Venous leg ulcers (VLU) have a profound socioeconomic impact, which is related to both VLU’s prevalence of 1 to 1.5 percent and its high recurrence rate. VLU is frequently associated with pain and a marked alteration in the quality of life due to the open ulcer, which have indirect cost implications. Dressings, compression garments, outpatient visits and occasional hospitalizations are required in the treatment of VLU. As a result, the care of VLU leads to significant resource consumption. The direct cost has been estimated to approximate 1% of total annual healthcare budgets of some Western European Countries. VLU is frequently associated with pain and a marked alteration in the quality of life due to the open ulcer, which have indirect cost implications, due to disability and subsequent time lost from work. [1]

The role of Guidelines:
Guidelines have been defined by the Institute of Medicine as “systematic statements to assist both the practitioner’s and patient’s decisions about appropriate healthcare for specific clinical circumstances”. [2] Guidelines are usually prepared by specialty societies and validate and transfer new techniques through evidenced based systematic reviews. As a whole, guidelines are best practices to achieve the best outcomes for the most reasonable expenditure of the healthcare dollar. Participants in guideline development sift through massive amounts of data to provide a consensus on the evidence for treatment of a specific condition. Several studies have shown that VLU guidelines can improve care, reduce the incidence, and contain the costs of treating VLU.[3, 4]

The genesis of The AVF/SVS VLU guidelines:
The SVS/AVF guidelines arose out of the Sixth Pacific Vascular Symposium, which was sponsored by the AVF. The mission of this initiative was to decrease VLUs by 50% in the next ten years. It was this author’s assignment to survey existing use of guidelines in North America and Europe for that meeting. In the survey of VLU guideline use by practitioners specific guidelines were employed infrequently for treatment of venous ulcer (20%) in the United States versus approximately 80% in Canada and Europe. By contrast, the use of guidelines to manage patients following DVT was three times as frequent in the United States (60%) by and a comparable number of 80% in Europe. A subsequent systematic analysis of published VLU guidelines was performed by our evidence based group at Tufts to synthesize a composite set of guidelines composed of those with strong recommendations and secondly to identify areas of disagreement and weak recommendations for further research and refinement.[5] Fourteen guidelines were reviewed, five of which were sponsored by governmental agencies and nine by physician or nursing societies. A strong recommendation due to a high degree of agreement was found for: compression 72%; wounds dressing 72%; pentoxifylline 73%; and prevention of recurrence with below knee stockings 70% or surgery 82%. It was thought that these recommendations might be implemented as to a common VLU guideline. By contrast,
weak recommendations with a low level of agreement were found for: diagnosis, wound care elements and adjunctive measures. Several areas of controversy were identified: the role of iliac obstruction and the need for stenting, treatment of perforating veins, the necessity for physical therapy to preserve ankle mobility and the use of skin grafts and artificial skin.

The Venous Ulcer Initiative Committee of the AVF, which meant at least monthly, was instrumental in advancing the mission of developing VLU guidelines. As a result, this committee responded to an RFP from the SVS Guidelines Committee for new vascular guidelines and our proposal for a VLU Guideline was approved by the SVS.

The SVS/AVF Guidelines Committee was divided into six working groups, each with the specific purpose of analyzing one aspect of venous ulcer treatment. The diagnosis group was chaired by Mark Passman and with members: Rob McLafferty, Bill Marston, Lori Pounds and Peter Henke. The compression group was chaired by Fedor Lurie with members: Tom Wakefield, Cynthia Shortell, Monika Gloviczki, Bo Eklof and Hugo Parch. The wound care group was co-chaired by Bill Ennis and Bill Marston and was comprised of Emily Cummings, Lori Pounds and Tom O’Donnell. Surgery endovascular group was co-chaired by Bob Kistner and Mike Dalsing with members: Julianne Stoughton, David Gillespie, Peter Gloviczki, Bo Eklof and “Raj” Raju. The ancillary group was chaired by Monika Gloviczki with members: Cynthia Shortell, Bill Ennis, and Julianne Stoughton. Finally, the prevention/recurrence group was chaired by Peter Henke with Fedor Lurie, Emily Cummings and Mike Dalsing.

The first task of the committee was to develop a critical, but broad set of questions. Three overarching questions were proposed: 1) what are the best strategies for treatment of active versus healed ulcer 2) what are the best strategies for prevention of recurrence and 3) what are the best strategies for prevention of the post-thrombotic syndrome? Each group then performed a review of the literature in their respective area to determine the best method for developing guidelines in that area from the following: 1) de novo development- the development of novel recommendations from a systematic review of the literature; 2) build on existing guidelines with a complimentary literature search 3) adaptation of existing guidelines and 4) total adoption of existing guidelines. This process served to determine the need for systematic and meta-analysis for each section. This analysis was to be performed by the Mayo Group under Hassan Murad’s direction. Two areas were chosen for a systematic and meta-analysis-compression and surgery/endovascular. SVS/AVF guidelines committee currently (July 30) has: 1) developed recommendations with their strength; 2) assessed the quality of the evidence supporting these recommendations and 3) provided a short summary of the literature specific to each guideline.

Vlu Treatment Costs:
To identify the key drivers of the costs for treating VLU we retrospectively studied a cohort of 84 patients with active VLU (CEAP VI disease), treated in a wound center by 5 vascular surgeons with a minimum follow up of 6 months and up to a year (median 368 days). [6] Actual costs (not charges) were obtained for outpatient and inpatient facilities,
visiting nurse services, and our physician practice group to yield true cost. The median Total Cost (TC) of treating VLU during this follow up period was $10,976. A total of 50 patients (60%) healed their VLU without recurrence in a median time of 91 days (6-379 days) at a cost of $8,183. This translated to $80/day to heal and $29/ulcer free day. In comparison the TC was 3-fold higher at $26,280 for the patients (N=17, 20%) who did not heal their VLU. Significant contributing factors were outpatient facility fees ($4,354) and visiting nurse services ($12,600), related to extended treatment of the open VLU. Inpatient admission, however, increased TC to $27,487. Of note, nearly two thirds of admissions were for treatment of cellulitis with IV antibiotics. VLU treated with surgical intervention did not significantly increase TC ($8,604 vs. $12,893 P>0.05) but significantly reduced recurrence rates (34% vs. 5%). This study has clear implications for emphasizing specific recommendations of VLU guidelines around the role of surgery and prevention and rapid treatment of infections.

The next step in the process will be submission of these guidelines to the SVS guidelines committee for review and comment. The guidelines are embargoed until the approval process is concluded. They should be ready to be presented at the meeting.

References:


