Preventing diabetic foot amputations: podiatry, protocols and perfusion

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Abstract:
Diabetic foot ulcers (DFU) are becoming a major problem around the world as the incidence of Type 2 diabetes grows. Since DFUs are a major risk factor for subsequent amputations, it is imperative that these lesions are treated appropriately and aggressively to arrest the causal pathway leading to amputation. DFU treatment and prevention protocols have been established in many centers as a method for improving care based upon established guidelines. This article is a republication of an interesting approach to this problem used at the San Francisco Veterans Affairs Hospital as a key component in their Amputation Prevention Program. The development and implementation of this DFU protocol is discussed and will be of interest to other centers seeking to establish similar programs.

Key words: Peripheral Artery Disease, Diabetic Foot Ulcer, “PAVE” Program

INTRODUCTION

Peripheral arterial disease (PAD) results in ischemic conditions in the lower limb that can lead to ulceration and amputation. Demographic data in the U.S. show increasing numbers of patients with PAD secondary to an increase in the geriatric population and an increasingly obese population which evokes a rapid escalation in the number of cases of type II diabetes in ever younger patient populations. The patient groups defined by type II diabetes predictably develop cardiovascular alterations leading to ischemic conditions in the leg and foot.

These patients are more likely to present with tissue loss and peripheral neuropathy rather than claudication. There are increasingly sophisticated and often expensive treatment modalities to combat the impact of diabetic foot ulcers; however, it is consistently true that failure to adhere to best practices is usually at the root of initial ulcer formation, delayed wound healing, expensive treatment modalities and amputations.

The objective of this article is to present a simple, evidence-based approach to prevent amputations which is tissue-focused and which has been demonstrated to have positive outcomes on morbidity and mortality as well as quality-of-life issues that carry significant financial, social, and psychological implications. It is a further objective to demonstrate that simple protocols can make amputation prevention an accessible reality for all clinics – private, university, or government.
Protocol for Diabetic Foot Ulcer Management

A multidisciplinary Amputation Prevention Team at the San Francisco VA Medical Center (VASF) developed the Protocol for Diabetic Foot Ulcer (DFU) Management. The protocol incorporates several elements of evidence-based products and services into an algorithm to support a comprehensive “PAVE” Program (Prevention of Amputations in Veterans Everywhere). The PAVE program has evolved from its former message and mission under PACT (Prevention, Amputation, Care and Treatment) into an improved goal-oriented pathway that delivers an improved goal-oriented pathway that delivers the final protocol. The guiding publications for development and on-going updates included notable lessons from experts in diabetic foot management: Davidson et al., 1981; Edmonds et al., 1986; Pecoraro et al., 1990; Thompson et al., 1991; Sanders et al., 1994; Larsson et al., 1995; Armstrong et al., 1998; Frykberg et al., 1997; Reiber et al., 1999; Holstein et al., 2000; Van Houtum et al., 2000; Horsewell et al., 2003; Driver et al., 2005; Robbins et al., 2006; Trautner et al., 2007; Krishnan et al., 2008; Iversen et al., 2009; Lavery et al., 2010; Rogers et al, 2010.

The VASF PAVE Team was led by podiatric surgery, vascular surgery, nursing, and prosthetics representatives. The team assessed level of evidence for incorporation of various elements into the final protocol. The guiding publications for development and on-going updates included notable lessons from experts in diabetic foot management: Davidson et al., 1981; Edmonds et al., 1986; Pecoraro et al., 1990; Thompson et al., 1991; Sanders et al., 1994; Larsson et al., 1995; Armstrong et al., 1998; Frykberg et al., 1997; Reiber et al., 1999; Holstein et al., 2000; Van Houtum et al., 2000; Horsewell et al., 2003; Driver et al., 2005; Robbins et al., 2006; Trautner et al., 2007; Krishnan et al., 2008; Iversen et al., 2009; Lavery et al., 2010; Rogers et al, 2010.

In order to further understand this population and to enable validation of end-result post-implementation of the PAVE DFU Protocol, the PAVE Team documented the patient demographics of all VA medical center populations in the Veterans Integrated Service Network (VISN) 21 to include Manila, Palo Alto, Honolulu, Reno (NV), Fresno, Northern California, and San Francisco. The result showed that significant populations of patients in all risk categories were being seen at VASF, which made it an ideal population to demonstrate the effectiveness of the VASF DFU Protocol (Figure 1) across a spectrum of DFU risk. Furthermore, it underscored that the VASF patient population is one that many podiatry practices can readily recognize as similar to their own.

The Amputation Prevention team members include representative providers not only from podiatric surgery, vascular surgery, nursing and prosthetics but also from plastic surgery, orthopedic surgery, infectious disease, physical therapy, dermatology and rehabilitation. Basic protocols were put in place and included: a nurse provider clinic to oversee routine foot care and administer a foot surveillance program; simple patient education materials; comprehensive shoe and offloading program; advanced cell-based biologics; and an automated primary care referral system for patients who were found to be “at-risk” in a risk stratification computer program (based on VHA Directive 2012-020). The Foot Risk & Assessment tool was developed and piloted at VASF.

Risk stratification is the heart of successful diabetic foot management protocols and podiary is central to driving this process (Figure 2). Each risk category (i.e., normal, low, moderate, high) has a corresponding management pathway within the clinic EMR and automated reminder system. The high risk patient is subjected to intense assessment and controlled triage according to proven care tracks i.e. Foot Care Education, Podiatry Consult (for patients not under podiatry management) and/or Prosthetists Consultation (Figure 3). Prevention of disease escalation is of primary importance and the key elements (Figure 3) are well understood but are easy to dismiss or overlook when controls are not in place.

A useful EMR includes the requirement that all parties are able to see and acknowledge that appropriate interventions for a particular diabetic foot risk level have been completed. The ability to confirm delivery of appropriate care and communicate this quickly to all care providers is elemental to timely intervention and successful outcome.
Another routine element of the VASF DFU Protocol is objective, reproducible assessment of foot perfusion to assess the “capillary vitality” of at least two foot angiosomes. Angiosomes are three dimensional vascular territories primarily supplied by a single artery and drained by a single vein (e.g. anterior tibial artery supplies the dorsalis pedis angiosome). Inclusion of skin perfusion pressure (SPP) and pulse volume recording (PVR) into the everyday workup of all patients has been published on the VHA National Intra-net for providers to reference (Figure 5).

As an integral component of the VASF DFU Protocol, SPP creates a blood flow challenge and then measures the pressure at which capillaries are able to refill. This is termed “reactive hyperemia” and is extremely useful in co-morbid disease secondary to pathologic alterations in vascular anatomy, collateral circulation and tissue. Coupled with PVR, these tests are used for baseline screening and again at the time of treatment. SPP of both the anterior and posterior tibial angiosomes determines whether or not a wound will heal and also facilitates more timely and more appropriate referrals to vascular colleagues. Skin perfusion pressure has been shown in numerous clinical publications to be an accurate and reproducible measure of ischemia, both predicting response to wound healing therapy and validating the effectiveness of surgical and endovascular interventions. While ABI is used in vascular algorithms, it has limited utility in the more complex tissue challenges associated with diabetic foot ulcer assessments. Additionally, patients with co-morbid diabetes and PAD have greater tissue challenges (e.g. neuropathy, bony foot deformity, HbA1C, ESRD) which require podiatry to consistently integrate vascular assessment into the protocol loop. This not only supports many aspects of foot care but also provides the vascular team with perfusion updates following vascular intervention. This creates an objective, evidence-based working relationship between podiatry and vascular surgeons. More importantly, mandatory inclusion of SPP and PVR data enable retrospective assessment of diabetic foot care practices. These assessments are routinely measured on patients seen in the VASF podiatry and vascular clinics in order to provide the best measurement of healing status and tissue perfusion.

Since implementing the VASF DFU Protocol, ulcer formation (rate/1000 patients) at VASF has consistently declined and is well below the National VHA average. Similarly, lower extremity amputations at the VASF have declined. In gratifying testimony to hospital-wide recognition of outcomes secondary to the VASF DFU Protocol, podiatry consults have consistently risen with a 10-fold increase seen from 2006 to 2011.

CONCLUSION

In conclusion, the VASF DFU Protocol was inexpensive to create and straightforward in implementation. Adherence to the protocol reduces amputations and promotes accountability among care providers. Inclusion of only those products and services which have validating, published evidence, served to hold down cost since initial wounding was minimized. When amputations were required, adherence to the protocol helped to make minor amputations a workable option.