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Utility of iliac vein stenting in elderly population older than 80 years

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Background: The geriatric population aged 80 years and older with severe manifestations of chronic venous disease face diminishing therapeutic options. Self-applied compression is often not possible because of frailty or arthritis. Significant limb swelling diminishes mobility, affects independent living, and precipitates institutionalization. Limb ulceration and pain diminish quality of life at a time when it is paramount. Cellulitis uniquely poses septicemic risk in this age group. Family caregivers are often able to continue home care if the intensity of care can be reduced. Iliac vein stenting may have a role as it appears to be safe and effective in this advanced stage of life.
Methods: Patients who had failed to respond to compression and desired palliation of continuing severe chronic venous disease symptoms were considered for iliac vein stenting. Intravascular ultrasound-guided stenting was carried out under fluoroscopy without venography in case of allergy to contrast material or decreased renal function. General anesthesia was used for better cardiopulmonary control.
Results: A total of 107 limbs (12 bilateral) were treated with iliac vein stents during a 13-year period, representing 5% of all stented limbs. Median age was 83 years (80-96 years), and 10 were ≥90 years; 59% were post-thrombotic. Clinical, etiologic, anatomic, and pathologic classification was as follows: C2 (with pain), 3%; C3, 32%; C4, 33%; C5, 5%; and C6, 27%. Concurrent saphenous ablation was carried out in 28% when saphenous reflux was considered ancillary and not the main disease. There was no mortality. Reintervention was required in 20% of limbs for nonocclusive stent malfunction; 2% of stents occluded. Primary and primary-assisted duplex patency rates at 5 years were 52% and 90%, respectively. The visual analog scale score of pain improved from median 4 (0-9) to 0 (0-10) after stenting ($P < .0001$). Pain was completely relieved in 43% of limbs. Cumulative improvement in the pain score of at least 3 points was 71% at 6 years. Swelling (grade 0, none; grade 1, pitting; grade 2, ankle edema; grade 3, gross) improved from median 3 (0-3) to 1 (0-3) ($P < .0001$). Swelling completely resolved in 25% of limbs. Cumulative improvement of at least one grade of swelling (examination) was 63% at 6 years; 70% of limbs (n = 33) with prior cellulitis were relieved of recurrence after stent placement; 61% of active ulcers healed, and 37% of patients were able to discard stockings ($P < .001$).
Conclusions: Iliac vein stenting appears to offer a safe and effective option in octogenarians and nonagenarians when compression fails, is difficult, or is impossible. (J Vasc Surg: Venous and Lym Dis 2015;3:58-63.)

The incidence of chronic venous disease (CVD) increases with age. Advanced manifestations (Clinical, Etiologic, Anatomic, and Pathologic [CEAP] class 3-6 disease) tend to be poorly tolerated in the geriatric set, particularly after the age of 80 years. Frailty, sedentary habits, and comorbidities accentuate symptom expression. Orthostatic pain and limb swelling retard mobility—the key to independent living. Recurrent cellulitis often requires hospitalization rather than outpatient treatment (Fig 1). Systemic sepsis from cellulitis or open ulcers, relatively rare in the younger population, is a unique geriatric risk.[1] Traditional conservative care is difficult or impossible in this advanced age group. Frailty and arthritis inhibit self-applied compression, although devices that assist self-application may be helpful in some (Fig 2). When ulceration breaks out, either home visits by nurses or frequent trips to a wound care center with transportation assistance are required, straining what little family and community support there may be (Fig 3). In many instances, CEAP class 3-6 disease may precipitate institutionalization in the very elderly. If compression fails, as will be the case in a large fraction, few options remain; open surgical measures, such as valve reconstructions and venous bypasses, are largely prohibited because of comorbidities. Persistence of advanced CVD symptoms in this setting degrades quality of life to a severe degree at a time when this is paramount. Minimally invasive techniques, such as percutaneous saphenous ablation and iliac vein stenting, offer some prospect of relief in this challenging situation. Saphenous ablation (outpatient) may be helpful in healing venous ulcers in some cases of failed conservative therapy.[2] The aim of this report is to describe our favorable experience with iliac vein stenting (with concurrent saphenous ablation in some) in patients aged 80 years and older in whom deep venous obstruction is the dominant disease.

METHODS

Iliac vein stenting was carried out in 107 limbs in 95 patients ≥80 years old (12 bilateral, of which eight were simultaneous and four were staged) during a 13-year

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Fig 1. This 81-year-old patient slumped over the walker has been hospitalized numerous times for control of cellulitis. Repeated admissions strain family resources and often lead to institutionalization.

period. This subset represented 5% (107 of 2349) of all iliac vein stents carried out during the same period. Three were recanalizations of chronic total occlusions; the remainder of the stents were for correction of stenoses. Demographics and CEAP classification are shown in Tables I and II. Swelling was assessed by physical examination and was graded 0 to 3 (grade 0, none; grade 1, pitting; grade 2, ankle edema; grade 3, gross). Pain was assessed by the visual analog scale (0-10). Median pain was 4 (0-9), and median swelling was 3 (0-3). Of these patients, 62% had a combination of pain and swelling; 33 of 107 limbs (31%) had prior episodes of cellulitis, and they were recurrent (three or more episodes) in 18 of these limbs.

Concurrent saphenous ablation was carried out in 30 limbs (28%) when the saphenous component was considered ancillary but not the main cause of clinical presentation (eg, grade 3 swelling) as previously described.[2,3]

Patient selection and informed consent. The procedure was offered to patients who had failed to respond to conservative therapy and were desirous of other methods of relief. Preoperative cardiopulmonary evaluation was routine, and the risks were presented to the patient for informed consent. Consent was obtained after extensive discussions with the patient and primary caregivers of three essential elements: (1) the disease generally posed little risk to loss of life or limb; (2) endovenous intervention was meant to palliate symptoms, which may improve quality of life if it is successful; and (3) the benefit of a favorable outcome (not ensured) has to be balanced against the inherent risk of the procedure at an advanced age and in frail health. Institutional Review Board approval was not sought as this was a retrospective analysis of past clinical data in aggregate.

Technique. A full workup including thrombophilia profile, duplex ultrasound, venous pressures, and transfemoral venography was carried out when feasible as previously described.[4] When this was not possible (33% or 35 of 107 limbs) because of extreme frailty, renal dysfunction, or allergy to contrast material, intravascular ultrasound (IVUS) was the only diagnostic modality, followed by iliac vein stenting in a single sitting. This was carried out with IVUS guidance alone under fluoroscopy when venography was contraindicated. General anesthesia was used in all cases because cardiopulmonary control is superior to that possible with local anesthesia. Furthermore, balloon dilation of the iliac veins is causative of intense pain with local anesthesia even with intravenous sedation as an adjunct. Aspirin was adequate for postoperative stent maintenance in nonthrombotic cases, in some post-thrombotic cases, and when the prothrombotic trigger was no longer in play.

Fig 2. This 87-year-old patient with bilateral venous leg ulcers is unable to self-apply stockings because of arthritis in her hands (*right*). The ulcers are being managed by home health care personnel with daily bandaging.

Fig 3. A 92-year-old nursing home patient with massive venous leg ulcer of the right lower limb (*top*) and cellulitis on the left side (*bottom*). Compression had failed, and nursing home personnel found management challenging. Substantial symptoms obviously degrade quality of life at a time when it is a paramount consideration in geriatric patients.

Details of stenting technique, anticoagulation, and follow-up protocols have been described in detail elsewhere.[4-6] Specific aspects are briefly summarized here.

Clinical follow-up. Stented patients were seen at 6 weeks, at 3 months, and at 6-month intervals thereafter by the physician or nurse practitioner. More frequent follow-up was necessary in some patients because of interval symptoms or comorbidities. Stent surveillance was carried out with duplex ultrasound the day after the procedure, at 2 weeks, at 4 weeks, and at each clinic visit as outlined. The limb was screened for deep venous thrombosis if swelling or symptoms recurred.

Reinterventions to detect and to correct stent malfunction were carried out in patients if symptoms persisted or recurred as previously described.[7]

Statistics. Paired and unpaired two-tailed *t*-tests were used for comparison as appropriate. Paired *t*-tests were used in evaluating pain and swelling in patients; other statistics were evaluated by unpaired *t*-tests. Significance was defined as $P < .05$. Stent patency, pain, and swelling are presented as cumulative curves. Left and right sides were combined, neglecting left side and right side interaction, if any, on survival estimates. All analyses were performed with Prism software (Prism Software Corporation, Irvine, Calif).

Table I. Demographics of patients (N = 107)

Median age, years (range)	83 (80-96)
Male:female	1:2
Right limb:left limb	1:2
Post-thrombotic, No. (%)	63 (59)
Primary, No. (%)	44 (41)
Concurrent saphenous ablation, No. (%)	30 (28)

RESULTS

Pathology

Forty-four limbs had nonthrombotic iliac vein lesions that were focal and subsegmental.[8] Ten had only the proximal lesion, six had only the distal lesion, and 14 had both lesions; four limbs had lesions involving the proximal, distal, and retroinguinal locations. Lesion detail was missing in 10 limbs. Sixty-three limbs were post-thrombotic, 10 of which were thought to be secondary to prior nonthrombotic iliac vein lesions. These were segmental lesions involving the iliac-caval femoral veins. Specific segmental detail was not kept in these limbs for presentation.

Overall, the mean stenosis was 68% (median, 70%) by IVUS planimetry. Specific thrombophilia was detected in 13 patients. Warfarin anticoagulation was prescribed for 32 patients after the procedure; the remaining 63 patients were discharged on long-term aspirin (325 mg).

Mean follow-up was 17 months (median, 8 months).

Mortality

There was no postprocedure mortality (30 days). Among the 95 patients, 45 (47%) are still alive, nine are

Table II. Clinical, Etiologic, Anatomic, and Pathologic (*CEAP*) classification

CEAP class	*No. (%)*
C2 (with pain)	3 (3)
C3	33 (32)
C4	34 (33)
C5	6 (5)
C6	28 (27)

deceased, and no information is available for 41. Those still living have survived a median 36 months after stent placement. The median survival after stent placement of the deceased was 24 months.

Morbidity

Postoperative deep venous thrombosis occurred in two cases (2%), one within 30 days and one after 30 days. One of these involved the stent as well, and the other was in the contralateral limb. There were two late (>30 days) stent occlusions. An attempt was made in one limb to reopen the occluded stent, which failed.

Even complex stenting procedures, such as simultaneous bilateral stenting including recanalizations, were well tolerated (Fig 4).

Stent patency

Cumulative primary and secondary stent patency rates are shown in Fig 5. The primary stent patency curve was censored when a reintervention for nonocclusive stent malfunction was required. There were only two stent occlusions that are reflected in the secondary patency curve. Primary-assisted patency is not shown as it nearly superimposed on the secondary patency curve. Reinterventions to correct stent malfunction due to recurrent symptoms were carried out in 21 limbs (20%) without mortality.[7] In four of these limbs, two reinterventions each were required. Clinical results presented here reflect status after reinterventions.

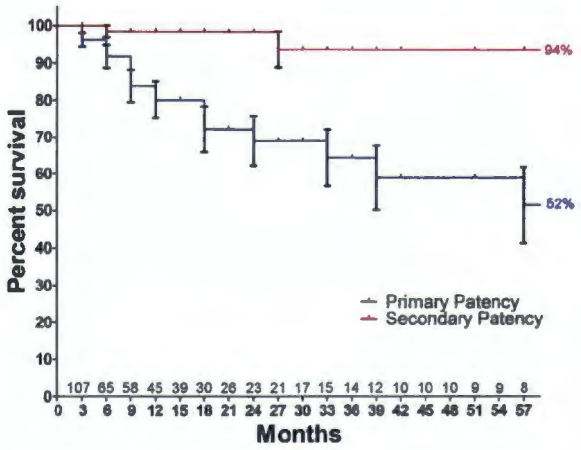

Fig 5. Cumulative primary and secondary stent patency rates in 107 limbs in patients aged ≥80 years. Curves were truncated when standard error of the mean was >10%.

Pain

Grade of pain (0-10) improved from preoperative median 4 (0-9) to 0 (0-10) on the visual analog scale after stenting ($P < .0001$). Pain was completely relieved in 43% of limbs.

Swelling

Swelling improved from prestent median of 3 (0-3) to 1 (0-3) ($P < .0001$). Swelling completely resolved in 25%

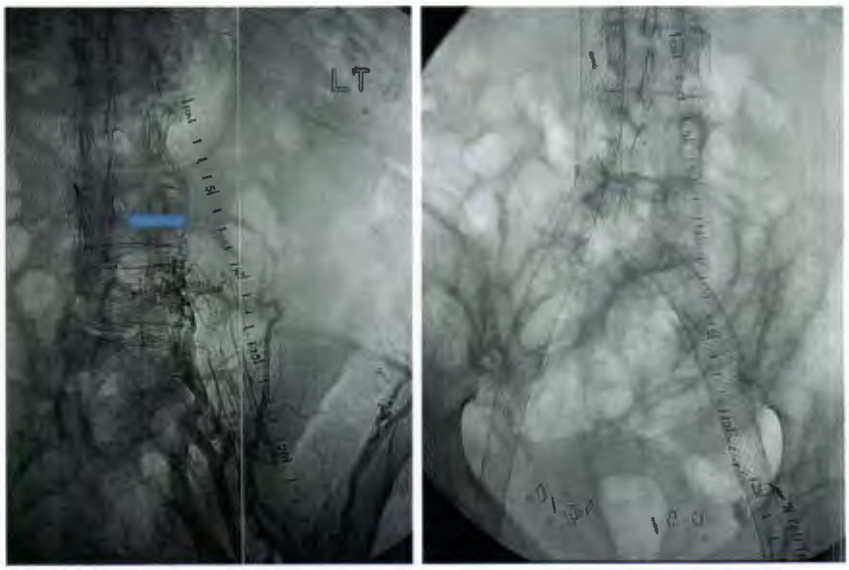

Fig 4. Same patient shown in Fig 3 had an occluded inferior vena cava filter (*left; arrow*) with chronic total occlusion extending to both iliac veins. Successful bilateral iliac-caval recanalization with stenting across the occluded filter was achieved (*right*).

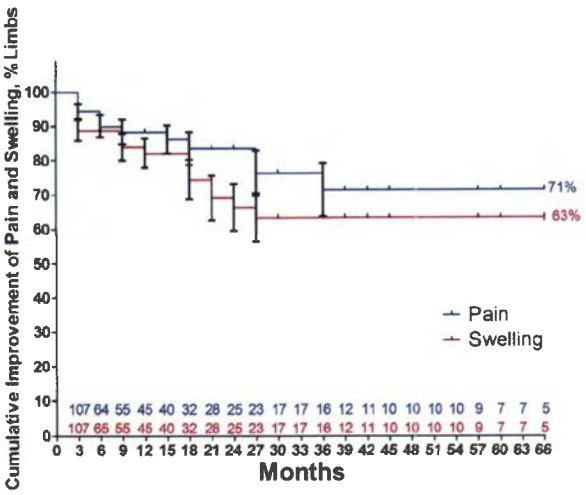

Fig 6. Cumulative improvement in pain (≥3 points on the visual analog scale) and swelling (≥1 grade of swelling) after stenting in advanced geriatric patients (n = 107).

of limbs. Of 33 limbs with prior cellulitis, 23 were relieved of this during the follow-up interval.

Cumulative rates of relief of pain and swelling are shown in Fig 6.

Ulcer

Of 28 ulcers, 17 (61%, noncumulative) completely healed after stenting. Conservative therapy was continued in unhealed ulcers.

Stockings

Prestent. Before stenting, 62% (66 of 107) could not or would not use stockings; 38% of limbs (41 of 107) used stockings before stenting.

Poststent. After stenting, 37% (15 of 41) of prestent stocking users were able to discard stockings ($P < .001$).

DISCUSSION

Whereas manifestations of advanced CVD are a significant cause of work loss and chronic disability in the young, their impact is more dire in octogenarians and nonagenarians, often leading to institutionalization (anecdotal; precise data unavailable). Lack of mobility from swelling or orthostatic pain compromises independent living. Venous ulceration and cellulitis often require hospitalization and impose wound care requirements that are not easily carried out in independent living conditions. Many patients and families prize home care, if it is at all feasible, and welcome interventions that can reduce the intensity of care required to make this possible. Even for institutionalized patients, this is desirable as better care may be provided in the context of the strained resources of many understaffed facilities. Relief of pain and suffering to the extent possible in the last stages of life is the central theme of geriatric care. Actuarial tables available through the Social Security Administration predict that an individual reaching the age of 80 years will live approximately another decade, and those reaching the age of 90 years can be expected to live another 4 to 5 years.

Compression is the first line of treatment in these difficult cases, as in the younger subset. However, many older patients are unable to effectively use compression because of the local condition of the limb, because of physical limitations, or simply because compression fails to yield adequate relief.[9] Nearly two thirds of patients in this analysis were not using stockings for these reasons. Franks et al,[10] in a randomized trial of compression stockings in 188 patients (mean age, 72 years; 31% were ≥80 years), found that 12% were unsuitable for stockings because of the local condition of the limb, 15% could not put them on, and another 26% could put them on only with great difficulty. Contact dermatitis with redness and itching occurred in 30% of patients. Despite stocking use, ulcers had recurred in 26% and 31% at 12 and 18 months, respectively.

When compression fails, a number of open surgical procedures, such as venous bypass and valve reconstruction, are available to the younger subset but are rarely used because of the complexity of the procedures, and the expertise required is not widely available. In the very elderly, such salvage procedures are seldom considered because of the associated morbidity. The advent of iliac vein stenting would appear to open a door for relief in these otherwise desperate cases.[11] Mortality and morbidity are low and symptom relief is noteworthy; long-term (>5 years) stent patency rates of ≈90% have been reported in several large series. Nearly three quarters of patients in this series experienced significant symptom improvement at 24 months; nearly half of the patients had complete relief of pain, and a quarter had complete swelling resolution. About two thirds of venous ulcers healed. In an estimated majority of treated patients, this resulted in retention of home care and restoration of mobility. Among 41 patients who were able to use stockings before, 15 were able to discard stockings, a significant quality of life benefit.

Venous stenting expertise is widely available and has the potential to benefit the geriatric population with advanced manifestations of CVD.

CONCLUSIONS

The very elderly geriatric population, with severe manifestations of chronic CVD, faces diminishing therapeutic choices if conservative therapy fails or cannot be used effectively. Iliac venous stenting may be applicable as a salvage procedure in many of these patients; mortality and morbidity are low, patency rate is high, and symptom relief is satisfactory. Its special appeal is that it is a minimally invasive procedure that can be applied in the geriatric subset that is unsuited to more invasive procedures with greater morbidity.

AUTHOR CONTRIBUTIONS

Conception and design: SR
Analysis and interpretation: SR
Data collection: SR, MW

Writing the article: SR
Critical revision of the article: SR
Final approval of the article: SR
Statistical analysis: SR, MW
Obtained funding: Not applicable
Overall responsibility: SR

REFERENCES

1. Raju S, Tackett P Jr, Neglen P. Spontaneous onset of bacterial cellulitis in lower limbs with chronic obstructive venous disease. Eur J Vasc Endovasc Surg 2008;36:606-10.
2. Raju S, Kirk OK, Jones TL. Endovenous management of venous leg ulcers. J Vasc Surg Venous Lymphat Disord 2013;1:165-72.
3. Neglen P, Hollis KC, Raju S. Combined saphenous ablation and iliac stent placement for complex severe chronic venous disease. J Vasc Surg 2006;44:828-33.
4. Neglen P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. J Vasc Surg 2007;46:979-90.
5. Neglen P, Berry MA, Raju S. Endovascular surgery in the treatment of chronic primary and post-thrombotic iliac vein obstruction. Eur J Vasc Endovasc Surg 2000;20:560-71.
6. Raju S, Neglen P. Percutaneous recanalization of total occlusions of the iliac vein. J Vasc Surg 2009;50:360-8.
7. Raju S, Tackett P Jr, Neglen P. Reinterventions for nonocclusive ilio-femoral venous stent malfunctions. J Vasc Surg 2009;49:511-8.
8. Raju S, Neglen P. High prevalence of nonthrombotic iliac vein lesions in chronic venous disease: a permissive role in pathogenicity. J Vasc Surg 2006;44:136-43; discussion: 144.
9. Raju S, Hollis K, Neglen P. Use of compression stockings in chronic venous disease: patient compliance and efficacy. Ann Vasc Surg 2007;21:790-5.
10. Franks PJ, Oldroyd MI, Dickson D, Sharp EJ, Moffatt CJ. Risk factors for leg ulcer recurrence: a randomized trial of two types of compression stocking. Age Ageing 1995;24:490-4.
11. Raju S. Best management options for chronic iliac vein stenosis and occlusion. J Vasc Surg 2013;57:1163-9.

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