absent or only mild reflux and substantiated by duplex scanning or descending venography, range from 75-100% at six months.[7,10,13,14] With follow-up of 6-48 months, the reported competency rate was 34-100%.[7,10-14] Although not always in a direct one to one relationship, a competent valve translates into a symptomatically improved limb. Restricting the patients to those with prior or concurrent recalcitrant ulcers, ulcer healing occurred in 95% and recurrence was prevented in 60% up to 10 years post-transplant.[11]

Cryopreserved tissue has only recently been used for this clinical scenario, the single published paper suggests a 6 month valve competency rate of approximately 60% with ulcer healing/prevention of recurrence of approximately 67%.[18] Issues of rejection and the need for long-term anticoagulation make this a secondary choice for most patients.

Summary

The number of patients suffering from disabling chronic venous insufficiency is not insignificant and is generally treated with conservative medical maneuvers. There are alternatives including surgical procedures to prevent massive venous reflux. Proper patient classification and a regimented diagnostic evaluation including non-invasive and invasive imaging can define the patient who may benefit from a specific surgical approach. The transplantation of valves from the upper to lower extremity is generally reserved for patients with secondary causes of deep venous insufficiency who have no other options. The environment into which the valve is placed is a damaged, scarred conduit which probably explains the less impressive long-term function of these valves when compared to primary valvuloplasty. Nevertheless, one can expect a clinical benefit defined as ulcer prevention in approximately 60% of patients. For those lacking an autogenous valve, a cryopreserved valve may substitute with encouraging early results.

References

1. Coon WW, Willis PW, Keller JB. Venous thromboembolism and other venous disease in the Tecumseh community health study, *Circulation.* 1973;XLVIII:839-846.
2. O'Donnell TF. Chronic venous insufficiency: An overview of epidemiology, classification, and anatomic considerations, *Sem in Vasc Surg.* 1988;1:60-65.
3. Kistner, RL. Primary venous valve incompetence of the leg, *Am J Surg.* 1980;140:218-224.
4. Kistner RL. Surgical repair of the incompetent femoral vein valve, *Arch Surg.* 1975;110:1336-1342.
5. Prepared by an ad hoc committee of the American Venous Forum chaired by A.N. Nicolaides. Classification and grading of chronic venous disease in the lower limbs. A consensus statement. In: Gloviczki P, Yao JST, eds. *Handbook of Venous Disorders.* New York, NY: Chapman & Hall Medical; 1996:652-660.
6. Kistner RL, Ferris EB, Randhawa MD. A method of performing descending venography, *J Vasc Surg.* 1986;4:464-468.
7. Masuda EM, Kistner RL. Long-term results of venous valve reconstruction: A four- to twenty-one year follow-up, *J Vasc Surg.* 1994;19: 391-403.
8. Raju S. Venous insufficiency of the lower limb and stasis ulceration. Changing concepts and management, *Ann Surg.* 1983;197: 688-697.
9. Raju S, Fredericks R. Valve reconstruction procedures for nonobstructive venous insufficiency: Rationale, techniques, and results in 107 procedures with two- to eight-year follow-up, *J Vasc Surg.* 1988; 7:301-310.
10. Eriksson I, Almgren B. Influence of the profunda femoris vein on venous hemodynamics of the limb, *J Vasc Surg.* 1986;4:390-395.
11. Raju S. Fredericks RK, Neglen PN, et al. Durability of venous valve reconstruction techniques for 'primary' and post-thrombotic reflux, *J Vasc Surg.* 1996;23:357-367.
12. Taheri SA, Heffner R, Budd T. Five years' experience with vein valve transplant, *World J Surg.* 1986;10: 935-937.
13. O'Donnell TF, Mackey WC, Shepard AD. Clinical, hemodynamic, and anatomic follow-up of direct venous reconstruction, *Arch Surg.* 1987;122:474-482.
14. Rai DB, Lerner R. Chronic venous insufficiency disease. Its etiology. A new technique for vein valve transplantation, *Int Surg.* 1991;76: 174-178.
15. Nash T. Long term results of vein valve transplants placed in the popliteal vein for intractable postphlebitic venous ulcers and pre-ulcer skin changes, *J Cardiovasc Surg.* 1988;29:712-716.
16. Raju, S. Multiple-valve reconstruction for venous insufficiency: Indications, optimal technique, and results. In: Veith, FJ, ed. *Current Critical Problems in Vascular Surgery, Volume 4.* St. Louis, MO: 1992:122-125.
17. Kistner RL. Valve repair and segment transposition in primary valvular insufficiency. In: Bergan JJ, Yao JST, eds. *Venous Disorders.* Philadelphia, PA: 1991:261.
18. Dalsing MC, Raju S, Wakefield TW, Taheri S. A multi-center, phase I evaluation of cryopreserved venous valve allografts for the treatment of chronic deep venous insufficiency, *J Vasc Surg.* In press.

ANGIOPLASTY AND STENTING OF THE OBSTRUCTED ILIAC VEIN

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Chronic venous insufficiency of the lower extremity is a complex disease with several etiological factors. In approximately one-third of the limbs with postthombotic disease an obstructive component is predominant. The treatment of the outflow obstruction has been hampered by difficulty in identifying hemodynamically significant obstruction and by a rather extensive surgery to correct it. Available surgical procedures like the crossover femoro-femoral bypass or axial iliocaval bypass graft constitute major surgery, always followed by long-term anticoagulation. The interest in venous obstruction is now rising owing to the development of the new technology to diagnose and treat stenosis and occlusion by percutaneous dilatation and insertion of stent. This study presents the technical aspects of this procedure and the results when applied in limbs with postthombotic disease.

Material

A prospective study of 78 limbs with post-thrombotic disease had balloon dilatation and insertion of stent to correct iliac vein obstruction (median age 47 [range 18-77], male/female ratio 1/1, left/right lower extremity 2.3/1). All patients had a thorough history taken and clinical examination performed. A visual analogue pain severity scale from 1-10, in which 10 is the most severe pain, was used to assess pain intensity. The clinical score as per the guidelines of the SVS/ISCVS was also used to assess swelling and pain.

The presenting limb complaint was active (24%, 24/79) or healed ulcer (8%, 6/79); lipodermatosclerosis, pigmentation and/or dermatitis (12%, 9/78); and swelling (50%, 39/78). Concomitantly, 35% of the patients had severe pain (> 5/10 as assessed by the analogue pain severity scale) and required analgesics. Only 16% of patients denied any pain. In addition, 97% of the patients complained of swelling. A comprehensive work up was performed prior to the intervention.

The following preoperative indicators of obstruction were used: occlusion or obvious stenosis on ascending or antegrade transfemoral venography, increased arm/foot pressure differential and/or abnormal hyperemia-induced pressure rise, and presence of pelvic collaterals on venogram. Positive preoperative pressure measurement was present in 38% of the limbs, radiological obstruction in 81%, and collaterals were visualized in 63%.

Intervention

All interventions were performed in a dedicated interventional room with ceiling mounted ISS equipment in the surgical suite with complete sterile precautions. The procedures were done under general anesthesia or local infiltration analgesia in combination with

monitored sedation. Initially, cannulation of the femoral vein was blind, but later it was performed with guidance of ultrasound. After cannulation and insertion of a pinnacle, an antegrade venogram was performed followed by intra-vascular ultrasound (IVUS). Degree, length, and site of obstruction were recorded, and the presence and type of collaterals were noted. Transverse vessel area and diameters were measured by IVUS. Intraoperatively pull-through pressure from the inferior vena cava to the femoral vein was then obtained. Femoral pressure distal to the presumed obstruction was obtained before and after injection of 30 mg papaverine intra-arterially to increase the venous flow. The obstruction was dilated with a balloon and the degree of waisting was noted. The venogram and IVUS investigation were repeated to measure any recoil. The dilated segment was then traversed with a stent of appropriate length and diameter (Wallstent). The venogram, IVUS investigation and pressure measurements were repeated to assess the final result. The sheath was removed and pressure applied for 10 minutes. The patients received 3-5,000 units heparin and 30 mg ketorolac intravenously during the procedure. All patients were admitted for less than 23 hours. Postoperatively, a foot compression device was used, dalteparin 5,000 units s.q. administered once daily; and a ketorolac injection repeated in the morning before discharge. Aspirin (81 mg p.o.) daily was started immediately postoperatively and continued. Only patients already on warfarin preoperatively owing to prior deep vein thrombosis and thrombophilia were anticoagulated postoperatively. Warfarin was not routinely discontinued prior to surgery.

The patients were followed clinically after 6 weeks and with repeat ascending/antegrade transfemoral venography and functional studies later.

Result

The deep system alone was involved in 42% of lower limbs. The minority (32%) had only obstruction and the remaining lower extremities had a combination of reflux and obstruction. The results of the hemodynamic studies performed before surgery were obviously affected by the high rate of concomitant reflux observed in these post-thrombotic limbs.

Intra-operative: Only one stent was used in the majority of cases, but as many as 6 stents were used in one patient. The median length of stented area was 8 cm (range: 4-26) and the median diameter of the inserted stent was 16 mm (range: 10-20 mm). The combined involvement of common iliac vein and external iliac vein (42%) was almost as common as of the common iliac vein alone (45%). The venogram underestimated the degree of narrowing by 10% compared to the findings of the IVUS investigation. Obvious waisting of the balloon on inflation, indicating the presence of resistance at the narrowed portion of the vein, was found in 87% of limbs. Minimal change was observed in 1% and no waisting occurred in 12%.

Venous collateralization was found on the intraoperative venogram in 78% of patients. Transpelvic collaterals were most commonly seen (89%), followed in frequency by a visualized ascending lumbar vein (32%), and axial collaterals (18%). After balloon-dilatation and/or stenting, the collaterals disappeared completely in 72%, substantially decreased in 17% and remained essentially unchanged in 11% of limbs. A subgroup of 17 limbs with diffuse narrowing of the iliac vein with no collateral formation was identified. After balloon dilatation the vessel in most instances recoiled towards the original dimension to varying degrees. The mean recoil percentage was 86% (± 26, SD). No iliac vein pressure gradient was observed in many of the limbs during the intraoperative measurement. A resting gradient of $\geq$ 2 mmHg was seen in only 18% of limbs. This rate increased to 54% after papaverine injection. The cross area increased from 0.44 ± 0.33 to 1.51 ± 0.41 cm^2 poststenting.

Post-operative: The early complication rate was low and there was no mortality. Thrombosis of the stented area occurred in 7 limbs within 3 weeks of the surgery. Thus, the postoperative occlusion rate was 8%.

During the initial part of this study (16 limbs) care was taken not to insert any stent into the inferior vena cava, but rather to place it slightly beyond the stenosis even when the narrowing was at the ilio-caval junction. Five of these patients (38%) had full relief of symptoms after treatment, but returned during the follow-up period with symptomatic recurrence 6-8 months later and restenosis central to the stent. All limbs were restented successfully with placement of the stent well into the inferior vena cava. When this late complication of stenting was realized, all subsequent stents have been placed well into the inferior vena cava. Neither deep vein thrombosis of the contralateral limb nor any recurrence of stenosis of the common iliac vein has occurred.

Clinical: The median clinical follow-up of 62/78 limbs (79%) is 9 months (range: 1-27). Antegrade transfemoral or ascending venograms was performed in 54 patients. Three stents had irregularities within the stent, indicating hyperplasia or partial rethrombosis but no obstruction to flow. During follow-up one limb was found with recurrent stenosis distal to the stent, and late occlusion occurred in 2 limbs (4%). The remaining patients (8) had duplex Doppler ultrasound performed, which showed no indication of obstruction of the iliac segment. The primary, primary assisted, and secondary patency rates at 1-year were 75%, 87%, and 89%, respectively, as per reporting standards of the SVS/ISCVS.

There was substantial pain relief after surgery. The rate of patients free from pain increased from 16% to 64% postoperatively. The mean value of the pain intensity scale decreased from 4.3 ± 2.5 (SD) before the intervention to 1.5 ± 2.4 (SD) ($p < 0.001$) on follow-up. The leg edema also improved. Prior to surgery 97% of patients complained of varying degree of swelling; this rate was reduced to 57% after the procedure. The clinical score of swelling decreased from 1.4 ± 0.5 (SD) to 0.8 ± 0.8 (SD) ($p < 0.001$).

Twenty-four limbs had active ulcer before the balloon dilatation and stenting. In eleven patients, the ulcer healed after the stenting before additional reflux surgery was performed (46%). The ulcer healed in two additional patients, but recurred quickly; four venous ulcers never healed, and seven limbs were not yet evaluated.

Conclusions

1. Venoplasty and stenting of the iliac vein is a safe procedure with no mortality, low morbidity, and substantial clinical benefits.
2. Iliac vein obstruction is a painful lesion, significantly improved by balloon dilatation and stenting.

3. The significant recoil after simple dilatation warrants a stent insertion in all cases following venoplasty.
4. Stents should be inserted well into the IVC to prevent recurrence of central stenosis.
5. The definite objective preoperative test to use for selection for this procedure needs to be defined.

CASE OF SECONDARY DEEP VENOUS DISEASE

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This 47-year old healthy male was referred with a 4-year history of chronic venous ulceration of the right lower extremity due to post-thrombotic disease of the femoral-popliteal-tibial veins.

The problem began 4 years ago with the spontaneous onset of itching, discoloration, and a small sore on the posterior aspect of the calf. Swelling and chronic aching with dependency were progressive, and the ulcer grew to a large, encircling lesion of the entire circumference of the calf. Treatment by a series of 8 physicians entailed many medications during this time, but elastic support was not prescribed. No objective tests were done. During this time the problem was progressive.

A clinically apparent DVT of the SFV was diagnosed one year ago and treated with heparin-coumadin. Workup for a hypercoagulable state was negative.

3 months prior to this referral, he consulted a new physician who diagnosed severe deep venous reflux and prescribed elevation of the leg, pneumatic compression and pumping of the leg, and limitation of activity. His ulcer closed over the next three months.

The dominant symptoms were aching and swelling of the leg, and venous claudication with walking. The need to pump his leg interfered with his occupation as a traveling sales person. He had to stop his hunting activities. The problem was that the treatment prescription to control the ulceration required a life-style change that was incompatible with his desired way of life, and with his occupation.

P.E.: Healthy, strong 47-year old male. 5'10" tall, 230 lbs. Normal physical examination including arterial pulses, except for venous findings in RLE: Right calf 1" larger than left; large discoloration encircling the leg, 6" in length on post-lat and 2" on medial sides; no induration of skin, good turgor. V.V. in leg, mild.

Doppler: Mild local reflux in Posterior tibial vein, local and sustained 4-second Valsalva reflux in the popliteal vein. Late onset reflux in GSV, as found with perforator reflux. Normal phasic flow in common femoral vein.

Phase II.
Duplex scan: Occlusion of SFV to adductor canal.
PFV-popliteal connection, with 2 second reflux
SFV-popliteal collateral, with 4 second reflux
Incompetent greater saphenous vein, with low velocity 4-second reflux
Popliteal, crural, and short saphenous reflux, low velocity, 4 second duration
Incompetent, 2.0 mm perforators, medial and lateral lower calf, single
Summary: Post-thrombotic extremity with mixed obstruction and reflux. Occlusion of entire SFV, and low velocity reflux in all veins.

APG: O.F.-normal at 50%
VFI - 2.72 ml/min
2.10 ml/min with superficial occlusion
VV - 75 ml
Ejection Vol - 58 ml Ejection Fraction - 77%
RVF - 51%
Summary: Normal outflow and reflux volumes. Calf muscle pump satisfactory. Elevated RVF

Venous Pressure:

AVP: GSV: sustained high pressure without fall while walking
Dorsal toe vein: Normal fall to 30mm HG, rapid rise (<10 sec)
Arm-foot: Resting: <4 mm. Hg. Difference
Post hyperemia: 7 mm. Hg difference
Summary: Sustained venous hypertension and rapid return to baseline
(Difference between GSV and toe tracings not explained)
Consistent with deep venous obstructive and reflux disease

Summary of Phase II workup and case analysis:

Findings diagnostic of post-thrombotic disease with elements of reflux and of obstruction shown on duplex. Physiologic confirmation of significant obstruction and reflux lacking in APG. Venous pressure consistent with venous disease, both obstructive and reflux.

Further workup needed to find a way to improve his symptoms since his present way-of-life was unsatisfactory.

Phase III.
Ascending venogram: Ascending flow preferentially by superficial veins, even with tourniquet at the ankle. Ankle and upper calf tourniquets required to force flow into severely distorted tibial, popliteal, and SFV-PFV veins. Popliteal vein distorted, becoming obstructed above popliteal space.
Large GSV, main outflow tract from the calf.
The LSV (SSV) ended in a Giacomini vein which ascended to join the saphenofemoral junction. There was no connection between the LSV and the popliteal.
Normal CFV-Iliac-IVC.
No significant calf or thigh perforator veins seen.

Descending venogram: Upright examination with Valsalva revealed:
Non-visualization of SFV
Reflux in distorted PFV down through PFV-popliteal branch into popliteal vein, and then reflux down into anterior tibial and muscular veins. One large lateral branch of the CFV (common femoral vein) showed a competent valve.
GSV showed slight reflux in thigh only. (Valve leaflets seen in GSV.)