Development of a Limb-Preservation Program

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Key Words

Limb preservation program · Multidisciplinary approach · Bypass · Amputation prevention

Abstract

In the global scenario, as the prevalence of renal failure and diabetes increases, healing and limb preservation assume increasing clinical importance for patients and healthcare systems. Unfortunately, there continues to be variation in the care delivered to patients at risk of losing a limb based on geography, race, socioeconomic status, and insurance status. There are also a variety of therapeutic approaches to patients with limb-threatening ischemia; 25% undergo primary amputation, 25% undergo medical therapy, and only 50% undergo any attempt at revascularization. Nearly 50% of patients undergoing major amputation have not had a simple diagnostic arteriogram to assess the possibility of limb preservation. The Society of Vascular Surgery and the American Podiatric Medical Association have recognized the benefits of a multidisciplinary approach to limb preservation. Benefits to the patient include rapid assessment, improved healing, and enhanced revascularization. Advantages for the providers include the ability to efficiently manage complex patients with help from the appropriate specialties, an increase in referrals, enhanced identity of the institution, and clinical research and trials. Such a program requires the coordinated effort of physicians, nurses, allied health professionals, and administrators dedicated to the preservation of functional limbs. Beneficial components include identifiable

space, a vascular laboratory, hyperbaric oxygen therapy, and protocol-driven care involving diagnostic and therapeutic modalities such as endovascular revascularization, open bypass, and soft tissue reconstruction. Prosthetic expertise is also important to maintain function in those patients for whom amputation is appropriate. But, the key to a program is cooperation and communication among the participants who have a passion for limb preservation.

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Introduction

A successful limb-preservation program requires coordinated effort from physicians, nurses, allied health professionals, and administrators dedicated to the cause of saving and maintaining functional limbs. Limb preservation is an issue of increasing clinical impact on individual patients as well as the entire healthcare system. Major amputation remains a significant cost to our healthcare system. Over and above the money spent on diagnosis and treatment, the cost of rehabilitation after an amputation is shown to double the original cost of the amputation itself [1]. This is a significant consideration because over 1.5 million people live after the loss of a limb; this number is expected to increase due to the aging of the population and the worldwide exponential rise in diabetes mellitus. Prompt and appropriate diagnosis fol-

lowed by a multidisciplinary treatment program is critical to treat these complex patients successfully. It must also be realized that prevention of foot ulceration is equally important; chronic ulcers are an antecedent event in 80% of nontraumatic amputations. Reduction in the occurrence of chronic foot ulceration through patient education and primary care surveillance of the foot in diabetics would impact limb loss in a significant way.

Although the incidence of amputation in this country has been shown to be decreasing, there is no evidence that without proper surveillance and management, the rise in the prevalence of diabetes will lead to an increase in lower extremity ulceration and limb loss. This problem does not only affect the quality of life, but it also has a negative impact on the longevity of patients with a significant mortality associated with major amputation; 30-day mortality ranges from 15 to 20% and 5-year mortality rate approaches 50%.

Unfortunately, there is a large variation in the care delivered to patients at risk of losing a limb due to nontraumatic causes. Of those patients with limb-threatening ischemic, 25% undergo primary amputation, 25% receive medical therapy, with only 50% attempting to undergo revascularization. Goodney et al. [2] have reported that 46% of patients having a major amputation do not have even a diagnostic arteriogram despite evidence that diagnostic arteriography in and of itself is a predictive factor for limb preservation [3]. There are also reported geographic variations in the delivery of care for patients in need of limb preservation as well as variations with regards to race, socioeconomic status, and insurance status [4]. A limb-preservation program would standardize care for the patients with critical limb ischemia and limb-threatening ischemia mitigating some of the factors that cause disparity in the care. There are data to support the fact that amputation is prevented by an increasing incidence of revascularization, whether endovascular or open surgical bypass, and that amputation rates are lower in centers with higher volumes of revascularization procedures [5]. Therefore, the tools required to put together a limb-preservation program have a significant impact both in a clinical sense to the delivery of care for our patients as well as a financial impact in terms of preventing amputation, improving quality of life, and decreasing mortality.

Multidisciplinary Approach

A successful limb-preservation program requires a multidisciplinary approach to the patient with a threatened limb due to critical ischemia. A multidisciplinary

approach fosters protocol-driven care involving a full complement of diagnostic and therapeutic modalities. This certainly involves revascularization, but also soft tissue expertise and medical support to optimize outcomes. Preventive care as well as expertise in prosthetics to maintain the function of the limb, if not entirely preserved, is also a critical component of the team approach. Additionally, such a program fosters education and research regarding wound healing and advanced revascularization techniques that continue to evolve. Most importantly, the multidisciplinary approach leads to enhanced healing, limb preservation, and increased patient satisfaction through a decrease in the morbidity and mortality associated with limb loss.

The key to such a program is communication. There may be different disciplines best positioned to assume leadership roles for such a program in each medical community. Leadership is based on the passion for the type of patients managed shown by the participants as much as a specific medical training. It is important to draw on the expertise and passion available in the local medical community to construct a limb-preservation team.

Improved Awareness through a Multidisciplinary Team Approach

The goal of a limb-preservation program is to decrease amputation rates and optimize the chances to maintain functional limbs in this group of patients. This is accomplished not only by specific clinical diagnosis and treatment but importantly, by raising awareness as to what such a program can accomplish. This awareness may be lacking in physician and patient groups as well as in governmental agencies. Raising awareness for the success that can be accomplished is especially important in those patients with diabetes mellitus and end-stage renal disease, in those who engendered pessimism in the past. A limb program can also serve as a referral source for the surrounding medical community by offering enhanced services to these complex patients. Ideally, such care would include a streamlined approach important for patients who have difficulties with mobility and transportation leading to improved patient satisfaction. Another goal of the multidisciplinary approach would be improved financial viability through the consolidation of care and limb preservation.

The Society of Vascular Surgery and the American Podiatric Medical Association have recognized these

goals and prospective benefits [6]. These leading Societies recognized benefits to patients and physicians involved in their care. Benefits to the patient include a reduction in time for vascular assessment, wound healing, institution of treatment for infection, and the time to final correction of podiatric and orthopedic deformities. Enhanced follow-up and increased surveillance of revascularization procedures after preservation was also recognized as a benefit to patient outcomes. Advantages for the physician include the ability to efficiently manage complex patients with help from the appropriate medical specialties, an expected increase in patient referrals, the ability to obtain leadership roles both regionally and nationally, the development of an important clinical area to enhance the identity of the institution, and the infrastructure for clinical research and trials.

In this age of evidence-based medicine, evidence does exist that such a multidisciplinary program can have an impact. Vicki Driver has documented a decrease in the number of amputations performed after the initiation of a multidisciplinary program [7]. Not only were major amputations decreased, but 70% of the amputations that were performed were at the level of the distal ankle, forefoot, or toe with avoidance of major amputation above or below the knee. This was found to be especially important for those patients with diabetes. Others have demonstrated a similar reduction in amputation rates with a multidisciplinary team approach [8].

Staff Components

Having a team of well-trained and suitable staff is the critical component of a multidisciplinary program. The team must share a dedication and passion for the goals as outlined above, as well as, create and maintain open lines of communication. The staff team includes the physician team, administrative support, physician extenders, nursing, and secretarial support. A medical director who has the authority and initiative to bring together other team members should lead the physician team. The background of the medical director can vary, but a person to suit this profile is most often drawn from vascular surgery, podiatry, or plastic surgery. It is important to have representatives from both the vascular and soft tissue perspectives in leadership roles and therefore co-director positions can be created. There should also be an administrator dedicated to the program with time available to guide the project on a daily basis. The administrative director can be either a physician (medical director) or

someone trained in medical administration. The administrator should have knowledge of the clinical and business aspects of the program, and be facile with interaction among Hospital, physicians, staff, and local community.

Physician extenders such as nurse practitioners or physician assistants serve a crucial role in the success of the program. These practitioners initiate the medical evaluation of each patient and coordinate the complex care required for an optimal outcome. Often, these providers can run clinics independently of course being supervised by treating physicians. This includes wound care, preoperative preparation, and prescription of medications used in the treatment plan. The physician extenders must work closely with trained wound nurses, medical assistants, and secretaries. Wound nurses or technicians play a vital role in a clinic setting. These specialized personnel perform much of the wound care and dressing changes as well as important patient education required to involve the patient in their own care. Coordination of visiting nurse visits is also organized by the wound nurses. The ideal complement of such personnel to optimize patient flow is approximately 3 physician extenders/wound nurses for each doctor involved in the clinic setting. Staff support should also include a receptionist and medical assistants. The medical assistants aid in moving patients through the clinic and completing initial demographic and historic data in the electronic medical record (EMR), and, may help in the removal and application of dressings under the direction of the wound nurse or physician. Ideally, case managers and prosthetists form part of the program. Case managers assist in the volume of work involving rehabilitation centers and insurance issues that patients often require, while a prosthetist, being familiar with the patients and with direct communication with the limb team, greatly enhances the patient's functional result.

Marketing and Community Relations

Marketing and community relations are essential in order to reach those patients who may be aided by the program and referring physicians who may wish to take advantage of such a program. Finally, the EMR can certainly impact staffing issues. The EMR is mandatory for data collection and tracking of results and there are a number of products available that are free-standing or can be integrated within larger systems. The EMR requires input of timely and accurate information, and implementation of the EMR can affect staffing requirements

as well as staff satisfaction. However, the EMR is necessary to assess results, maintain governmental compliance, and guide future improvements in the program. The EMR can also greatly enhance the research arm of the program to push the field forward in an area fruitful for research. In addition, EMR data analysis can significantly enhance marketing by demonstrating benefits related to care within a comprehensive center.

Space

Appropriate space is also very important. There should be an identifiable outpatient space, which is accessible by the patients who have mobility problems. The outpatient space should be in proximity or connected to the hospital, as limb patients require frequent hospital services. Space for exam rooms is also important, as patient flow is critical to clinical viability and patient satisfaction. There should be approximately 6 rooms for every 30 patients seen in any given session in order to allow for optimal use of the time and talents of the physician and physician extender team.

An identifiable hospital ward is ideal for these patients when they are admitted. The nursing staff on an identifiable ward becomes familiar with the medical issues surrounding the threatened limb patients. And, wound dressings and other medical material can be centrally located in proximity to the admitted patients. The identifiable limb ward in the hospital continues to adhere to the team approach and continuity of care to and from outpatient to the inpatient setting.

Space Noninvasive Vascular Laboratory

A noninvasive vascular laboratory is important and this requires appropriate space and equipment. Vascular laboratories are used routinely and consistently in the care of the limb patient both for initial diagnosis, decision for more invasive therapy, and follow-up care. Therefore, the lab should be situated locally in the limb center in order to allow convenient and accessible testing on a regular basis. Conference rooms should also be available for teaching conferences to enhance the interaction between physicians and staff in terms of case review and educational lectures.

Diagnostic imaging is especially important to the limb patient. As mentioned earlier, noninvasive vascular laboratory testing is an integral part of patient care. The vas-

cular lab should possess the ability to perform the standard tests including ankle brachial index (ABI), segmental waveforms and pressures, post-volume recordings and digital pressures as well as duplex ultrasound imaging. Diabetes is associated with increased calcification of the arterial media, often rendering the tibial arteries incompressible by the blood pressure cuff and a falsely elevated ABI. Many diabetic patients have falsely elevated segmental pressures (ABI) that may mask an ischemic foot. In diabetic patients, measurement of the toe/brachial index may be useful. Although many centers favor digital pressures to determine healing potential, there are other modalities that can be included in the vascular lab to aid in the assessment of tissue perfusion and healing ability. Some centers favor transcutaneous oxygen measurements, while others have used skin perfusion pressure. Transcutaneous oxygen values are measured at the chest wall as the baseline with additional measurements made in the lower extremity in the area of the wound and usually at the calf, ankle and foot level. An absolute value greater than 20–30 mm Hg is consistent with healing as is an index of the foot and ankle area compared to the chest wall of greater than 0.4. However, TcO₂ measurements are time consuming and need to adhere strictly to methodology. The measurements may not be accurate in edematous limbs and the reimbursement can be poor. Compared with toe pressures, TcO₂ better predicted healing, but positive predictive values for both were only 67 and 79%, respectively. Measurement of skin perfusion pressures utilizes a Doppler shift effect in laser light reflected from capillary flow with the pressure measured at which the blood flow first returns to the capillary bed of the skin envelope. A skin perfusion pressure greater than 30 mm Hg is predictive of healing and has been shown to be more effective in determining healing than TcO₂ in one study.

Space for Hyperbaric Oxygen Therapy

Space for hyperbaric oxygen therapy (HBO) is important. HBO will serve a certain segment of the limb-threatened population, so there must be room and the appropriate technology available. The lack of confidence surrounding its use may result from inappropriate use in the past, and HBO may be of particular value in patients with irradiation-based ulcers or diabetic feet. HBO may be useful if an increase in tissue oxygenation can be demonstrated when the patient is given supplemental oxygen [9]. HBO does require a facility with dedicated staff who recognize the associated medical risks.

Space for Outpatient Endovascular Procedures and Minor Surgery

Outpatient endovascular procedures and minor surgery are also becoming more common and accepted by both patients and insurance reimbursement companies. Consideration should be given to space for an interventional room and/or minor surgery suite to offer timely and convenient care. An endovascular suite is important to perform the state-of-the-art catheter-based procedures, which have become increasingly common in the revascularization procedure for limb preservation. However, the operating room and especially a hybrid operating room remain important to treat these patients.

Diagnostic Imaging

When intervention is deemed necessary by patient history, exam, and vascular lab studies, then arterial imaging is required to plan the appropriate revascularization; CT angiography (CTA), MR angiography (MRA) or standard catheter-based arteriography. CTA does not involve the direct arterial puncture and can allow 3D reconstruction while demonstrating calcium and the calcium load in the arterial tree. Unfortunately, CTA can use a fair amount of contrast, and, timing of the injected bolus of contrast is critical to image quality. The heavily calcified arteries can also impact image quality. MRA is a flow-dependent analysis using MRI. MRA is noninvasive and does not require standard contrast. However, best images are obtained with the administration of gadolinium that is problematic in patients with renal insufficiency due to the chance of nephrogenic systemic fibrosis. Additionally, MRA images can overestimate the degree of stenosis due to signal dropout, and certain patients cannot tolerate the time required to acquire the images in a fairly closed space. Therefore, catheter-based arteriography continues to play an important role in diagnostic imaging for limb preservation, especially in terms of defining distal tibial occlusive disease. Often the diagnostic study can be combined with a primary intervention at the time of the arteriogram and this is done on a little over half of the diagnostic arteriograms in our practice. A vascular surgeon should perform, or at times assist, by choosing the appropriate imaging study and subsequent plan for revascularization.

Revascularization

Revascularization in the context of a limb program requires a wide range of options for both endovascular therapy and open surgical bypass. Patients requiring revascularization for limb preservation have complex issues with distal occlusive disease, lack of autogenous conduit, concomitant infections, and prior failed attempts at revascularization. In this era of endovascular revascularization, the number of endovascular procedures has certainly increased as documented by Goodney et al. [10]. In our own limb practice; we have noticed an increase in endovascular procedures with a reduction in bypass procedures. But, the procedures have stabilized at approximately 75% endovascular first revascularization and 25% open bypass, which may be reflective of a limb-preservation practice as compared to a practice dealing primarily with claudication. In terms of endovascular revascularization, the entire range of therapies should be available to treat the patient appropriately; however, we have found that a great majority of patients can be treated with standard balloon angioplasty and stent deployment. Atherectomy, mechanical and laser, and cryoplasty have a select role in certain patients based on the operator's experience and currently available data. Success with more aggressive endovascular techniques has been reported, such as extensive tibial angioplasty with crossing of chronic total occlusions and distal pedal loop revascularization [11]. The use of drug-elution technology will almost certainly have an increasing impact in the future for patients in need of revascularization for limb preservation.

There is a subset of patients in whom bypass should be considered for optimal revascularization to enhance healing and limb preservation. In our practice, these are patients presenting with large volume tissue loss (greater than 2 cm), patients with prior attempts at endovascular therapy that have not been clinically successful, and patients in whom angiosome revascularization may be important with the target artery best perfused with a bypass. This patient group represents approximately 25% of our practice that is reflective of the type of procedures attracted by a limb-preservation program. In order to offer this subset of patients a bypass for limb preservation, developments to enhance surgical bypass are important to add to the armamentarium of revascularization options in the limb program. These developments include prosthetic conduits with a venous adjunct at the distal anastomosis, prosthetic grafts with heparin bonding, the addition of an arteriovenous fistula at the distal anastomosis, or a com-

bination of these techniques, when there is lack of autogenous conduit, as well as in the presence of poor arterial runoff [12–16].

Wound Care and Soft Tissue Reconstruction

In a limb-preservation program, wound care and the soft tissue reconstruction is equal in importance to the revascularization procedures. The goal of wound care should be salvage of tissue to maximize functional length in a biomechanically sound limb. This often involves multiple staged procedures with aggressive debridement to obtain a clean granulating wound surface. The majority of leg ulcers can be effectively managed with nonsurgical debridement, typically in the form of dressing changes or wound ointments that encourage tissue healing. Whether performed in the operating room or in the clinic, the goal of debridement is to remove all nonviable, infected tissue and reach bleeding tissue or viable fat, tendon, or fascia.

Consideration should be given to the delayed wound closure and the vacuum-assisted closure device (VAC) or other biologic wound care adjuncts. The VAC is a negative pressure wound therapy that enhances granulation tissue ingrowth through the reduction of edema and removal of proteases [17]. The VAC must be used properly with relatively clean wounds, cautiously with ischemic wounds, and must not be used with wounds that are known to be malignant. The VAC can convert emergency wounds for which flap coverage is required into wounds that can be treated more simply. VAC therapy can be discontinued when the wound is small enough to close with simpler, less expensive dressing changes or can be closed primarily or with a skin graft.

The limb team should have the ability to perform advanced soft tissue flaps when primary wound care is insufficient. Three types of flaps are employed in the lower extremity: local random-pattern flaps, local pedicle flaps, and free tissue transfers. Local random-pattern flaps include such flaps as Z-plasties, advancement flaps (e.g., V-Y), rotation flaps, and transposition flaps. These are extremely useful for closing small defects of the foot. One limitation to their use is the tautness of the skin in this area, which limits flap mobility. Local pedicle flaps are employed for coverage in both the leg and the foot, especially for closure of larger foot wounds and deeper wounds that expose bone or hardware. These flaps are based on axial vessels, typically branches of arteries supplying the angiosomes. The use of VAC therapy and other flaps have

led to a decline in the use of microsurgical free flaps in the lower extremity. But, there are certain wounds for which free flaps may still be useful, such as large defects and wounds characterized by significant exposure of bone. Free flaps can also be used for wounds with venous insufficiency. Soft tissue expertise and flap coverage can also be helpful when there are challenging perioperative complications from the revascularization procedures themselves.

Ideally, wound care in the limb program should be performed under the auspices of wound care protocols, which can stabilize the uniformity of the procedures and optimize results in a limb-preservation program as carried out by the medical and ancillary staff. Such protocols should emphasize the importance of debridement performed to viable tissue with any exposed bony edges cultured for infection. Soft tissue reconstruction should be delayed until the inflammation is gone and granulation has begun to appear and the VAC may be utilized as a temporary closure device until this occurs. Obviously, any infected or wet gangrene should be aggressively debrided as soon as possible with resection of all necrotic tissue to obtain the best functional result. Care should be taken to explore all tendon sheaths and fascial compartments during debridement for infected or wet gangrene. And, there are times when primary amputation may in fact be the right choice to preserve the patient's life and what functional limb can be maintained.

Amputation

Although the goal of a limb program is limb preservation, primary amputation may be appropriate when there is true lack of tissue for reconstruction and when the patient is non-ambulatory and/or demented and unable to cooperate with rehabilitation. When amputation is required, there are certain principles that are important to recall. Proper limb biomechanics is the key to a successful amputation. In order to optimize biomechanics and obtain an ideal result, anatomy must be thoroughly appreciated and the procedure performed with technical expertise. Viable tissue should be maximized especially along the plantar surface of the foot, as this tissue is often used for forefoot reconstruction. Skeletal stability is also important. The patient should not be left with any pressure points or potential areas of decubitus ulceration after amputation. It is also important to consider rigid postoperative dressings with early ambulation.

There are several amputations with which one should be familiar including ray, transmetatarsal, Lisfranc, Chopart's, Symes as well as above- and below-knee amputation. All amputations can be technically challenging to obtain long-term function, but the below-knee amputation must be done especially carefully to design a well-constructed posterior flap with maximal length from the tubercle of the tibia. It is also important to construct a smooth anterior surface without a rough or cornered edge. Tenodesis to the tibia does help maintain function and diminish deformity postoperatively.

Education and Research

A limb-preservation program should also include a patient support group, as there is a significant mental component to loss of limb or living with a foot ulcer. A patient support group can be very important both preoperatively and postoperatively in helping patients deal with the clinical situation in maintaining functionality and mental outlook. Education can be incorporated into the program in the form of seminars for patients and referring physicians. Education is critical to achieve the goal of limb preservation through the reduction of amputation and enhancement of the patient's quality of life. The limb program also provides a format for multidisciplinary research that is increasingly important to the healthcare system.

Financial Considerations

There certainly are financial considerations to a limb program, both in terms of the healthcare system and the program itself. With over 7 million chronic wounds

treated in the country annually at a cost approaching [20] billion dollars, this is an obvious area of interest [18]. In order for a limb-preservation program to be cost effective, there must be assessment and review of direct and indirect costs with careful analysis of the revenue stream to allow the center to function. Direct costs include salaries, supplies and space requirements. Indirect costs include maintenance, electricity, other utilities and any loans that must be availed to finance the program. Revenue must be considered both in terms of the reimbursement generated by the immediate activities of the program as well as the incremental downstream revenue realized by the hospital and healthcare system. The most important sources of downstream revenue are often inpatient diagnostic and therapeutic procedures. Revenue related to the limb program itself often takes a form of debridement performed in the outpatient setting and that generated from HBO. If this is done carefully and with organization and thought, such a program can in fact generate significant cash flow for the hospital and healthcare system. Financial viability has been demonstrated in hypothetical models and real-world experience [19, 20]. The institution of a limb-preservation program is labor intensive and requires communication and cooperation among the interested parties. However, such a program can preserve limbs and improve the longevity and quality of life of our patients. Limbs can be preserved and amputations avoided in the context of a viable financial entity to the hospital and healthcare system.

Disclosure Statement

Nothing relevant to disclose.

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