Journal of
Vascular Surgery
Venous and Lymphatic Disorders™

Compression use in the era of endovenous interventions and wound care centers

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Background: **Compression has long been the mainstay of treatment in chronic venous disease (CVD). The current treatment paradigm emphasizes compression as primary treatment, awarding saphenous ablation only an optional role. The advent of endovenous interventions, such as endovenous ablation (EVA) of the saphenous vein and iliac vein stenting, has dramatically expanded therapeutic options. The relative roles of the old and newer techniques are in a state of flux and need to be redefined. Herein we provide a broad review of compression use in the context of emergent endovenous therapies.**

Methods: **Relevant key literature is selectively reviewed. It includes many past randomized controlled studies but also newer case series with a lower level of evidence that reflect evolving practice trends.**

Results: **Compression may correct local reflux, arguably improve calf hemodynamics, and control some end manifestations of CVD. Its efficacy varies widely because there is a large variability in the actual compression delivered by different products and individual bandaging techniques. Approximately 50% of ulcers recur with compression alone when it is used long term. Noncompliance with stocking use is a major issue that ranges >50% in some reports. EVA has no such compliance issues, and there is little aftercare required. EVA reduces long-term recurrence and may shorten healing time in wounds that are slow to heal with compression alone. Failure of compression can be detected as early as 2 to 6 weeks by monitoring ulcer healing metrics. Endovenous interventions yield durable clinical results in a large subset of patients in whom compression failed or could not be used. Initial costs of interventions are higher than those of compression, but long-term direct and indirect costs are likely to be substantially lower.**

Conclusions: **Compression is the appropriate initial treatment in symptomatic CVD patients, even those with ulcer. The main concern at this time is ulcer care and quick control of symptoms. However, compression is not a long-term solution, particularly in venous leg ulcers as the majority of ulcers will recur without interventional correction. The option of interventional correction should be offered early, preferably concurrently with start of compression, as delay allows progression of disease, prompts recurrence, and increases overall costs. Persisting with compression alone fruitlessly for months or years does not seem justified, given the efficacy and the minimally invasive nature of newer treatments. A treatment paradigm that emphasizes intervention side by side with compression in symptomatic CVD patients at the outset should be considered. (J Vasc Surg: Venous and Lym Dis 2016;■:1-9.)**

Compression is the mainstay of treatment in symptomatic chronic venous disease (CVD). It has a long tradition of use and is perceived to be "simple" and innocuous, if not always effective. In the last two decades, minimally invasive endovenous therapies (saphenous ablation, iliac vein stenting) have emerged that are safe, effective, and in most cases carried out in an outpatient setting. They are fundamentally different from compression as they provide correction of specific offending pathologic processes, whereas compression largely attempts to control end effects. However, endovenous treatments are mostly used only when compression has failed. In case of varicosities, third-party payers mandate compression use for a variable length of time (because of presumed cost "savings") before ablation can be considered. In the case of venous leg ulcers (VLUs), the belief that compression is essential to heal ulcers and interventional correction is only for prevention of long-term recurrence has taken root. Herein, we review in some detail the mechanisms of action, efficacy, and cost of both compression and endovenous techniques. On the basis of this review, we suggest that the current paradigm of "compression mandatory, intervention optional" be replaced with a more balanced application of these modalities. Early intervention may shorten healing times, reduce recurrence, and lower costs overall.

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Author conflict of interest: S.R. is a current shareholder in Veniti, Incorporated (endovenous therapies).

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

http://dx.doi.org/10.1016/j.jvsv.2015.11.001

Compression

Mechanism of action. Compression has been in use since antiquity; early versions of compressive leggings are probably among the first ever "medical devices" invented. Compression is known to effectively control at least some manifestations of CVD. It controls edema by decreasing capillary filtration and enhancing lymph flow, eliminates local reflux, arguably improves local oxygenation and

Table I. Classification of compression hosiery and stockings

Compression class	*Compression intensity*	*Compression, mm Hg*
I	Low	18-21
II	Moderate	23-32
III	High	34-46
IV	Very high	49 and higher

Recommended by the International Compression Club.

flow, and may downregulate inflammatory cytokine mechanisms.[1-4] Several of these concepts are unsettled as the literature is controversial. For example, contradictory findings regarding hemodynamic improvement with compression have been reported.[5-8] This may be related to the variable mechanical efficiency of stockings/compression used in different studies.

Surprisingly, many aspects of compression efficacy still remain obscure despite centuries of use. Not surprisingly, dogmas and opinions accreted over millennia are taken as fact when none exists. A central dogma is related to compression itself as a therapeutic modality. Compression bandaging is an art. Many who have become expert at it believe that it is the only effective treatment for CVD manifestations, particularly venous ulcer; treatment failure is attributed to technique, not the method itself. The International Compression Club led by Mosti and Partsch has begun a systematic examination of myths and controversies on the topic to shed light on compression.[9] For example, there is evidence that graduated (higher at ankle and less above) compression is *not* necessary to promote forward flow; on the contrary, there is evidence that higher pressures in the calf than below may enhance flow, presumably because the venous reservoir is much bigger in the calf region compared with the ankle. Contrary to "intuitive" logic, compression may constrict deep veins more than the superficial veins in initial stages. Less compression than used in ulcerated legs may be effective in relieving leg edema.[10]

Compression devices and mechanics. Compression stockings (CS) are the most common way in which compression is applied. The fabric is commonly synthetic, but a device with a rubber base is available. In case of allergy or contact dermatitis, which is common ($\approx$30%), a fabric switch is often helpful.[11] The business portion is below the knee, and higher lengths may be prescribed to control thigh varicosities and swelling or for better comfort and fit. Nonadhesive elastic bandaging is used for hard-to-fit legs and adhesive bandaging for initial healing of active ulcers. Nonelastic Velcro strap leggings (CircAid, San Diego, Calif) can apply greater pressure than stockings and may be easier to apply.

The therapeutic element in any compression device is the interface pressure—the compression "dose"—and its maintenance without decay over time of wear. There is considerable variation in this feature among different makes.[12] An international standard classification of CS based on interface pressure applied is now widely used (Table I).[13] Whether the elastic or stiff component of compression is important is controversial and unsettled.[9] Stockings commonly used for prevention of thromboembolism provide <15 mm Hg pressure at the ankle, much less than recommended for the Clinical class, Etiologic, Anatomic, and Pathophysiologic (CEAP) class 4 and higher CVD.

Bandages are commonly applied by "feel," and the pressure applied is unknowable unless pressure sensors are used. The bandaging terminology used can be misleading. Single-layer bandaging, for example, is not truly single layer because of application overlap. The four-layer bandage (4LB) is a multicomponent bandage consisting of orthopedic wool, crepe bandage, elastic bandage, and elastic cohesive (outer) bandage. With the necessary overlap, the final pressure and elastic property are variable with technique. Frequently, the final bandage is no longer elastic but stiff because of friction between layers even when materials with elastic components (Coban 2, Coban Lite, Acrylastic, Tricoplast) are used. Short-stretch bandages are single component but "multilayer" when applied. The result is that technique and postapplication factors determine the functional characteristics of a particular bandage in the leg, not its bench values in the laboratory. For example, such stretchable material as Gelocast forms a rigid zinc paste cuff on the leg exerting high pressures during walking, even when the pressure at application is low. The errors introduced from such variability in material and application technique are an uncontrollable factor in randomized "controlled" trials in this sphere, often yielding wildly different results that confound systematic reviews and meta-analyses. A recent systematic review concluded that identifying the most efficient compression system for wound healing based on existing literature is practically impossible.[14]

Currently, there are no data demonstrating superior benefits of intermittent pneumatic compression over standard compression.[15] Therefore, recommendation for its use is limited to patients in whom a standard compression cannot be used.[16]

Local care of venous ulcers. In most wound care centers, local VLU care is per "standard practice" with addition of compression. Yet, there are reasons that special care in VLU is needed. In CVD, the allergic dermal barrier is breached, allowing the easy development of allergies to locally applied chemicals and antibiotics.[17] The erythema

Table II. Efficacy of compression in healing of venous leg ulcers (VLUs)

First author	*Type of study*	*Comparison*	*Main findings*
O'Meara[1]	Meta-analysis	Compression vs no compression	Healing rate is significantly better with compression
Wong[22]	RCT	SS or 4-LB vs no compression	67%-72% healed at 24 weeks with compression vs 29% without compression
Nelson[15]	Meta-analysis	Compression vs no compression	Compression significantly reduces recurrences at 6 months
Nelson[23]	RCT	4LB vs single-layer bandage	4LB yields better healing rate and percentage of healed ulcers at 24 weeks compared with single layer
Ashby[24]	RCT	2-layered CS vs 4LB	No difference in time to heal between 2-layered CS and 4LB
Pham[25]	RCT	SS vs 4LB	Similar cost-effectiveness between SS and 4-LB

CS, Compression stockings; *4LB,* four-layer bandage; *RCT,* randomized controlled trial; *SS,* short-stretch bandages.

associated with induced local allergy is often mistaken for cellulitis, prompting even more intense use of local applications, perpetuating the cycle. Venous ulcers are superficial (unlike full-thickness diabetic or ischemic ulcers), often sparing elements of the dermal layer, which may resemble white patches of dead tissue. Débridement should be avoided as this layer is the source of re-epithelialization during healing. Typically, VLUs heal after bandaging or intervention within a matter of weeks; epithelial growth from the center as well as from the periphery rapidly coalesces to close the wound.[18] In contrast, healing of diabetic or ischemic ulcers is more prolonged as epithelial growth can take place only from the periphery of the wound.

Supported indications for compression use. Compression is indicated to relieve swelling, local variceal pain, and diffuse venous leg pain and to heal ulcers about 1 inch (<500 mm^2 area) or less in size. Larger ulcers often require ancillary measures as compression by itself is slow or ineffective to heal the ulcer.[18,19] Because compression is empirically effective in relieving many manifestations of CVD, it is often prescribed for conditions even when there is no clear evidence of its efficacy. For example, there is no current evidence that stockings have any prophylactic value to prevent new onset of varices or recurrent varices after surgery; nor are they effective in reducing varices already formed. Currently, there is no firm evidence that they are less effective in post-thrombotic disease vs primary disease, although anecdotal clinical experience suggests as much. Their efficacy in controlling hyperpigmentation or lipodermatosclerosis has not been convincingly documented. Compression is known to reduce deep reflux, but long-term clinical utility on this score is lacking.[9,20] It is not known if compression is more or less effective in venous obstruction vs reflux. The general principle in combined arterial and venous ulcers is to correct the arterial component first, which may be sufficient to heal the ulcer, with venous correction reserved only if it fails. Stockings are contraindicated if the ankle pressure is <60 mm Hg or ischemic symptoms are present (although most clinical trials exclude limbs with pressures <90 mm Hg).[9] A recent controlled trial (SOX) suggests that compression may not prevent post-thrombotic syndrome, contradicting results of earlier studies.[21] Some limitations of the study (partial unblinding, uncontrolled compliance) have drawn criticism. Further confirmation will be necessary before its recommendations are implemented in clinical practice.

Efficacy. Compression outcome is most clear in ulcer disease; relevant end points include time to complete healing, percentage of wounds that heal, and recurrence rate (Table II). Randomized controlled trials consistently show that percentage healing is significantly higher when compression is used than not, and ulcers are two to four times more likely to heal with compressive bandages compared with noncompressive bandages.[1,22] Four-layer bandaging is superior to single-layer compression.[15,26] Evidence quality was graded 1A for the use of compression in ulcer disease in the guidelines recommendations by the Society for Vascular Surgery and the American Venous Forum (SVS/AVF).[16] However, >50% of all ulcers recur with compression alone, and more than a third of the ulcers recur multiple times.[11,23] Recurrences increase with time. Thus, compression is effective in healing many ulcers short term but is not nearly as effective if it is used long term for prevention.[14] Surgical correction of saphenous reflux disease in combination with compression therapy reduces ulcer recurrence.[27] These somewhat contradictory findings are probably related to patient noncompliance with self-use stockings after the ulcer has healed with bandages applied by others (forced compliance). Stocking use declines over time. Noncompliance with compression has been associated with a twofold increase in recurrence rate.[23]

Compression fails to heal the ulcer in 10% to 40% in different studies. Causes of failure are many, including technique, large ulcer size, colonization with certain bacteria, local perforator reflux, and extensive local fibrosis with a "frozen ankle" interfering with calf pump function.[19,28-31] Systemic diseases that retard healing will be a factor in some venous ulcers because of common coincident occurrence. Compression failure is detectable as early as 4 weeks and is grossly evident by 6 weeks if wound healing metrics are closely monitored.[18,28,29] Overall time to healing will be shortened if compression failure is recognized early, switching to alternative treatments. Currently,

this is not a common practice in wound care centers, where compression is often extended to months or even indefinitely.

Compression compliance. Compliance is the Achilles heel of compression treatment and is under-reported. In compression trials in which these data are provided, noncompliance has ranged from 21% to 67%.[6,32,33] In the recent SOX trial, 3% and 16% of patients in the test group were completely or partially noncompliant (zero use and use <3 d/wk, respectively) as early as 1 month after trial start, increasing to 31% and 44%, respectively, at 24 months.[34] The puzzlingly high noncompliance in such trials after voluntary enrollment, mandatory discussion of compression benefits, and subsequent close monitoring under physician supervision suggests that factors beyond lack of "patient education" (universally blamed for noncompliance) are at play. Most compression studies either omit noncompliance data altogether or state them without inclusion in analysis of compression results. A greater problem is that there is no consistent and objective way to monitor compliance other than what is reported by the patient. As noncompliance is substantial but not included, published compression results are likely to be vastly overstated as they are not based on an "intention to treat" standard; real-life results will be substantially less than predicted by the study. In a survey of 3144 patients referred to a tertiary care center, nearly two-thirds (63%) of patients were *not* using stockings/compressive devices at referral; 25% were not prescribed stockings by the primary care physician mostly for valid reasons (local condition of the limb, obesity, arthritis, frailty), but the rest had abandoned stockings after some period of initial use: 30% cited wear comfort factors (fit, warmth), 14% cited inefficacy, and 30% could not cite a specific reason.[35] Noncompliance was similar regardless of age, sex, and CEAP clinical class. In patients with open chronic ulcers of several years' duration, >60% of patients could not or would not use compression for a variety of reasons cited before. CS themselves appear to pose serious quality of life issues to many patients. Compression regimens administered at facilities impose significant burdens on time and resources of the patient and interfere with many aspects of daily living.

Endovenous treatment

Because the endovenous techniques are minimally invasive with excellent safety and efficacy, they can be considered if compression is slow, ineffective, or contraindicated. Compliance is not an issue in interventional treatments, unlike in long-term stocking use.

Endovenous ablation (EVA) of the saphenous vein is an effective solution in addressing superficial disease. An estimated 25% to 50% of patients with VLUs may have saphenous reflux. EVA appears to be less effective if there is associated deep venous reflux.[36] EVA is unlikely to be successful if the great saphenous vein is of small size (<5.5 mm), the reflux is trivial, or there is associated calf pump disease.[37] Saphenous reflux is usually not the main agent in causing edema extending above the ankle; EVA is likely to yield only partial and transient relief, if any, in such patients; deep venous obstruction sometimes with a lymphatic component is the major cause of high-grade swelling. Large ulcers require prolonged healing times even when endovascular correction is combined with compression; ancillary techniques to provide rapid skin coverage are necessary in such cases and should be used early.[18,19]

EVA of the saphenous vein by laser or radiofrequency has been shown to be equivalent to old-style surgical stripping in a number of randomized clinical trials; there was no significant difference in saphenous recanalization, recurrence of varicosities, need for reintervention, and quality of life measures between older and newer techniques.[38] The role of saphenous surgery in ulcer healing has been investigated by a number of randomized controlled studies, usually in combination with compression therapy (Table III). The largest such study, the Effect of Surgery and Compression on Healing and Recurrence (ESCHAR) trial, has had an outsized influence on the current ulcer treatment paradigm because it was the first large randomized controlled study on the subject.[20] The study randomized 500 patients to two groups: compression alone and compression plus saphenous surgery (stripping or saphenofemoral disconnection). There was no control group with surgery alone *without* compression. At 1 year, ulcer healing was similar in both groups. This was not surprising because compression eliminates local reflux (akin to a "medical" saphenectomy), and an added stripping should not be expected to show detectable additional antireflux benefit. There was a long-term significant difference at 4 years; 27% of patients who underwent saphenous surgery plus compression had recurrence compared with an ulcer recurrence of 51% ($P < .001$) in the compression only group. The authors interpreted these results to mean that saphenous ablation is *not* necessary for initial healing of the ulcer but may help prevent long-term recurrence. Besides the apparent internal contradiction, the study was not designed to assess the utility of saphenous surgery alone *without* compression as there was no such arm in the study. Because the healing rate with compression alone at 3 years was already high (89%), the incremental benefit of adding ablation (93%) was not significant. In other studies in which primary healing rate of compression was not so high, the additional benefit of saphenous ablation to compression was noticeable and significant.[28,38-40] ESCHAR conclusions have become the basis of the current ulcer treatment paradigm, awarding primacy to compression. Current guidelines issued by the SVS/AVF suggest that a saphenous vein with axial reflux directed to the bed of the ulcer should be ablated (grade 2 level of evidence) in addition to compression.

Use of intravascular ultrasound has shown that iliac vein obstruction is common in both primary and post-thrombotic limbs, often combined with reflux disease. When saphenous ablation is not indicated in CEAP class

Table III. Comparison of compression and endovenous correction[a] in healing of venous leg ulcers (VLUs)

First author	*Type of study*	*Comparison*	*Main findings*	*Comment*
Gohel[20]	RCT	Compression vs compression + saphenous ablation	Surgery added no benefit in short-term healing but reduced long-term recurrence	Surgery alone without compression not tested; underpowered to show incremental benefit of surgery in compression + surgery group
Harlander-Locke[28]	Case series	Superficial or perforator ablation in ulcers failing compression	76% of ulcers healed	
Alden[39]	Case series	Compression vs compression + superficial and perforator ablation	There was a better healing rate and lower recurrence in surgery + compression compared with compression alone	
Viarengo[40]	RCT	Compression vs compression + saphenous ablation	Saphenous ablation + compression had better percentage healing and lower recurrence	
Scriven[36]	Case series	Saphenous ablation without compression	All 16 of 16 ulcers healed	
Raju[18]	Case series	Compression and no compression after endovenous correction	Short-term and long-term percentage healing was the same with or without compression	

RCT, Randomized controlled trial.
[a]Includes surgical saphenous ablation.

≥3 limbs as described before or has failed, endovenous stenting of intravascular ultrasound-identified treatable iliac vein lesions may be considered. Venous stent technology is less readily available than EVA because of higher requirements of training, facilities, and cost.

In a recent evidence review of iliac vein stent experience, low morbidity, high medium-term and long-term stent patency, and excellent symptom resolution including ulcer healing were consistently reported.[18] In the largest series published, there was no mortality, and morbidity was minor among 982 stented limbs.[41] Cumulative secondary stent patency at 6 years was 93%. All of the stent occlusions occurred in post-thrombotic patients. Complete relief of pain and swelling at 5 years was 62% and 32%, respectively; 58% of the ulcers healed, and quality of life measures improved significantly. Residual uncorrected reflux, even when severe, did not affect clinical relief and ulcer healing.[42,43] Unlike with almost all other treatment modalities including compression, ulcer healing curves after stent placement are stable and flat long term with little decline (recurrences). Even though no randomized trials have been published to date, SVS/AVF guidelines for VLU management gave a grade 1C recommendation for the stenting approach in appropriate patients.

Is compression necessary after endovenous correction?. This question is not merely academic but has cost and care implications. Perioperative compression is a significant portion of the overall cost, particularly when it is administered in a wound care setting. It is also the least liked aspect of the patient's experience with the procedure. Most practitioners routinely prescribe compression after endovenous interventions because of long tradition and current recommendations; and it may provide a sort of double insurance—coat-over-vest strategy. Scriven et al performed saphenofemoral disconnection in 16 legs in elderly patients with isolated saphenous reflux; all healed their ulcers at a median of 81 days *without* compression with ambulatory pressure improvement.[36] In a consecutive series of 192 VLUs managed by saphenous ablation for isolated reflux (n = 30), iliac caval stenting (n = 89), or both (n = 69), patients were prescribed new stockings (in 62%) if they were already using compression at the time; no new stockings were prescribed if they were noncompliant (in 38%).[44] Patients in both groups were instructed to clean the wound with soap and water and to apply a simple unmedicated (to avoid local allergy) nonadhesive sorbent dressing. Postintervention attendance at wound care centers was discouraged to avoid damage to the regenerating epithelium by "débridement" frequently practiced between dressing changes. By 14 weeks, 81% of ulcers 1 inch in size or less had healed with no difference between the stocking and nonstocking groups. There was no long-term (4 years) difference between the two groups in ulcer survival or recurrence rate. In most centers, iliac vein stenting is being undertaken only in patients who have failed to respond to or cannot use compression therapy. The patient pool in which compression cannot be used or fails is large, and the results appear to be as good as or better than with conventional compression treatment. This obviously means that compression is not mandatory to achieve ulcer healing. There is currently no head-to-head comparative randomized trial between compression and endovenous interventions. The evidence cited earlier, although not determinative, suggests that there is basis for equipoise to justify such a trial. There are ethical concerns in devising trials without compression because of the current treatment

Table IV. Cost of venous ulcer care

Country and reference	*National annual expenditure*[a]	*Cost per patient*[a]
Australia Agu[45]	N/A	A$10,000 (US $7259) (3% national health care budget)
France Levy[46]	N/A	€1223 (US $1387)
Germany Purwins[47]	N/A	€8658 (US $9817)
Sweden Oien[48]	73 million SEK (US $8.7 million)	5351 SEK (US $645)
United Kingdom Iglesias[49]	£300-600 million (US $460-$900 million)	£1526 (US $2357)
United States Ma[50]	US $2.5 billion	US $15,732

N/A, Not available.
[a]Dollar equivalent based on October 2015 exchange rate.

paradigm. An ethically controlled trial with crossover protection should be feasible in a disease with high recurrence and chronicity even *with* compression; trials with more serious end points (stroke, myocardial infarction, and even death) are now commonplace with adequate protections consistent with the Helsinki Declaration.

Cost

Health care systems around the world are restricting *access* (if not the treatment per se, when self-funded) based on cost; efficient allocation of limited resources is considered both ethical and necessary for overall societal benefit. The Affordable Care Act (ACA) will expand medical coverage to new entrants and increase benefits to all with the stated aim of *reducing* overall costs without sacrificing quality. Venous disease in all its manifestations is a major slice of health care budgets (Tables IV and V).[45-54] In the United States, the cost of acute care of in-hospital deep venous thrombosis (DVT) alone is $1.5 billion/y.[55] The cost of treating VLU is $2.5 billion/y.[56] Treatment of lesser CEAP clinical classes and the burgeoning vein ablation treatments (350,000 EVAs/y with nearly triple-digit growth per year) probably range between $7 billion and $9 billion/y. The spiraling costs are unsustainable. Stringent price and quality controls in various forms are already emerging (Table VI). Cost control measures include *value-based payment* by the Centers for Medicare and Medicaid Services and various provisions of the ACA restricting payments to intermediaries and hospitals.[57] Quality control measures linked to payment are yet to be crystallized. They will likely involve different benchmarks specific for the disease: simple morbidity and mortality rates; cost utility, where symptom relief is combined with patient-reported quality of life; and patient-centered "comparative effectiveness research" of therapeutic interventions.[58] Dollars per quality-adjusted life years (QALYs), which measures mass utility, not individual benefit, is in use elsewhere but was specifically forbidden in ACA implementation. Nevertheless, it will likely have indirect influence because of widespread academic focus prompted by the economics of nationalized health care systems.

Wound care centers. The majority of leg ulcers in Western populations are venous in origin.[59] In a pioneering public health initiative in Sweden, community-wide prevalence was nearly cut in half by systemizing care to include early detection of compression failure and interventional correction.[60] The rapid evolution of wound care centers in the United States holds similar promise, albeit at necessarily increased personnel and facility costs. Most small venous ulcers (<1-inch size) will not require specialized treatment if the pathologic process is promptly corrected. Indiscriminate referral of such cases to a wound care center may simply increase cost without any benefit. At present, compression and débridement remain the

Table V. Cost of deep venous thrombosis (*DVT*) and pulmonary embolus (*PE*) treatment

Country and reference	*National annual expenditure*[a]	*Cost per patient*[a]
France Tilleul[51]	€60 million (US $67 million)	N/A
United Kingdom House of Commons Health Committee[52]	£640 million (US $986 million)	N/A
United States Cundiff[53] Dasta[54]	US $3.2-$15.5 billion	DVT: US $9407 PE: US $11,486

N/A, Not available.
[a]Dollar equivalent based on October 2015 exchange rate.

Table VI. Cost-saving methods and metrics in provider reimbursement

Method	*Description*
Medicare Shared Savings Program (Accountable Care Organization) Section 3022	A clinically integrated group of primary and specialty physicians who agree to a multiyear contract with CMS or private insurers. The latter assume risk for outcomes and savings of a defined patient population
Episode-based payments (Section 3023)—bundled payments	A contract between a payer (CMS, employer, plan) and provider that requires all anticipated services for an episode of care be included in a single payment (fixed price), with risk for both costs and clinical outcomes borne by providers
Alternative quality contract	Based on a modified global payment (fixed payments for the care of a patient during a specified time period). This plan is currently in operation by Massachusetts Blue Cross Blue Shield. Reimbursement is related to achieving quality goals and cost savings. Rate of increase is stipulated for each contract group's budget during a 5-year period.
Comparative effectiveness research	Research field focused on providing evidence and information on the effectiveness of various treatment options (surgeries, drugs). Evidence is typically validated through clinical trials and studies.
QALYs	Methodology that measures the disease burden of an individual in relation to the quality and quantity of life. Specifically, it weighs these factors with the fiscal aspects of medical interventions. The outcome of these comparisons is then evaluated on a QALY scale, which typically has values ranging between 0 and 1.

CMS, Centers for Medicare and Medicaid Services; *QALYs,* quality-adjusted life years.

mainstay for venous ulcer care in most wound care centers. Resort to intervention is ad hoc, not systematized.

Available cost studies in the venous sphere are summarized here.

Venous ulcer treatment. The Venous leg Ulcer Study IV (VenUS IV) randomized trial compared two-layered CS against 4LBs in 457 VLU subjects.[24] There was no difference in the median time to healing or in quality of life between the groups. The cost per year of treatment was $486 less per patient for the CS group, but 38% of CS patients changed their allocated treatment. The incidence of recurrence was lower in the CS group. CS had more QALYs (0.034) than 4LB, so that CS was the better treatment in cost/quality measures.

The Canadian Bandaging Trial compared 424 VLU patients randomly assigned to either 4LB or short-stretch bandages.[25] Treatment with 4LB led to a small increase of 15 more ulcer-free days per patient and a gain of 0.009 QALYs but at increased cost of $420 per patient compared with short-stretch bandages. The investigators concluded that both systems resulted in a similar combined cost/quality parameter.

In a recent study, 84 patients with VLU treated with 4LB and local ulcer care in a wound care center for a year were compared with a subset of 36 patients with unhealed ulcers from the same pool. Fifteen patients underwent saphenous ablation by radiofrequency (EVA) with compression/wound care, whereas 21 patients had treatment with only compression/wound care.[50] The overall yearly cost to treat the 84 patients with 4 LB was $15,732 per patient per year. The 4LB treatment costs, when the ulcer did not heal ($33,907), were three times the cost of those that healed ($10,563). Cost in the EVA arm was higher in the first year ($15,074) vs 4LB ($9474) because of the additional front cost of outpatient EVA. However, projected costs of the EVA arm based on recurrence estimates at the end of 3 years were lower ($17,811) per patient than costs of the compression/4LB arm ($26,930) per person.[61] Most important, EVA was associated with higher ulcer-free days (+105) because of lower recurrence rate, which resulted in better QALYs (0.0091 gain) and improved quality of life.[62] Ulcer recurrence is an important cost driver, not only in direct costs but in indirect opportunity costs of work hours lost and long-term disability. These extended cost parameters are not included in most cost comparison studies. The higher initial cost of EVA vs compression is likely offset by opportunity cost benefits over the long term because of lower recurrences.

Treatment of varicose veins. Compression with 20 to 30 mm Hg stockings (CS) has been advocated as the initial approach to the management of symptomatic varicose veins, and a trial of compression is a requirement by the majority of U.S. insurers before authorization of EVA.[22] The National Institute for Health and Care Excellence, which issues guidelines in the United Kingdom, however, has recommended EVA for patients with symptomatic varicose veins rather than CS because EVA was more cost-effective with better QALYs.[63]

In a study comparing interventional treatment of varicose veins with "conservative" therapy with CS, a large insurance claims database (Truven Health MarketScan) was analyzed; 44,026 patients received interventional treatment at different time points.[64] Early intervention with surgical treatment was associated with a lower disease progression than with continued use of CS. Early intervention resulted in lower total treatment-specific cost and all-cause costs compared with conservative treatment ($4445 and $17,564, respectively, per patient). The highest disease-specific costs were when treatment was delayed to at least 8 months.

Prevention of DVT. CS and intermittent pneumatic compression have long been used for DVT prevention.

A 2014 Cochrane review of CS and intermittent pneumatic compression for DVT prophylaxis identified 19 trials (nine general surgery and six orthopedic) with 1681 patients, in which 9% of CS patients and 21% of controls developed DVT.[65] This was associated with an overall effect favoring treatment with CS ($P < .00001$). Most important, pulmonary embolism developed in 5 of 283 (2%) participants in the treatment group, in contrast to 14 of 286 (5%) in the control group ($P < .04$). Because of the overall low incidence of pulmonary embolism and iliac vein thrombosis is often missed, the data available to date (although suggestive) are not robust enough for definitive conclusions to be drawn; comparative efficacy, safety, and quality of life of the various modalities used for DVT prophylaxis remain unknown.

CONCLUSIONS

An initial trial of compression is worthwhile in most CVD patients without advanced skin damage or ulcer. Compression failures should be recognized early and specific corrective interventions sought in time. Large ulcers (>500 mm^2) are tardy to heal and require skin coverage in addition to compression or endovenous correction. Interventional corrections can be safely undertaken in the presence of open ulcers that are not grossly infected. Even when compression is initially successful in healing the ulcer, interventional correction is indicated for long-term maintenance. Delay in interventional correction risks recurrence at higher cost. There is a large segment of the CVD population in which compression is inappropriate, and these are candidates for endovenous correction without a trial of compression. Cost, a major factor in the era of socialized health care, is an important element in choice of therapy. Although initial direct costs may be higher, savings in direct and opportunity costs over time from reduction of recurrences would seem to favor interventional correction in many CVD patients over prolonged compression regimens.

Long-term utility of compression alone is crucially dependent on daily compliance, which is apparently difficult for many patients. Compression may not be necessary after endovenous correction of the underlying pathologic process.

AUTHOR CONTRIBUTIONS

Conception and design: SR, FL, TO
Analysis and interpretation: SR, FL, TO
Data collection: SR, FL, TO
Writing the article: SR, FL, TO
Critical revision of the article: SR, FL, TO
Final approval of the article: SR, FL, TO
Statistical analysis: SR, FL, TO
Obtained funding: SR, FL, TO
Overall responsibility: SR

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Submitted Aug 20, 2015; accepted Nov 20, 2015.