclusion criterion.[3] A number of articles followed that included treating saphenous veins with diameters exceeding 12 mm in their series.[3-6]

In May 2006, the ClosureFAST received an FDA 501(k) clearance letter. This RFA ablation device no

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longer had extendable prongs making the maximum catheter contact diameter significantly smaller than most saphenous veins. In the large series of cases reported by Proebstle et al,[7] saphenous veins with diameters as large as 18 mm were treated with ClosureFAST. However, the group of saphenous veins with diameters greater than 12 mm was not separated for analysis.[7]

Despite the widespread use of the first- and second-generation RFA devices in saphenous veins larger than 12 mm with the use of tumescent anesthesia, insurance carriers have been slow to approve RFA procedures for veins more than 12 mm.[8] More recently, a carrier that administers Medicare for several Mid-Atlantic states reversed a previous policy and reinstated the less than or equal to 12 mm inclusion criterion.[9]

The goal of this study was to determine whether saphenous vein diameter greater than 12 mm is associated with different closure rates than smaller veins, using the new generation ClosureFAST RFA catheter.

Methods

A single-center, 2 operator (D.C., J.A.R.) experience with consecutive RFA saphenous vein procedures using the ClosureFAST catheter was analyzed. The procedures were performed over an 8-month period. All procedures were done in the office with tumescent anesthesia without any systemic analgesics or sedation. The procedures were done by percutaneously placing a 7F sheath in the saphenous vein under ultrasound guidance. The ClosureFAST catheter was then introduced and positioned with the end 2 cm from the saphenofemoral or saphenopopliteal junction. Tumescent anesthesia was made by adding 50 mL 1% lidocaine containing epinephrine 1:100 000 plus 10 mL 8.4% sodium bicarbonate to 500 mL normal saline. The tumescent solution was placed around the saphenous vein with the use of a Klein infusion pump (HK Surgical, San Clemente, California), thus making contact between the vein and the catheter and creating a heat sink between the vein and the surrounding structures. Generally, all the tumescent solution was used for great saphenous procedures, with less used for closing the small saphenous vein. The volume of tumescent used was not recorded for each case. Closure was performed with the patient supine for the great saphenous or prone for the small saphenous, with the head of the bed lowered slightly. Saphenous veins were closed at 120°C. The proximal 7-cm length of vein was treated twice (40 seconds) and the remaining segments treated once (20 seconds). Occasionally, a more distal section was treated twice if the temperature did not rise to 120°C with 4 seconds, but these instances were not specifically recorded. Retrospective review was performed on prospectively gathered data entered into the electronic medical record. Saphenous veins were divided into 2 groups. Group A had diameters less than or equal to 12 mm. Group B had saphenous diameters exceeding 12 mm. All measurements were taken in the upright position by ultrasound prior to the procedure. The diameter recorded was at the first full transverse circle of saphenous vein that could be imaged below the saphenofemoral or saphenopopliteal junction. Follow-up ultrasound evaluation was done between 2 and 5 days, and again at 6 months following the procedure. Clinical evaluation was performed 2 weeks and again at 6 months following the procedure. Closed was defined as no vein segments open in treated area. Partial closure meant vein had some patent and some closed sections. Patent meant vein was open.

Measurable parameters were expressed as mean $\pm$ standard error of the mean (SEM). Statistical analysis was performed using Microsoft Excel 2002 for Window XP with the Analysis ToolPak Add-Ins (Microsoft, Redmond, Washington). Methods for each *P* value calculation were indicated in Table 1. Yates correction was used in the case of low occurrence frequencies.

Results

The results, including *P* values, are summarized in Table 1. A total of 342 great and small saphenous veins were attempted to be treated in 310 patients. There were 246 veins in group A with a mean diameter of 8 mm $\pm$ 2 mm (mean $\pm$ SEM, range 3-12 mm). Group B consisted of 96 saphenous veins with a mean diameter of 17 $\pm$ 4 mm (mean $\pm$ SEM, range 13-30 mm). In 4 patients in group A, a sheath could not be placed due to vessel spasm, and the procedure terminated. All veins in group B had successful sheath placement.

Early results were available for all veins. Complications occurred in 40 cases (12%). The most

Table 1. Summary of Results

	Group A	Group B	*P* Values[a]
No of patients	246	96	NA
Age (SD) in years	53 (13)	53 (14)	.81[b]
Mean size (SD; range) in mm	8.3 (2.3; 3-12)	16.6 (3.8; 13-30)	NA
Types of veins			
GSV	210; 85%	88; 92%	.17[c]
SSV	36; 15%	8; 8%	
No available for early follow-up	246 (100%)	96 (100%)	NA
Early closure rates			
Closed	231; 94%	92; 96%	.77[c]
Partial	11; 4%	4; 4%	
Patent	0; 0%	0; 0%	
Failure[d]	4; 2%	0; 0%	
Early clinical assessments			
Asymptomatic	210; 85%	81; 84%	.84[c]
Symptomatic	9; 4%	2; 2%	
Complications[e]	27; 11%	13; 14%	
No available for 6-month follow-up	114 (46%)	43 (45%)	.80[f]
Six-month closure rates			
Closed	112; 98%	43; 100%	.94[c]
Partial	0; 0%	0; 0%	
Patent	2; 2%	0; 0%	

NOTES: GSV = greater saphenous vein; NA = not applicable; SD = standard deviation; SSV = smaller saphenous vein.
[a] Statistical significant when *P* value <.05.
[b] Unpaired double-sided Student *t* test.
[c] χ^2 test with Yates correction.
[d] Sheath could not placed in vein due to spasm, and procedure terminated.
[e] Mild complications from the procedures (superficial phlebitis, pain at 2 weeks postoperative, failure to place sheath, ecchymosis, cellulits, edema, skin numbness).
[f] χ^2 test without Yates correction.

common complication was occlusion of overlying varicose veins with a variable amount of inflammation or superficial thrombophlebitis in 15 cases (4%). Additional complications included discomfort at the 2-week postoperative visit (12, 4%), inability to cannulate vein (4, 1%), ecchymosis (2, 1%), cellulitis (2, 1%), edema (2, 1%), and skin numbness (3, 1%). There were no instances of deep venous thrombosis or puncture site thermal injury. Neither total nor individual complication rates differed between the groups. Complete closure was seen in 94% group A and 96% group B (NS). Of the veins that did not have complete closure in each group, all had partial closure and none had retrograde flow by duplex.

Six-month results were available in 155 saphenous veins, 112 in group A and 43 in group B. All complications noted at the early visit had resolved. Complete closure was achieved in 98% group A and 100% group B (NS). Of interest, all vein segments that were only partially closed on early scan were closed by 6 months. The veins that were noted not to be completely closed at 6 months had been completely closed on early scan.

Discussion

The addition of tumescent anesthesia to RFA allows the vein to be compressed against the catheter that should allay initial concerns about the treatment of large veins. However, this question has not been specifically addressed, especially with the newest generation RFA device.

Several authors have reported results of RFA in veins exceeding 12 mm diameter using the initial device, which had extendable prongs. Merchant et al[1] reported on 1222 limbs treated in the RFA registry. Although mean vein diameter was 7.5 mm, diameters ranged from 2 to 24 mm. In a follow-up registry paper, Merchant et al[3] reported on a

subcohort with vein diameters exceeding 12 mm. This group of 59 limbs had an average diameter of 14.5 mm. Occlusion rates were 97% at 1 week and 96% at 6 month or 1 year.[3] Elias[4] reported on RFA for 12 great saphenous veins with diameters exceeding 12 mm with closure of 100% at 6 weeks and 89% at 6 months. Niedzwiecki[5] reported on 62 great saphenous veins with mean diameters ranging from 12 to 25 mm. Absence of reflux was noted in 98% at 1 week, 100% at 6 months, and 94% at greater than 6 months.[5] Reporting further on the initial device, Sichlau[6] published results on 37 great saphenous veins with diameters exceeding 12 mm treated with RFA. There was 100% technical success and all veins remained closed at 6 months.[6]

With the advent of the second-generation RFA device (ClosureFAST), there were no longer prongs with maximum extended diameter of 12 mm. The current device fits through a 7F sheath making much smaller diameter than most veins treated. Proebstle et al[7] reported on 252 great saphenous veins treated with ClosureFAST. The mean saphenous vein diameter was 5.7 mm but the range extended up to 18 mm. There was an overall closure rate of 99.6% at 3 days, 3 months, and 6 months, but the larger diameter group was not subdivided in the report.

Our report was undertaken to specifically address the question of whether saphenous vein diameter exceeding 12 mm had any effect on closure rate with the ClosureFAST device. We measured saphenous diameter in the standing position. At the time of the procedure, the patient is supine or prone with the head of the bed slightly lowered. Adding the effects of tumescent anesthesia, the diameter of the vein is not much greater than the sum of the catheter diameter and the 2 vein walls. Using neither standing nor recumbent diameter measurements will reflect diameter at the time of ablation. In 342 great and small saphenous veins where the procedure was attempted in 310 patients, the procedure could be completed for treatment of 338 veins. When divided into groups of veins less than or equal to 12 mm, and greater than 12 mm, no difference was found in the closure rate. These data confirm the clinical impression that using tumescent anesthesia to compress the vein against the RFA catheter should allow for the successful treatment of large veins.

Conclusion

Saphenous vein diameter exceeding 12 mm had no effect on closure rate with the ClosureFAST catheter. These data do not support some currently existing insurance coverage manuals, which consider vein diameter greater than 12 mm to be an exclusion criterion for RFA. These results are not surprising when one considers that with the use of tumescent anesthesia, the vein is compressed against the RFA catheter so initial diameter should not have strict relevance. However, this has not been previously addressed in prior publications using the ClosureFAST catheter.

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