The Decision for Amputation Versus Limb Salvage in Patients with Limb-threatening Lower Extremity Indications: An Ethical Analysis

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KEYWORDS

• Amputation • Limb salvage • Ethics • Patient autonomy • Shared decision-making • Beneficence • Access to care

KEY POINTS

- The decision between amputation and reconstruction must consider patient-specific factors as well the etiology of the limb-threatening injury, broadly acute traumatic versus chronic medical indications.
- All efforts must be made to maximize patient autonomy and engage in shared decision-making prior to proceeding with one of the surgical options.
- Successful limb salvage requires coordinated multidisciplinary care and a high level of surgeon experience; unavailability of these resources may favor amputation in the appropriate context.

INTRODUCTION

By 2050, a projected 3.6 million individuals in the United States are expected to be living with limb loss, an over 2-fold increase from the 1.6 million estimate in 2005.[1] Sixty-five percent involve the lower extremity; of these, over half are considered major amputations (eg, below-knee or above-knee level). Although various conditions can place a limb at risk, 82% of new lower extremity amputations occur secondary to sequelae of dysvascular disease with or without concomitant diabetes. The second leading cause is acute trauma at 16%, followed by congenital and oncologic etiologies each comprising less than 1% of new lower extremity amputations.[2] With modern medical and surgical advancements, recent years have seen a decrease in the amputation rate for all limb-threatening etiologies.[3–5] Limbs that once would have been amputated are now routinely managed with complex reconstruction protocols.

The decision between amputation and limb salvage is patient-specific and context-dependent. Scarce ethical analyses comparing these treatment options exist and primarily in the context of acute traumatic injury.[6,7] To our knowledge, the ethical considerations of amputation versus limb salvage for patients with limb-threatening chronic medical conditions has not been fully addressed. Here, we explore the ethical landscape around the decision for lower extremity amputation versus limb salvage, including a focused evaluation of differences for patients with limbs at risk due to diabetic

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complications versus acute trauma. Of note, all discussion in further sections refers to major lower extremity amputation. Minor amputations (eg, transmetatarsal) will not be addressed in this ethical analysis.

DISCUSSION

Risk–Benefit Profile

The first consideration for amputation versus limb salvage is the difference in risk–benefit profiles for varying indications. In ethical terms, the 2 procedures' ability to maximize the good of the patient (beneficence) is highly dependent upon the patient population. Although the discussion on how to maximize the patient's good is usually the basis of considering how to proceed, physicians must also adhere to the principle of nonmaleficence, or avoiding preventable harm. The framing of preventable harm should be broad given the life-changing nature of limb-threatening medical conditions, and it may include factors such as time off work, time in the hospital, and financial costs.

For all patients, the decision for amputation versus limb salvage is founded on the goal of preserving lower extremity mobility, and it must consider each patient's functional capabilities, including ambulation potential and the ability to perform activities of daily living. However, achievement of this goal must be weighed against the risks of each option. Further, we compare the specific risk–benefit profiles for acute and chronic indications for which the decision for amputation versus limb salvage must be made.

General considerations

Amputation is favored for patients who are unable to withstand multiple surgeries, prone to recalcitrant infection, or possess factors that preclude successful reconstruction (ie, lack of lower extremity vessel perfusion, end-stage renal disease that can lead to flap failure).[8,9] Generally, as compared with reconstruction, amputation has shorter operative times, less time spent in the hospital, fewer procedures, and expedited wound healing compared. Given the requirement for fewer surgeries, patients who undergo amputation have quicker recoveries with a faster return to weightbearing. They also tend to be managed with shorter courses of prescription pain medications and thus are placed at a lower risk of opioid dependency. The advantages of amputation thereby may not be limited to only patients with contraindications to limb salvage. Furthermore, first-line amputation removes the possibility of delayed amputation after reconstruction, the latter of which is associated with a higher likelihood of wound complications, osteomyelitis, musculoskeletal disorders. Compared with early amputation and limb salvage, late amputation also has the highest prevalence of psychological disorders, including mood, substance use, anxiety, and tobacco use disorders, which in turn translates to increased pain.[10,11]

Compared with amputation, limb salvage seems more beneficial when the psychosocial components of quality of life are considered. An important consequence of limb loss is the construct of "social death," which has been associated with greater physical pain and a higher risk of mortality.[12] It is constituted by social isolation, loneliness, ostracism, loss of personhood, altered role and identity, and personal harm, which may be prevented with limb salvage.[13] This has been demonstrated by patient-reported outcome measures. Compared with patients who undergo amputation, those who pursue limb salvage score higher in the mental health domain and the mental component summary.[14] In addition, novel microsurgery techniques that utilize free tissue transfer have demonstrated patient satisfaction as high as 96% with regard to esthetic outcomes.[15] Thereby, reconstruction may be more psychologically acceptable. Further, the psychological harm associated with amputation may be greater in certain cultural contexts; for example, individuals from communities where the maintenance of physical integrity is emphasized (ie, native Americans) may be more prone to experiencing social rejection if amputation is pursued.[16] With regard to physical function, limb salvage offers an opportunity to preserve or even regain sensation in the lower extremity.[17] Reconstruction also does not carry a risk for phantom limb pain, which continue to impact patients after amputation despite recent improvements seen with targeted muscle reinnervation,[18,19] although chronic pain is also common in reconstruction patients.

Traumatic indications

For high-energy lower extremity trauma (HELET), the decision for amputation versus limb salvage is often made in a state of clinical equipoise. That is, the 2 surgical treatment options yield near equivalent outcomes for patients with traumatic, limb-threatening indications. This conclusion resulted from the Lower Extremity Assessment Project, which was initiated to better understand HELET injuries and has been the leading provider of evidence on amputation

versus salvage for the past two decades.[20] Two years after HELET injury, there is no significant difference between the surgical options with regard to Sickness Impact Profile scores, which measures patients' perception of their own health status regarding disease impact.[21] The metric is composed of the following 12 domains: sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, and communication. Pain and return-to-work rates are also comparable.[21] Given analogous long-term outcomes, the decision for amputation versus limb salvage for traumatic indications should be guided by the condition of the limb, influence of comorbidities, the patient's preferences, and the surgeon's own expertise. However, it is important to note that reconstruction is associated with a higher risk of complications, additional surgeries, and rehospitalization within the 2 years after index surgery.[21]

Diabetic complications

The predominant argument favoring amputation in cases of traumatic lower limb-threatening injury is the ability of prostheses to provide excellent, near baseline function. Ambulation with prosthesis requires increased energy expenditure, which rises as the amputation levels become more proximal.[22] For patients with diabetes, normal walking utilizes up to 80% of an already diminished cardiorespiratory capacity, thereby leaving little reserve remaining for the demands necessary for biomechanical adaptation to prosthetic ambulation.[23] Most prosthetic devices are passive, meaning that all power for mobility must be generated by the remaining musculature. Patients with diabetes experience a 30% to 50% reduction in maximum muscle strength in both upper and lower extremities.[24] Associated polyneuropathy may also impair proprioception, leading to deficits in balance and postural control.[25] As a result, many patients do not undergo successful rehabilitation after major lower extremity amputation, and only two-thirds will be able to ambulate with prosthesis. In addition, in this population, reduced healing capacity and diabetic-related neuropathy contribute to higher rates of surgical site infection and revision surgery. Approximately 22% of diabetic amputations require secondary reamputation at a more proximal level within 12 months regardless of initial amputation level, as compared with 12.6% of nondiabetic amputations.[26] Risk for reamputation of the ipsilateral limb is highest within 6 months of initial amputation.[27] These patients also experience a high rate of contralateral limb loss, with 20.5% undergoing contralateral amputation within 5 years of initial amputation.[28] This risk is greatest for those with high-level initial amputations, likely due to increased dependence on the contralateral limb for ambulation or due to more advanced, widespread disease. Overall, major lower extremity amputation is associated with a severe reduction in survival and quality of life that is on par with malignant disease, with 1, 3, 5, and 10 year survival rates as low as 78%, 61%, 44%, and 19%.[29] Even short-term data are dismal, with reported 30 day, 90 day, and 6 month postoperative mortality rates up to 11%, 18%, and 25%.[30,31] Postoperative mortality is higher for patients who are unable to be fitted for prosthesis.[32,33]

Given the high postamputation mortality and challenges with prostheses in this population, reconstruction is the management of choice for patients with diabetic complications, carrying as high as 93% flap success and 76% limb salvage success rates. It limits postoperative decline and allows achievement of markedly higher rates of independent ambulation relative to amputation.[34] Following limb salvage with skin flap application, patients may begin weight-bearing and achieve ambulation as early as 3.5 and 6 weeks postoperatively, respectively.[35] Studies have further shown that patients with diabetes who undergo limb salvage have persistent nonsurgical wound (eg, ulcer) healing and a mortality rate comparable to that recorded for the general population with diabetes, with patient survival rates reported as high as 86.8% at 5 years postoperatively.[36,37] Despite these benefits, up to 21% of patients require conversion to major amputation within the first 2 years after index surgery.[34,37]

Patient Autonomy

Issues pertaining to patient autonomy are central to the ethical discussion on amputation versus limb salvage. When faced with this decision, patients with limb-threatening injury assign the greatest important importance to regaining preinjury function level and minimizing costs, and the least importance to changes in appearance.[38] Previous studies have consistently demonstrated patient fears and anxiety regarding amputation, largely citing perceived loss of independence and negative psychosocial impact as the main contributing factors.[16,39,40] A decision analysis revealed that patients strongly prefer reconstruction to primary amputation, attributing a

quality-adjusted life year (QALY) of 30.8 for reconstruction versus 24.9 for primary amputation. Patients also anticipate significantly worse function with amputation, assigning utilities of 0.83 for limb salvage and 0.67 for amputation.[41] In contrast, surgeons assign comparable QALY (34.1 vs 33.4) and utility values (0.97 vs 0.95) to these procedures for traumatic indications.[41]

Given these differences in opinion and the known improvements in quality of life and high-level function that can be achieved with modern prostheses,[42] the importance of shared and informed decision-making for patients with limbs at risk must be highlighted. Patients—or surrogate decision makers in the setting of acute trauma where patients are unable to consent for themselves—must be presented both options as well as the prognosis associated with each procedure. It is the responsibility of the surgeon to provide unbiased transparency and ultimately, demonstrate respect for patient autonomy when a decision is made with the information disclosed. When both amputation and limb salvage are appropriate options, such as with the state of clinical equipoise seen for traumatic indications, shared decision-making is essential. The surgeon cannot convey judgment if the patient's choice is not in line with what they would have chosen for themselves. For example, it would be unethical for a surgeon to express disapproval or attempt to sway the decision if a patient indicates that preserving their native limb is more important than the potential to achieve better function with a prosthesis. However, it must be noted that in cases where one option is not medically appropriate, patient autonomy plays a smaller role in the decision for amputation versus salvage; instead, more emphasis must be placed on beneficence and nonmaleficence.

Overall, this conversation between surgeon and patient about treatment options should focus on the story, rather than the end result.[43] Even in the setting of trauma where a state of clinical equipoise can be reached at 2 years postoperatively, the journey to reach this outcome can be vastly different. For high stakes surgical decision making, Gretchen Schwarze MD, MPP, FACS, has advocated a "best case/worst case" approach.[44] In this decision-making model, the surgeon would frame the best case, worse case, and most importantly, the intermediate case—or most likely scenario—with inclusion of details on surgery, initial hospitalization, progression of weightbearing, rehabilitation, and possible complications for each. An example of this breakdown for a healthy patient with a traumatic limb-threatening injury is displayed in Fig. 1. This approach allows the patient to better understand the range of potential postoperative courses and make an informed decision that best aligns with their life values. Such a comprehensive discussion requires time and thereby may not be adequately pursued in cases of acute trauma. To prevent violation of autonomy, these patients may undergo provisional treatment with irrigation and debridement, splinting or external fixation, and application of a negative pressure dressing. After this initial stabilization, further discussion can be permitted where patient and family preferences can be appropriately taken into account.

Patient Selection

There are known disparities by race and socioeconomic status in amputation rates and outcomes. For diabetic complications, Black and Native American patients have 2 to 3 fold the likelihood of major lower extremity amputation when compared with White patients, respectively.[45–47] Hispanic patients have up to a 30% greater risk.[48] These differences hold at both 1 and 5 years after diagnosis with diabetes or dysvascular disease.[45] The incidence of more proximal level amputations is also higher for Black versus White patients.[49] Compared with patients of other races, Black patients are less likely to undergo an attempt at revascularization prior to amputation.[50] Even among those where limb salvage is attempted, Black patients have significantly lower amputation-free survival rates at 2 years after the index procedure (68.4% vs 75.4%), with this disparity increasing over time.[50] For traumatic indications, Black patients experience an age-dependent higher rate of amputation that cannot be explained by injury mechanism.[51,52] These disparities persist even after adjusting for the presence of medical comorbidities and socioeconomic factors including disability status, household income, insurance type, urban versus rural residence, and neighborhood disadvantage.[46,51,52] In addition, low income and public health insurance are also independently associated with higher rates of amputation.[53] For both amputation and limb salvage, patients have worse Sickness Impact Profile scores if they possess one of the following factors: non-White race, low education level, poverty, lack of private health insurance, or poor social support.[21]

The disparities for the management of limb-threatening diabetes-associated complications tend to be attributed to delayed presentation as well as barriers to appropriate, effective, and timely care. Owing to their nonelective nature,

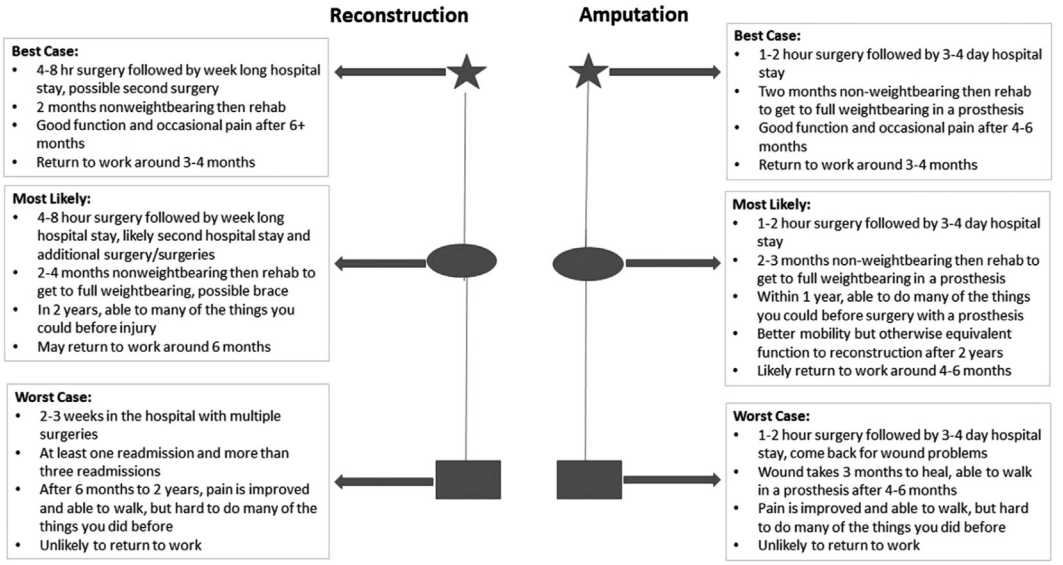

Fig. 1. "Best case/worst case" framework for traumatic limb-threatening injury in a healthy patient. (*From* Humbyrd CJ. Virtue Ethics in a Value-driven World: Seeking the Story. *Clin Orthop Relat Res.* 2022;480(2):241-243;[43] with permission.)

traumatic indications are less susceptible to racial and socioeconomic differences in care. However, patient factors may be overly influencing the selection for reconstruction, given the subjective nature of these decisions. Surgeons may preferentially select "more optimal" patients and—consciously or unconsciously—avoid patients at higher risk for worse outcomes. Although this may be argued as a protective measure, unconscious biases may also be a factor, as there are persistent disparities in amputation rates even within well-resourced, high-volume centers where operations are performed by experienced surgeons.[54] This difference—which exists not only among patients groups with presumptively similar medical conditions but also carries a negative impact for marginalized communities—warrants scrutiny.

Access to Appropriate Care

Successful limb reconstruction requires access to coordinated multidisciplinary care, early family meetings, and goal-of-care discussions, and surgeons with the training and expertise to carry out complex procedures.[55] The ideal care team would be composed of an endocrinologist, vascular surgeon, orthopedic surgeon, infectious disease specialist, orthotist, physical therapist, nutritionist, and wound care nurse. As a result, specialty limb salvage programs are typically established at large teaching hospitals or tertiary referral centers.[56] These necessary structures and resources are frequently lacking in rural areas, leading to a higher likelihood of major lower extremity amputations for patients who reside in these locations.[45,57,58] Similar trends have also been noted for the southern region of the United States, which has both the highest amputation rate and the lowest intensity of specialty care when compared with the northeast, west, and midwest regions.[57,59] Many of these patients prefer medical care within their own communities, that when coupled with shortcomings in transportation to specialty limb salvage centers, results in presentation to community hospitals with limb-threatening conditions. This phenomenon is most applicable to cases secondary to chronic etiologies, whereas acute traumatic indications are preferentially transferred to and treated at designated trauma centers.[60] However, a subset of HELET injuries remain at nonteaching and rural hospitals where the odds of amputation are significantly higher, even for pediatric patients who are typically indicated for reconstruction.[61,62] Therefore, both patient preferences for local care and limited resources in some areas may increase the rate of amputation.

Surgeon Experience

Similarly, surgeon experience must be considered in the decision for amputation versus limb salvage, as annual case volumes are associated with adverse limb events.[63,64] Surgeons have a responsibility to act as fiduciaries to their patients and in this role, advocate for their best

interests. They must be aware of their own capabilities, as inexperience can place patients at greater risk for longer operative times, perioperative complications, and worse outcomes. To respect patient autonomy in the case of a threatened limb, surgeons must provide adequate education on the range of treatment options available even if they are unable to perform the procedures themselves. Ethical conduct should thus involve disclosure of the surgeon's expertise regarding both amputation and limb salvage during the informed consent process. If the surgeon is not equipped to handle complex reconstruction and it is the patient's preferred option, appropriate referral is warranted. Efforts should be made to coordinate care with a more experienced surgeon or utilize regional referral networks that allow transfer to specialty limb salvage centers.

SUMMARY

Ethical decision-making in the amputation versus limb salvage context requires the physician to consider the principles of respect for autonomy, beneficence, and nonmaleficence. The surgical options demonstrate near equivalent outcomes for traumatic indications, whereas reconstruction is generally favored for threatened limbs due to diabetic complications. The decision for amputation versus limb salvage must be considered in each individual patient's situation, with a shared decision-making process of paramount importance. As techniques and prostheses evolve, the considerations around both reconstruction and amputation are likely to change.

CLINICS CARE POINTS

- The ethical principles of beneficence, nonmaleficence, and autonomy are at the forefront of the decision for amputation versus reconstruction in the context of a patient with a threatened limb.
- There are near equivalent postoperative outcomes for acute traumatic indications for amputation versus limb salvage, while reconstruction is strongly favored for diabetic complications due to high mortality rates associated with amputation.
- To respect patient autonomy, surgeons should frame the best case, worst case, and most likely case for each surgical option to allow the patient to better understand the range of potential postoperative courses and make an informed decision.
- Patient selection, access to appropriate care, and surgeon experience are additional factors that carry ethical implications and must be considered in the decision-making process.

DISCLOSURE

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