Transcommissural valvuloplasty: Technique and results

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Purpose: **The purpose of this study was to describe the technique of a variation of closed external venous valve repair (transcommissural valvuloplasty), its complication rate, and duplex scan durability.**
Methods: **The "blind" transcommissural valve repair of the vein was performed by placing transluminal sutures along the valve attachment lines, which simultaneously closed the valve attachment angle and also tightened the valve cusps. A total of 179 successfully repaired valve sites of 141 limbs in 129 patients were followed up 1 to 42 months through clinical observation and with duplex Doppler ultrasound scan.**
Results: **Postoperative complications (< 30 days) occurred in 12 (9%) of 141 limbs: superficial (1) and deep (1) wound infection, large wound hematoma (4), seroma (1), and deep vein thrombosis (5), with associated pulmonary embolus in one patient. Seventy-eight percent (reflux time ≤ 0.5 seconds) and 81% (reflux time ≤ 1.0 seconds) of valve sites were competent. The cumulative competency rate at 30 months was 59% and 63%, respectively. The cumulative ulcer recurrence-free interval was 63% at 30 months (n = 92). The pain score and swelling grade substantially improved.**
Conclusion: **Transcommissural valvuloplasty is a safe procedure with low morbidity. It is relatively rapid and simple to perform, and its competency rates are comparable to those of internal valvuloplasty. Advantages over the internal repair are that venotomy is not required, repair can be extended to small-caliber veins, and multiple valve stations can be repaired in a single stage. (J Vasc Surg 2000;32:969-76.)**

In 1968, Kistner[1] described successful correction of "primary" venous reflux by open repair of valve leaflets. Since that time, various open approaches to internal valvuloplasty have been developed.[2,3] In 1990, Kistner[4] reported a new closed technique of external valvuloplasty that did not require an open venotomy. The object of this repair was to bring the two valve attachment lines in proximity, by placement of transmural sutures, abolishing the wide angle between the valve attachment lines observed with a refluxive valve. The free edge of the valve cusps was not involved in the sutures. In 1991, Gloviczki et al[5] described a semiclosed repair of proximal superficial valves in which sutures were placed under angioscopic visualization. This repair was similar to the external valvuloplasty, except the sutures were made to pass through the valve cusp edges in addition to the approximation of the valve attachment lines. Satokawa et al[6] have independently developed a variation of this basic angioscopy technique. Using the angioscopic technique ourselves, we discovered that directional guidance of suture placement by the angioscope was unnecessary and, in fact, was cumbersome. The sutures inserted along the valve attachment lines in a certain way routinely passed through the valve cusp edges (confirmed by angioscope *after* the sutures were placed). On the basis of this initial experience, we attempted "blind" placement of sutures without the angioscope and were rewarded with uniform restoration of competency to the repaired valve station. The major focus of this study was to describe this "transcommissural" technique and report its complication rate and durability; the clinical outcome is reported only briefly.

MATERIAL AND METHODS

We studied 141 limbs in 129 patients (left/right = 62/79; men/women = 59/70; median age, 56 years

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Table I. Venous function studies in all 141 limbs before venous repair

	Total material (n = 141)	*Preoperative results (n = 76)*	*Postoperative results (n = 76)*
Ambulatory venous pressure drop (%)	49 ± 16	46 ± 17	57 ± 15*
Venous recovery time (s)	14 ± 16	12 ± 13	23 ± 19*
Venous filling $index_{90}$ (mL/s)	4.1 ± 3.0	4.1 ± 2.8	3.1 ± 2.4†
Hand/foot pressure differential (mm Hg)	1.6 ± 1.6	1.8 ± 1.7	1.2 ± 1.1†
Hyperemia pressure elevation (mm Hg)	4.8 ± 4.9	4.9 ± 4.2	4.8 ± 3.7^{ns}

Results in these patients are compared statistically (mean ± SD).
*$P < .001$.
†$P < .05$.
ns, No significance, Wilcoxon rank paired test.

Table II. Distribution of 141 limbs according to the CEAP classification

Clinical class (n)	*Etiology (n)*	*Anatomic (n)*	*Physiology (n)*
2: 4	Primary 98	Superficial 0	Reflux 106
3: 27	Secondary 43	Deep 29	Obstruction 0
4: 18		Superficial/deep 112	Reflux/obstruction 35
5: 20			
6: 72			

a, Asymptomatic; *s,* symptomatic.

Table III. Distribution of vein sites undergoing transcommissural valvuloplasty (n = 179)

Anatomic sites, n = 179 (n)		*Combined multiple sites, n = 36 (n)*	
Posterior tibial vein	10	Proximal superficial femoral vein + profunda vein	31
Popliteal vein	23	Common femoral vein + proximal superficial femoral vein	2
Distal superficial femoral vein	2	Popliteal vein + posterior tibial vein	2
Proximal superficial femoral vein	95	Profunda vein + popliteal vein	1
Profunda vein	47		
Common femoral vein	2		

The valve repair was performed at a single vein site in 105 limbs and multiple sites in 36 limbs during the same operation.

[range, 32-86 years]). The primary complaint was active ulcer in 92 limbs, marked pain in 29, presence of lipodermatosclerosis or dermatitis in 10, severe leg swelling in 5, recurrent cellulitis in 3, and recurrent deep venous thrombosis in 2. The prevalence of leg swelling was 86% and of leg pain, 82%. Air plethysmography (APG-1000; ACI Medical, Inc, Sun Valley, Calif); duplex Doppler scan that used rapid inflation/deflation cuffs; ascending and descending venography; arm/foot pressure differential; dorsal foot venous hyperemia pressure; and ambulatory dorsal foot venous pressure measurements were performed in all patients before surgery. The techniques are described elsewhere.[7,9] The results of the preoperative venous function studies are given in Table I.

The CEAP classifications according to the Reporting Standards of The North American Chapter of the International Society for Cardiovascular Surgery and The Society for Vascular Surgery are given in Table II.[10] Surgery was performed when compression therapy failed or complications (intractable pain, infection, or phlebitis) developed. We repaired and studied 179 sites (Table III). Removal of an incompetent long saphenous vein was performed simultaneously in 83 limbs.

Outcome assessment. Patients were seen in clinical follow-up at 6 weeks, 3 to 6 months, and annually thereafter. Venous function studies were repeated on follow-up.

Each repaired vein site was followed by duplex Doppler ultrasound scan to record patency and competency of the valve segment. Valve repairs were classified as competent, mildly refluxive, or moderate to severely refluxive according to the duration of reflux exceeding 0.5, 1.0, or 2.0 seconds, respectively, as

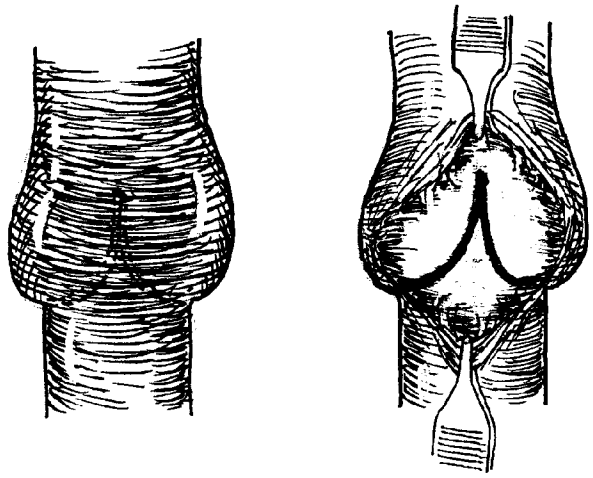

Fig 1. The adventitial dissection performed under loop magnification by sharp excision or by peeling to identify valve insertion lines is necessary in performing a transcommissural valvuloplasty. Absence of valve attachment lines in their *entirety* signifies thrombotic destruction and is an indication for alternate type of repair. More extensive adventitial dissection is necessary in post-thrombotic valve stations.

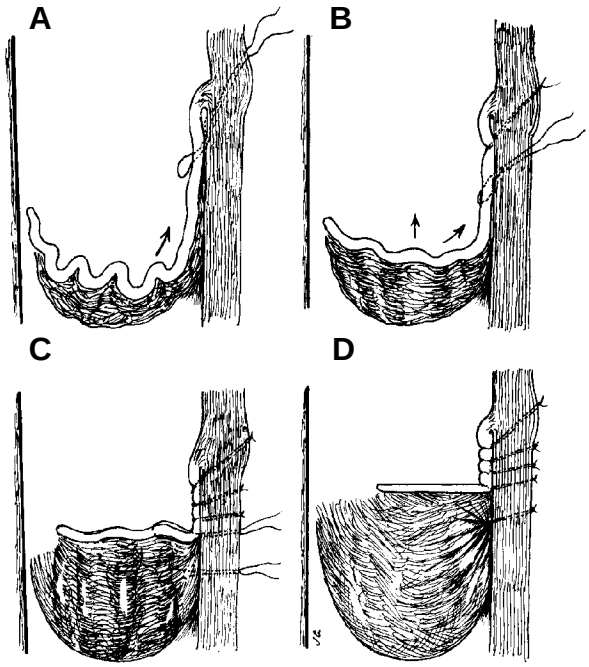

Fig 2. The initial through-and-through oblique transluminal suture placed at commissural apex catches sagging leaflets and resuspends them. **A** to **D**, Transluminal sutures with each successive suture biting deeper and less oblique than suture above to pull up valve, tighten cusp edge, deepen sinus, and appose valve attachment lines. Each suture is tied before the next is placed. One or two of the most caudally placed sutures may actually pass through body of leaflet rather than edge, with no subsequent ill effects.

proposed by Masuda and Kistner.[11] *Healing of stasis ulceration* was defined as complete epithelialization. Any breakdown of the ulcer after healing was considered a recurrence. The degree of pain was evaluated with a visual analog scale from 0 to 10, wherein 10 is the most severe pain.[12] Patients were presented with a scale with the numbers hidden and picked a point on the scale representing their level of pain. The corresponding numeric scale value was then recorded. Swelling was assessed as grade 0 (absent), grade 1 (pitting, not obvious), grade 2 (visible ankle edema), and grade 3 (massive, encompassing the entire leg).

Wilcoxon rank paired tests were used in the appropriate setting to evaluate statistical significance. A P value of less than .05 was considered significant. Cumulative ulcer, recurrence-free, and valve competence durability rates were calculated by means of survival analysis with the Kaplan-Meier method.

Surgical technique. A groin incision was preferred for first-time repairs because simultaneous superficial femoral and profunda femoris valve repairs could be undertaken and proximal femoral repairs were more durable than other sites.[13] The valve-bearing vein segment was dissected free around its entire circumference, and all tributaries or collaterals were clipped and divided. Adventitial dissection was then performed to identify the thin valve attachment lines (Fig 1). This is the most critical part of most valve reconstruction techniques. When these delicate lines cannot be convincingly visualized in their entirety by careful adventitial dissection, transcommissural valvuloplasty should be abandoned and other techniques used. The commissural apices on both sides of the bicuspid valve should be clearly visualized in the form of an inverted V. A "strip-test" was then performed to confirm incompetence of the valve. The repair was performed on a vein distended by blood without clamping. A through-and-through transluminal resuspension suture (7-0 Prolene) was placed obliquely across the inverted V, traversing the valve cusps "blindly" near their wall attachment to pull them up. Engagement of the valve cusps may be evident by noticeable puckering of the valve attachment lines in thin-walled valve stations. Two to four additional interrupted stitches were placed distally, each a little deeper and less oblique than the previous one (Fig 2). In elongated valve stations, the first suture at the commissural apex should travel quite aggressively in a caudal direction after luminal entry to catch the

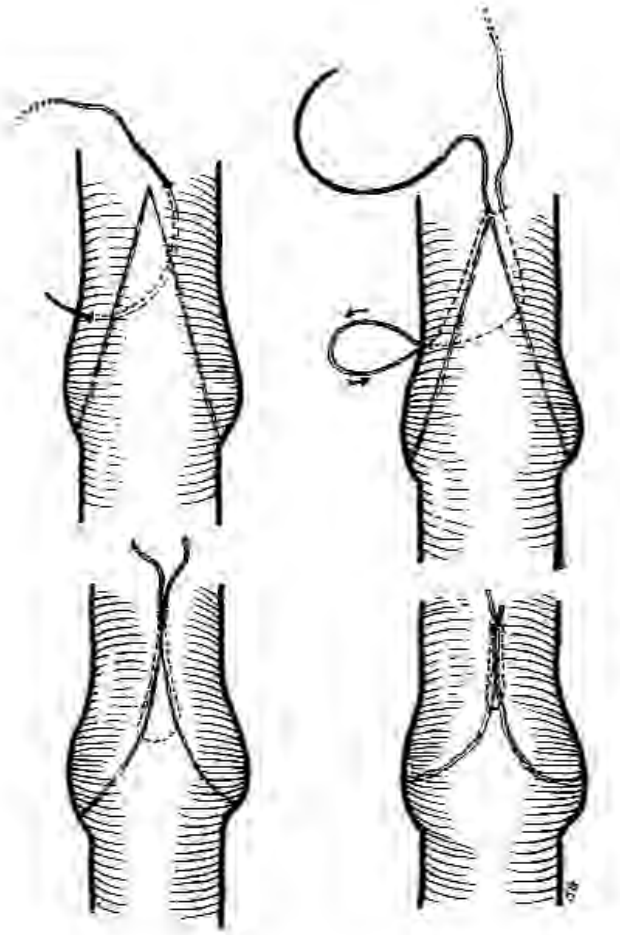

Fig 3. Caudally directed anchoring suture in elongated valve. Increasing curvature of the needle with a gentle manual bending may facilitate placement of anchor suture, which has to travel in the form of a U. After traversing both valve cusps, the needle is shown exiting temporarily to the outside to facilitate placement of initial suspension suture. Needle is reentering through the same needle puncture site to reemerge at commissural apex to complete U-shaped suture.

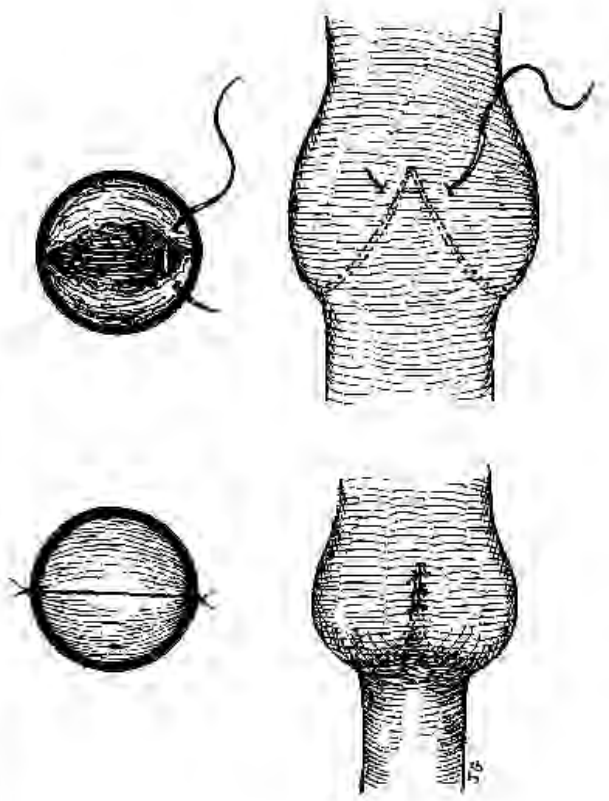

Fig 4. Correct suture placement narrows angle between valve attachment lines and tightens cusps, resulting in good apposition.

leaflets near the maximum bulge of the valve housing (Fig 3). In a normally bulbous nonthrombotic valve, the depth of the needle bite should aim for shortening of the valve cusp length by about 20% at each commissural end. The last suture was placed at a point, 1 to 2 mm beyond the maximum bulge of the valve station (Fig 4). The procedure was then repeated on the opposite side after the vein was rotated as necessary. After completion, a positive strip-test was repeated by milking the contents of the proximal venous segment in reverse direction against the valve. Care should be exercised because substantial pressures against a competent repair can be generated by this maneuver. The valve is competent if there is no retrograde leak through the repair. Valve repairs remaining leaky can often be rendered competent by the addition of one or two additional distal sutures. The repair should not be extended caudally beyond a point when further suturing would result in luminal stenosis (ie, the repaired valve station should not be smaller than the adjacent distal venous segment). If the repair is still incompetent after the additional sutures, it should be abandoned and salvaged with an axillary vein transfer. Because the post-thrombotic valve station is less bulbous and more shallow than the valve in primary reflux, the needle should travel in a less angular caudal direction and not so deep in these veins.

A prophylactic dose of cefazolin (1 g) was given intravenously before surgery and continued three times daily for 3 days after surgery because of the high prevalence of open ulcers or dermatitis in patients who underwent operations. Postoperatively, foot/leg sequential compression devices were applied until the patient became fully ambulatory. Patients were encouraged to ambulate the first postoperative day and use a compression stocking or

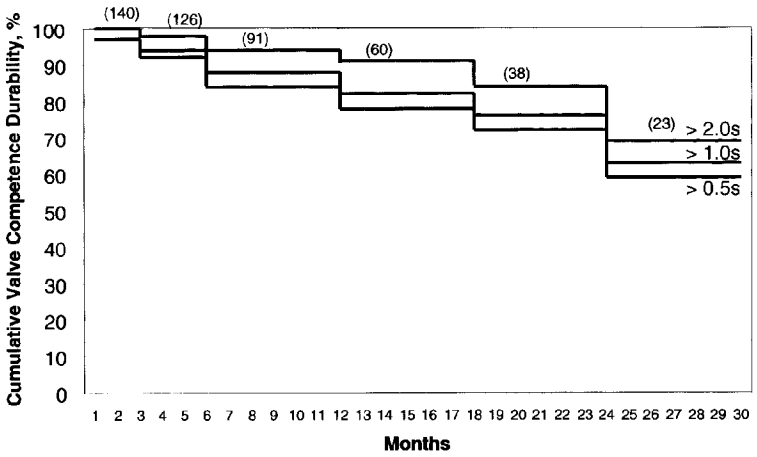

Fig 5. Actuarial durability of transcommissural valvuloplasty through follow-up period as assessed with serial duplex Doppler ultrasound scan, with incompetence defined at different reflux times of more than 0.5 second, more than 1.0 second, and more than 2.0 seconds. *Number in parentheses* represents total sites at risk for each interval.

CircAid legging continuously for the first 6 to 8 weeks postoperatively and thereafter as necessary.

During the procedure 3000 to 5000 IU of heparin was given in fractionated doses. Protamine reversal was not used. A drain was inserted through a separate incision and kept for 1 to 2 days. Dalteparin (Fragmin) given subcutaneously was started preoperatively and was then continued postoperatively in a daily dose of 5000 IU, until oral anticoagulation was effective. Anticoagulation with warfarin was started the day of operation and continued to keep the international normalized ratio at approximately 2.5 to 3.0 for 6 to 8 weeks to cover the endothelial healing period after valvuloplasty.[14] Then, the target international normalized ratio was lowered to 2.0-2.5 for 4 months. Permanent anticoagulation with a full-dose warfarin regimen was recommended for patients with known factor deficiencies. In patients who were at increased risk for thrombosis or rethrombosis for other reasons, a lifelong "minidose" warfarin regimen[15] at 1 to 2.5 mg daily was recommended after the 4-month period.

RESULTS

There were no in-hospital deaths; however, one patient with a prior history of dysrhythmia died at home 2 weeks postoperatively of unknown causes. He had discontinued anticoagulation on his own and refused readmission by his local physician for evaluation of weakness and shortness of breath. Postoperative complications (< 30 days) occurred in 12 (9%) of 141 limbs. Superficial (1) and deep (1) wound infection occurred in 2 limbs, wound hematoma necessitating surgical drainage in 4 limbs, and seroma in 1 limb. Deep vein thrombosis was found in five limbs (four "primary" and one post-thrombotic disease). Four of these thrombi involved the operated side (two including the repair) and one the contralateral limb. The patient with the thrombus in the contralateral limb had associated pulmonary embolus, the only documented instance of this complication in this series. All of the five limbs were treated aggressively with catheter-directed thrombolysis with complete resolution in three, including the pulmonary embolus, and partial resolution in two. One of the two valve repairs involved in the thrombosis was salvaged.

Three cases of interval recurrent thromboses at 6 months, 3 years, and 4 years after the initial surgery were detected during the course of routine duplex scan examination. All patients were treated conventionally. All of the late thromboses occurred in post-thrombotic limbs and involved the operated side. In two, the repaired valve site was involved, and the leg ulcer recurred. In the third patient, the thrombus was limited to the iliac vein, which resulted in increased leg swelling but no ulcer recurrence.

Assessment of patency and competency of the repaired vein site with duplex Doppler ultrasound scan was possible in 140 (78%) of 179 sites and in 109 (84%) of 129 limbs. The time range of follow-up was 1 to 42 months. Using reflux times of less than 0.5 seconds, less than 1.0 seconds, and less than 2.0 seconds as criteria for varying degrees of competence resulted in 78%, 81%, and 88% rates of

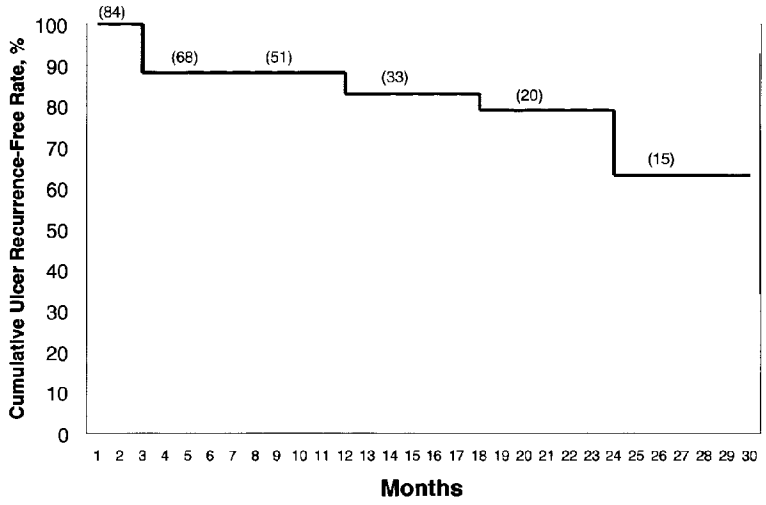

Fig 6. Cumulative ulcer recurrence-free rate after repair with inclusion of limbs that initially failed to heal. *Number in parentheses* represents total limbs at risk for each interval. Eight limbs with primary nonhealing after surgery were scored as recurrences at 3-month interval to construct the curve. Elimination of this group would result in a curve approximately 10% better than presented curve at each censored interval.

competent valve sites, respectively. The cumulative competency rates of 140 sites were 84% (88% and 94%, respectively) at 12 months, 72% (76% and 84%, respectively) at 24 months, and 59% (63% and 69%, respectively) at 30 months (Fig 5). Median time to failure was 11 to 16 months (range, 2-35 months) depending on the criteria used. Among 36 multiple valves repaired, duplex scan revealed 11 failures. All 11 valves were single failures (ie, only one of the repaired valves in the individual limb failed, the other[s] remaining competent).

The clinical outcome was evaluated in 131 (93%) of 141 limbs. The cumulative ulcer recurrence-free rates are shown in Fig 6. Of the original 92 limbs with ulcer, 84 (91%) were available for follow-up. All ulcers except those in eight (10%) of 84 limbs promptly healed within a maximum of 3 months after surgery. The eight limbs with primary nonhealing were marked as ulcer breakdowns at the end of the 3 months' grace period in constructing the ulcer-free recurrence curves. In five of eight limbs (three patients refused further workup), the valve repair had already failed. Thus, initial repair failure was the probable cause of primary nonhealing. Repeat valve repairs were undertaken in three limbs, which resulted in ulcer healing in two. Among the 76 limbs with healed ulcers, 13 (17%) recurred during the follow-up period. Only three of the 13 limbs with ulcer recurrence had a failure of the repaired valve site. In the remaining 10 limbs, the causes of recurrence were judged to be new onset of saphenous reflux (2), progression of reflux at another valve site (2), untreated iliac vein stenosis (1), onset of arterial insufficiency (1), and unknown/uninvestigated (4). Eight of these 13 limbs underwent further procedures, and ulcer healing was achieved in six with problem-focused interventions. Among the recurrences, the venous filling index (available in 12 limbs) was above 2 mL/s in 8 (67%), and venous recovery times (available in 10 limbs) were abnormal (< 20 seconds) in 7 (70%).

The pain score substantially improved in the patients with both a primary complaint of only pain and the entire patient cohort (Table IV). Similarly, the leg swelling decreased significantly. The frequency of totally pain-free patients increased from 15% before surgery to 64% at follow-up, and those with complete absence of swelling increased from 14% preoperatively to 51% postoperatively.

Venous function studies were performed before and after surgery in 76 limbs (Table I). Ambulatory venous pressure improved significantly on average, and the mean venous recovery time almost doubled. Although the mean venous filling index decreased significantly after valve repair, it still remained above the normal value. With the exclusion of patients who had postoperative thrombosis, no significant increment (> one grade) over preoperative values in the arm/foot differential was noted. This indicates that the transcommissural repair did not result in mea-

Table IV. Comparison of preoperative and postoperative assessment of pain and swelling in patients with primary complaint of pain (Group A) and the total patient material (Group B) (mean ± SD)

	Group A (n = 29)		*Group B (n= 116)*	
	Pain score	*Degree of swelling*	*Pain score*	*Degree of swelling*
Preoperative	5.7 ± 1.9	1.4 ± 0.8	4.3 ± 2.7	1.3 ± 0.8
Postoperative	2.2 ± 2.4*	0.7 ± 0.9*	1.4 ± 2.2*	0.7 ± 0.9*

*$P < .001$, Wilcoxon rank paired test.

surable iatrogenic hemodynamic stenosis. Also, there was no difference between the primary and post-thrombotic valves in any of the outcome measures (clinical or laboratory) described above.

DISCUSSION

The cumulative competency rate of the transcommissural repair, 59% to 69%, depending on which reflux criteria are used, is comparable to those reported for internal and external repair.[11,13,16] The technique of internal valvuloplasty has an established track record with excellent clinical outcome and the best duplex scan competence durability as compared with other techniques. Despite this variance in endurance of valve competence, all the commonly used techniques appear to yield similar *clinical results* in the long term,[16] even up to 10 years of follow-up.[13] The internal valvuloplasty technique, though precise, is time-consuming and is restricted to use in large-caliber veins. The transcommissural technique is rapidly executed because a venotomy is not required and it can be used in smaller veins (eg, the posterior tibial or profunda femoris veins).

A refluxive valve has been noted to have a redundant elongated valve cusp[1] and often a widened valve commissural angle.[4,5,17] The internal technique repairs the redundant valve without correcting the widened valve angle. The external technique of Kistner narrows the widened valve angle without addressing the redundancy of the valve cusps.[4,18] Similar to the angioscopic technique, the transcommissural technique attempts to correct both pathologic conditions simultaneously. Even when the sutures are placed blindly with the transcommissural technique (ie, without visualization of the valve cusps), intraoperative competence, as per strip-test, is achieved in more than 95% of attempted repairs, as long as the valve insertion lines are clearly visualized externally in their entirety. For those with some background in valve reconstruction techniques, facility in performing the technique can be acquired easily with minimal guidance and practice.

Both the internal and external techniques experience loss of duplex scan competence at a certain rate over time.[13] This article documents a similar experience with transcommissural valvuloplasty. The basis for this is unknown. The deterioration in competence of the repaired valve appears to occur in two phases: an early marked loss of about 20% in the first few months after surgery and a more gradual loss in subsequent years of follow-up.[13] Kistner has indicated that in at least some instances of external valvuloplasty, loss of competence was due to torn out valvuloplasty sutures (oral communication, Feb 2000). Lane[19] has made a similar observation in experimental animals. To limit this type of loss, we have recently started wrapping repaired valve segments with reinforced silicon sleeves. The outcome of this recent modification is unknown. Wrapping dilated valve stations with prosthetic sleeves when the valve cusp architecture is normal has yielded excellent long-term results.[2,13,18,20]

The incidence of both early and late deep venous thrombosis in this series was quite low, lower than that after some commonly performed nonvenous procedures. The three cases of late interval thromboses occurred in post-thrombotic limbs and were probably related to this underlying pathologic condition rather than the valve repair itself. At the same time, there were only four instances of wound hematoma and no other generalized bleeding perioperatively. This may be related to our anticoagulation protocol, particularly the minidose warfarin regimen, which has evolved empirically over time. Post-thrombotic patients and even patients with primary reflux who have had distal thrombosis[11,13,21] are probably under increased risk from recurrent thrombosis. The minidose regimen has been effective in other situations associated with a high risk of thrombosis.[22] Routine protime determinations are not required, and the bleeding complications of full-dose warfarin are absent. Therefore, we have been liberal with the use of minidose warfarin, even in patients without prior documented thromboses. The

use of warfarin for this purpose is not proven and is open to challenge.

A discussion of the role of valvuloplasty (vs compression therapy) in the treatment of chronic venous insufficiency is beyond the scope of this article and can be found elsewhere.[23-25] Symptoms such as leg swelling and pain improved significantly after transcommissural valvuloplasty. The cumulative ulcer recurrence-free rate of 63% at 30 months is in line with previously published results for other repairs.[2,11,13,16] Overall, ulcer recurrence appears to follow failure of repair. This might not be true in individual patients, depending on how their disease evolves. New onset of saphenous reflux and progression of reflux elsewhere are sources of recurrence in some of our patients with intact valve repairs. When there is recurrence, repair failure cannot be assumed, and a detailed workup is necessary. Many of the recurrences can be healed again with problem-focused therapy. There is a marked improvement of the venous hemodynamics at postoperative follow-up, which is influenced, in part, by previous and concomitant surgery.

In conclusion, transcommissural valvuloplasty is a safe procedure with low morbidity and low risk of thrombosis. This technique of valve repair is relatively rapid and simple to perform and has competency rates comparable to those of internal valvuloplasty in the shorter term. Multiple valve stations and small caliber veins can be repaired because venotomy is not required. Because of these considerations, the transcommissural technique is currently our method of choice for performing single-stage multiple valve reconstructions.

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