Closure® procedure for treating varicose veins

M. Perrin

General Principles of the Closure® Procedure

The VNUS Closure® System shrinks a dilated vein wall by means of controlled, resistive heating. Using the VNUS Closure catheter, radiofrequency energy is delivered into the vein wall causing the collagen in the vein wall to contract, resulting in complete occlusion of the vessel. The current Closure catheters are intended for the endovascular coagulation of veins in patients with symptomatic superficial venous reflux.

Materials and Methods

The Closure System (VNUS Medical Technologies, Inc., San Jose, CA) is comprised of a dedicated bi-polar radiofrequency generator, and the 6F and 8F catheters with expandable electrodes. The two catheter sizes allow for treatment of veins with diameters between 2 and 12mm. Both catheters incorporate a central lumen for fluid infusion and to allow passage over a guide wire[1]. The collapsed catheter is fed through an introducer sheath and positioned at the intended treatment site under ultrasound imaging, An elastic compression wrap, such as an Esmark bandage, is wrapped from foot to groin. The wrap helps exsanguinate and collapse the treatment vein. When treating near the sapheno-femoral junction where wrapping may be difficult, the treatment leg is wrapped up as proximally as possible and augmented with consistent external compression applied over the groin. Once effective compression has been achieved, the catheter electrodes are deployed by retracting their protective sheath. The electrodes expand to touch the vessel wall. When the RF energy is activated, the catheter is pulled back slowly and target temperature of 85°C ± 3° maintained. As the catheter is withdrawn, collagen contraction results in occlusion of the vein.

Clinical Study

The prospective trial reports results on 297 limbs treated prior to September 30th, 2000, with the Closure method for symptomatic long saphenous vein (LSV) reflux. One-year follow up was available on 198 limbs. These patients were similar in clinical class presentation to those patients usually treated with traditional stripping and crossectomy. Of the 297 limbs treated, 238 (80,1%) were above calf LSV, 5 (1,7%) were below calf LSV, 47 (15,8%) were entire LSV, 6 (2,0%) were short saphenous vein (SSV), and 1 (0,34%) were accessory saphenous veins. Phlebectomy and sclerotherapy were performed in 60% and 7% of the patients, respectively. No adjunctive crossectomy was performed.

Results

Table 1 shows treatment results at the standard follow up intervals of 1 week, 3 months, 6 months, 12 months and 24 months.

Follow-up	Reflux Free
1 week	259/269 (96%)
3 Months	178/191(93%)
6 Months	207/224 (92%)
12 Months	198/221 (90%)
24 months	90/100 (90%)

Table 1.
Clinical Follow Up Results

	CEAP Class 0 or 1
Pre-Treatment	14%
1 week	84%
3 Months	86%
6 Months	84%
12 Months	85%
24 Months	86%

Table 2.
Post-Treatment Symptomatic Improvement

Table 2 illustrates the progressive improvement in symptoms reported by patients following treatment, as determined by a CEAP Clinical Class rating of 0 or 1.

Comparison to Stripping and Crossectomy

Table 3 shows a comparison at one year between Closure and reported results of saphenectomy and crossectomy.

There is presently a multi-center, prospective, randomized study in progress comparing the results of Closure to saphenectomy. No prospective randomized studies that compare sclerotherapy of the LSV to Closure, saphenectomy, or crossectomy exist at this time.

Complications

Complications following Closure were primarily associated to the spread of thermal energy into surrounding soft tissue. These adverse events were skin burn, paresthesia (presented as focal lesions of hypoesthesia), and superficial clinical phlebitis. Additionally, there were 3 reported incidences of thrombus extension into the common femoral vein. Table 4 shows the incidence of all reported complications post-Closure.

The fact of these complications afforded the investigators the opportunity to develop procedural modifications that could more predictably prevent subsequent occurrences. Specifically, thermal energy-related problems were effectively overcome by identification of potential risk factors and protection of perivascular soft tissues with fluid infiltration between the skin and the dermis. The identified risk factors for skin burns were males and patients with thin or muscular legs.

Saphenous nerve paresthesias were more prevalent when the LSV was treated below the level of the calf. 4 of the 8

	Endovenous RF Occlusion	Saphenectomy[3]	High Ligation[4]
Absence of Reflux	91%	91% Jones 91% Rutgers	73% Jones 75% Rutgers
Absence of Varicose Veins	92%	85% Jones	86% Jones
	N = 221	N = 55 N = 89	N = 66 N = 92

Table 3. Comparison of Closure to Saphenectomy and Crossectomy

isolated treatments of the SSV resulted in sural nerve paresthesias. The incidence of thrombus propagation into the deep system was reduced by the use of intraoperative duplex imaging to confirm final tip position of the catheter prior to RF energy delivery.

Conclusions

- Mid-term results suggest the Closure procedure is effective at abolishing reflux
- Most failures occur within 3 months of treatment
- Patient symptoms and CEAP clinical class are reduced
- The incidence of paresthesia declines markedly by 12 months after treatment
- Continuing follow up will determine long term outcomes
- The Closure procedure provides a promising alternative to traditional crossectomy plus saphenectomy surgery and injection sclerotherapy in the management of major varicose veins.

DVT		
Resulting in PE	3/297	1.01%
	1/297	0.34%
Skin Burn	6/297	2.02%
Superficial phlebitis		
At 1 week	6/269	2.23%
Paresthesia		
At 1 week	39/269	14.5%
At 12 months	7/221	3.16%
At 24 months	7/100	0.07%

Table 4. Complications

Bibliography

1. Chandler JG, Pichot O, Sessa C, Schuller-Petrovic S, Kabnick LS, Bergan JJ. Treatment of Primary Venous Insufficiency by Endovenous Saphenous Vein Obliteration 2000;34:201-14.
2. Pichot O, Sessa C, Chandler JG, Jones CS, Henderson DA, Nuta M. Endovenous Saphenous Vein Obliteration: A Basis for Comprehensive Minimally Invasive Management of Superficial Reflux and Varicosities.
3. Jones L, Braithwaite BD, Selwyn D, Cooke S, Earnshaw JJ. Neovascularization is the Principle Cause of Recurrence: Results of a Randomized Trial of Stripping the Long Saphenous Vein. *Euro J Endovasc Surg* 1996;12:442-5.
4. Rutgers PH, Kitslaar P. Randomized Trial of Stripping Versus High Ligation Combined with Sclerotherapy in the Treatment of the Incompetent Greater Saphenous Vein. *Amer J Surg* 1994;168: 311-5.