Limb-salvage surgery in trauma leg injuries. Does it offer patients better quality of life and functional capacity than amputation?

La chirurgia di salvataggio d’arto dopo trauma degli arti può offrire ai pazienti una miglior qualità di vita e capacità funzionale rispetto all’amputazione?

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Available from: http://www.preventionandresearch.com/

Key words: limb salvage, amputation, regenerative medicine, health costs

Parole chiave: salvataggio d’arto, amputazione, medicina rigenerativa, costi per la salute

Abstract

Background: The decision to salvage or amputate the injured limb has generated much controversy in Literature, with studies to support advantages of each approach. All scoring systems have proved unreliable in predicting the need for amputation or salvage. ‘Making decision’ and ‘timing’ can be difficult even for experts.
**Objectives:** Obviously, it is to avoid amputation of a limb which could be saved, as well as not always trying the revascularization. This is the challenging problem. In our opinion, the issue is not to perform revascularization just because it is technically feasible, but when it should be performed.

The purpose of this study is clarify some decisions about management of severely injured legs.

**Methods:** We reviewed the Literature and analyzed our clinical experience of 89 cases of high-energy trauma of lower limbs (Gustilo, grade III a, b, c), with extensive damage of soft and deep tissues, from 2004 to 2012. All of them were ischemic limbs with high risk of amputation. To evaluate the results we analyzed: length of hospital stay, total rehabilitation time, cost, clinical outcomes, failure rate for limb salvage, factors associated with poor outcome, function and quality of life, return to work, and patient choices.

**Discussion:** To be considered valid, absolute results of this kind of research should be made considering the welfare relating to the capabilities of Health Services and benefits in individual countries. The outcomes may have been influenced by the expertise of physicians and other caregivers.

When it’s impossible to obtain the anatomical and functional recovery after limbs’ complex trauma, the amputation still remain the first choice. Recently new technological frontiers in surgery connected with regenerative medicine, new treatment of post traumatic lesions, such as wound care and ‘loss of substance’, have been highlighted in Literature.

**Conclusions:** The introduction of autologous progenitor integrated biomaterials and biotechnology in order to stimulate tissues regeneration made possible avoiding limb amputation revascularizing and obtain a complete and faster healing. A scale which takes into account most of the criteria highlighted it is required, clinical before and social then. We reiterate the difficulty to attribute universal criteria considering the different realities of National Health Systems. The presence of a team dedicated to trauma is very important to assess immediately the possibilities and difficulty elements of the entire surgical procedure and rehabilitation.

The limb functional recovery achieved by the intervention with ‘integrated’ polyspecialistic skills, including orthoses and physiotherapists seems to have a favorable impact on the level of collective social costs, besides the QoL of the patient and his family. We conclude that for potentially salvageable legs reconstruction is still and anyway advisable.

**Abstract**

**Introduzione:** La decisione di salvare o amputare un arto danneggiato ha generato molte idee controverse in Letteratura, con studi che supportano i vantaggi di entrambi gli approcci. Tutti i sistemi di punteggio utilizzati si sono rivelati non affidabili nel predire la necessità di amputazione o di salvataggio d’arto. Il trauma ‘complesso’ degli arti porta con sé aspetti che rendono difficile le scelte su modalità e tempistica di trattamento anche per gli specialisti.

**Obiettivi:** Ovviamente, bisognerebbe evitare di amputare un arto che potrebbe essere salvato, così come non bisognerebbe sempre tentare una rivascolarizzazione. Secondo la nostra esperienza, non bisognerebbe tentare una rivascolarizzazione solo perché è tecnicamente fattibile, ma solo quando andrebbe davvero tentata. Scopo di questo studio è quello di chiarire la gestione di arti severamente danneggiati.

**Metodi:** A tal fine si fa riferimento alla Letteratura e alla nostra esperienza clinica. 89 casi di trauma degli arti inferiori ad alta energia (Gustilo, grado III a, b, c), con danno esteso dei tessuti molli e profondi dal 2004 al 2012. Tutti erano casi di arti ischemici con alto rischio di amputazione. L’analisi dei risultati ha valutato: durata media di degenza ospedaliera, tempo totale di riabilitazione, costi, risultati clinici, fallimento di salvataggio d’arto, fattori associati, funzionalità e qualità di vita, ritorno al lavoro, scelta del paziente.
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Discussion: Quando non è possibile ottenere una ripresa anatomica e funzionale dopo una trauma complesso degli arti, l’amputazione rimane ancora la prima scelta chirurgica. Di recente nuove frontiere tecnologiche in chirurgia correlate alla medicina rigenerativa, nuovi trattamenti delle lesioni post traumatiche, come anche della perdita di sostanza, sono state messe in evidenza in Letteratura.

Conclusioni: L’introduzione di progenitori autologhi integrati con i biomateriali e la biotecnologia, stimolando la rigenerazione tessutale ha reso possibile evitare l’amputazione rivascolarizzando l’arto, ottenendo così una completa e più rapida guarigione. Una scala di punteggio che prenda in considerazione più criteri possibili di quelli messi in evidenza è necessaria, che sia clinica e anche ”sociale”. Ribadiamo qui la necessità di attribuire criteri universali considerando le differenti realtà dei Sistemi Sanitari Nazionali. La presenza di un team dedicato al trauma è di estrema importanza per valutare immediatamente le possibilità e gli elementi di difficoltà di tutto l’iter chirurgico e di riabilitazione.

La ripresa funzionale dell’arto raggiunta grazie all’intervento ”integrato” polispecialistico, ortopedico e fisioterapico inclusi, sembra avere un impatto favorevole sul livello dei costi della collettività, oltre che sulla qualità di vita del paziente e dei suoi familiari. Allo stato attuale, perseguire il tentativo di salvataggio d’arto è comunque consigliabile, quando potenzialmente possibile.

Background

Studies support advantages of each approach, about decision to salvage or amputate the injured limb. All scoring systems have proved unreliable in predicting the need for amputation or salvage; however, a recurring theme in the Literature is that the key to limb viability seems to be the severity of the soft-tissue injury. Factors such as associated injuries, patient age, and comorbidities also should be considered. Attempted limb salvage should be considered only if a patient is hemodynamically stable enough to tolerate the necessary surgical procedures and blood loss associated with limb salvage. For persistently hemodynamically unstable patients and those in extremis, life comes before limb. Recently, LEAP (The Lower Extremity Assessment Project study) attempted to answer the question of whether amputation or limb salvage achieves a better outcome (1). The study also evaluated other factors, including return-to-work status, impact of the level of and bilaterality of the amputation, and economic cost. There appears to be no significant difference in return to work, functional outcomes, or the cost of treatment (including the prosthesis) between the two groups. A team approach with different specialties, including orthopaedics, plastic surgery, vascular surgery and trauma general surgery, is recommended for treating patients with a mangled extremity (2). "Complex" traumas of limbs are not only a serious clinical problem, but also a social one. Highest incidence appears to be between 15 and 44 year-old patients (Istat, 2005). The outcomes often result in functional disability and compromised quality of life (QoL) for many patients and their families. The coexistence of complex bone fractures, vascular and neurological injuries may, in severe cases, require amputation, even after repeated attempts in rescuing the leg. Leg threatening injuries leave patients and clinicians with a difficulty in making decision: primary amputation or limb salvage? ‘Making decision’ and ‘timing’ can be difficult even for experts (3-7). There is no agreement on functional results obtained with primary amputation or revascularization. By some Authors, there are no long-term functional outcomes differences between limb salvage and primary amputation: both are associated with high rates of self-reported disability (40% to 50%) and worsening of functional status (5, 6).

Obviously, it is to avoid amputation of a limb which could be saved, as well as not always trying the revascularization. This is the challenging problem. In our opinion, the issue is not to perform revascularization just because it is technically feasible, but when it should be performed.

The decision to amputate a limb is mainly dictated by the severity of local injury, associated injuries and the general state of the patient, as to confirm the recent Literature (6, 7, 8).

In case of severe injury, during the initial assessment, recovery expectations should be based on reliability and objectivity as much as possible. Giving a “score” to the trauma over the years has been introduced for this purpose. However, none of those “scales” proved to be fully working (8-13).
Multidisciplinary approach can really modify the outcome of the patients with severe injuries of the legs. In the '60s, the presence of a crush injury or vascular injury was severe enough to warrant amputation. Since the '80s, with the evolution of microsurgical reconstruction techniques, together with the development of modern and more sophisticated devices for osteosynthesis and reconstruction of the tissues, the limb salvage has become technically possible even in the most extreme cases. VAC (Vacuum-Assisted Wound Closure) and regenerative medicine that uses various biomaterials have a favorable impact on the reconstructive phase, allowing to address the complexity of the extensive loss of substance, planning and managing the best functional recovery of these patients, reducing the recovery time and thereby optimizing the costs (14-20).

**Methods and Results**

We treated 89 cases of high-energy trauma of lower limbs (Gustilo, grade III a, b, c), with extensive damage of soft and deep tissues, from 2004 to 2012. All of them were ischemic limbs with high risk of amputation.

4 patients underwent amputation as the first choice, and 85 underwent reconstruction. NPWT and hemoautologous blood concentrations were used during the treatment.

To evaluate the results we analyzed: length of hospital stay, total rehabilitation time, cost, clinical outcomes, failure rate for limb salvage, factors associated with poor outcome, function and quality of life, return to work, and patient choices.

14 revascularized patients were amputated during the initial hospitalization because of failing reconstruction, 8 underwent amputation after the initial hospital discharge. Of those eight patients, 5 were amputated after three months of discharge, 2 of them between three and six months, and 1 of them after six months. The remaining 63 patients had limb salvage.

In 45 patients, were used NPWT at first, and autologous blood products and Moist Wound Therapy (MWT) after, by an original method in order to assess the effects of angiogenic growth factors. Endothelial precursors cells (EPCs) are able to improve the functioning of ischemic organs through induction of vasculogenesis and angiogenesis in areas with reduced oxygen supply, as suggested by recent studies (5, 6). Our results are presented in other study (14).

The mean number of interventions is 2 for amputated group, with a failure rate for limb salvage of 25.8%, and 6 for revascularized one.

Length of hospital stay is similar in all patients operated for limb salvage, followed or not by amputation. This data became different if consider the first time amputated patients in which the length of hospital stay is shorter than revascularized group.

Higher rehabilitation time was 12 months for amputation d’emblèè and considered 18 months for other amputated patients. The same value for reconstruction patients was 30 months (p<0.009).

Changes in lifestyle (at the beginning and the loss of hope) were consistently more important in the amputee group with permanent working disability and no return to work (74% vs 33%). Twenty six percentage of the amputees and sixty-seven percentage of the reconstructed patients were retrained to a different profession (p < 0.025). Social disintegration, due to the long treatment, is referred in both groups. Both forms of management are associated with high rates of self-reported disability (50% to 65%) after 12 months. Functional outcome was measured with use of the Sickness Impact Profile, a multidimensional measure of self-reported health status.

Patients always prefer “limb salvage” as first choice; 3 patients, with poor quality of life, changed their mind during heavy and long rehabilitation time. QoL also depends by caregivers and compliant situation of the family. It’s impossible calculate total costs due to many variable factors and differences in health national system. We can tell the cost during the hospitalizations was higher for limb salvage patients and the costs in the first instance for amputated cases was lower than revascularization treatment. But if we consider the first four year-time after hospitalization (including retirement money paid, orthopedic aids, wheelchairs, periodic replacement of the prosthesis) the cost became almost similar in amputated and revascularized groups.

We can classify poor outcome of the patients as clinical and psychosocially. Both clinical and psychosocial factors are associated with poorer functional outcomes.

Clinical factors contributing to poor outcome are time of ischemia, loss of function (especially sensitivity); psychological and social elements are the age, the social environment and dissatisfaction of the patient.
Discussion

Literature doesn’t suggest same evidence. Some AA. report that while length of hospital stay is similar for limb salvage and primary amputation, length of rehabilitation and total costs are higher for limb salvage patients (21, 22, 23). The current evidence suggests that a salvage patient requires greater additional surgery and is significantly more likely to undergo re-hospitalization. Long-term functional outcomes (up to 7 years post injury) are equivalent between limb salvage and primary amputation; both forms of management are associated with high rates of self-reported disability (40% to 50%), and functional status continues to worsen over time. Report of pain following limb salvage or primary amputation is similar. Return to work is essentially the same between limb salvage and primary amputation groups, with approximately half of such patients returning to competitive employment at 2 years post injury. Both clinical and psychosocial factors are associated with poorer functional outcomes. At the time of injury patients prefer limb salvage, but the majority of failed salvage patients would opt for early amputation if they could decide again. Nine observational studies contributed data to our systematic review. Research to optimize triage decisions to avoid failed limb salvage as well as on interventions targeting important psychosocial prognostic variables should be considered a priority.

Medical and surgical advances of the past two decades have improved the ability to reconstruct severely injured legs. Limbs that once would have been amputated are now routinely managed with complex reconstruction protocols. Because most studies evaluating reconstruction have been small and retrospective, the results are not definitive and leave with questions clinicians as well as patients. Although the results are contradictory, some investigators have suggested that functional outcome is often poorer after successful limb reconstruction than after treatment with early amputation and a good prosthesis. Different Authors report that after adjustment for the severity of the limb injury, the presence and severity of other injuries, and other characteristics of patients, those undergoing amputation would have better outcomes than those undergoing reconstruction. It is important to take account of the impact of complications during recovery that involve the need for a rehospitalization: late amputation or stump revision, fracture nonunion, hardware failure, flap failure, wound infection, or osteomyelitis.

The rating scale of traumas (MESS, LSI, PSI, NISSSA and HFS-97) has been discussed in a recent prospective longitudinal study “LEAP” (Lower Extremity Assessment Project), in 601 patients with 16 complex inferior limb traumas. The review is conducted in the U.S. in 8 Level I Trauma Center to establish predictive reliability of amputation. Authors concluded that the scales were predicting limb salvage, not amputation. Another review point the attention on “cost and quality of life (QoL)” in outcome of these patients. The 'Quality of Life' was expressed as "Quality Adjusted Life Year” Index (QALY = No. x year survival quality of life), relationship between life expectancy and quality of life for patients divided by age group. The cost for a patient undergoing reconstructive surgery was estimated in the first two years after the injury as $8,316, in the 2 years following as $81,966, and the total final cost was $133,704. As for an amputee, the costs were respectively $91,105, $418,170 (from the third year onwards) and $350,465, taking into consideration the need for change the prosthesis every 2.3 years. It has been estimated that patients undergoing reconstruction showed a broadly similar amputees QALYs (0.969 vs 0.954) (22).

The limits of this review, highlighted by the Authors themselves, are represented by the absence of other costs such as pharmaceuticals, the working days lost, the housing infrastructure necessary adjustments, "compliance" welfare of the family. To be considered valid, absolute results of this kind of research should be made considering the welfare relating to the capabilities of Health Services and benefits in individual countries. The outcomes may have been influenced by the expertise of physicians and other caregivers.

Recent developments in biotechnology and ‘regenerative’ medicine have changed the treatment of these lesions. The "restitution ad integrum" of damaged tissue is facilitated and accelerated by integrated arrays of biopolymers from cellular components that induce the recruitment and differentiation of precursor cells which are able to revascularize and to repair tissues. The study we developed, already mentioned, which aims to assess the efficacy of treatment through the regenerative neoangiogenesis stimulated locally, confirms the efficacy of the ‘precursor cell’ in stimulating peripheral locally neoangiogenesis and thus promote tissue regeneration (14).

The treatment with all this new therapeutic possibilities allowed us in our clinical experience to save limbs otherwise lost. Cost / benefit is a favorable result for NPWT treatment in a randomized clinical trial, compared with the traditional principals (21). This study demonstrates that patients treated with this system, while presenting a cost unit higher (353 vs. €273 €), accelerated mean time to healing (16 vs. 20 days), with a reduction in access to outpatient after
discharge, a reduction of working days lost. Despite the clear advantages, the ability to organize the administrative and logistics home treatment is, in some places, yet complicated. So the resulting need for treatment in hospital leads to prolonged hospitalization time while limiting the extensive usage of this products.

Conclusions
All scales showed a low sensitivity and cannot therefore be used as a primary criterion for selection of amputation. Research to optimize triage decisions to avoid failed limb salvage as well as on interventions targeting important psychosocial prognostic variables should be considered a priority. Physical health and psychosocial health, which reflects limitations, must be better considered.

Regenerative medicine has opened new frontiers and it is something we have to take advantage on. Amputation is more expensive than salvage independent of varied ongoing prosthesis needs, discount rate, and patient age at presentation. Moreover, amputation yields fewer QALYs than salvage. Salvage is deemed the dominant, cost-saving strategy. Unless the injury is so severe that salvage is not a possibility, based on this economic model, surgeons should consider limb salvage, which will yield lower costs and higher utility when compared to amputation.

A scale which takes into account most of the criteria highlighted it is required, clinical before and social then. We reiterate the difficulty to attribute universal criteria considering the different realities of National Health Systems. The presence of a team dedicated to trauma is very important to assess immediately the possibilities and difficulty elements of the entire surgical procedure and rehabilitation (24, 25).

The limitations of our study must be acknowledged. Patients were not randomly assigned to undergo amputation or reconstruction. Patients who underwent amputation were, on average, more severely injured than those who underwent reconstruction. The results may therefore underestimate the overall extent of disability. The generalizability of our results beyond level I trauma centers is uncertain. The outcomes may have been influenced by the expertise of physicians and other caregivers. Finally, the results are based on outcomes during the first year or two after injury, a period in which many patients have not yet completely recovered. Eventual amputation of dysfunctional or chronically painful limbs may ultimately improve function among patients who undergo reconstruction.

Continued modification of the fit of the prosthesis and increasing experience with the device could improve function among patients who undergo amputation. Although not considered in this study, the costs of treatment and rehabilitation (including lifetime costs of prostheses) will also be important in guiding treatment decisions. The subjective and objective benefits of limb-salvage surgery compared with amputation are not fully clear (26).

These data suggest that limb-salvage surgery offers better gait efficiency and return to normal living compared with above-knee amputation, but does not improve the patient’s perception of quality of life. Contrary to what you might think, at two years, the outcomes among patients who underwent reconstruction were not significantly different from those among patients who underwent amputation. Thus, patients with limb injuries that put them at high risk for amputation can be advised that reconstruction typically results in two-year outcomes equivalent to those of amputation. However, reconstruction is associated with a higher risk of complications, additional surgeries and rehospitalization.

We conclude that for potentially salvageable legs reconstruction is still and anyway advisable.

**Age: 79 yrs. old, Male:** Trauma and acute limb ischemia of the right leg. The patient is actually walking without orthopaedic aids.

- **a)** Soft and deep tissues lost in site of fasciotomy.
- **b)** After debridement the diameters of the lesion are 14x5cm.
- **c)** The treatment with autologue LeucoPlatelets Concentrates.
- **d)** After 8 months of treatment the reduction of the lesion is greater than 50% (4x2,5 cm).
- **e)** It will be heal after 3 months again.

**Age: 39 yrs. old, Male:** Trauma and acute limb ischemia of the left leg. The patient is actually walking with orthopaedic aids.

- **A)** post-traumatic ischemic limb.
B) surgical exploration of tissues damaged.

C) bone stabilization and autologous saphenous vein graft.

D) NPWT.

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