Predictive Outcome Score in Lower Limb Reconstructive Surgery. Preliminary Test

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ABSTRACT

Introduction: Post-traumatic sequelae in the limbs are a very difficult condition to approach due to the severity of the injuries and the lack of treatment protocols, which considerably hinder the choice of the best treatment alternative. The objective of this study was to analyze the outcomes of reconstructive treatment with a pre-surgical score designed ad-hoc and to evaluate its predictability. **Materials and Methods**: A retrospective cohort-type analysis of the outcomes of external fixation treatment was performed in 32 patients with traumatic leg sequelae in the last 7 years who were staged with a pre-operative score designed ad-hoc. This was compared with the results obtained with the ASAMI score with a minimum 2-year follow-up. **Results:** We obtained a direct relationship between pre-surgical staging and the final outcome. This relationship is reflected by obtaining a high percentage of excellent outcomes in low-risk patients (50%) and 60% of poor outcomes in high-risk patients. **Conclusions:** The current evidence is contradictory and there is controversy over which is the best treatment option. We found that high-risk patients have a high percentage of poor outcomes and may not benefit from reconstructive surgery. **Key word:** Tibia; Ilizarov; post-traumatic sequelae.
Level of Evidence: IV

Puntaje predictivo de resultado en la cirugía reconstructiva de miembros inferiores. Ensayo preliminar

RESUMEN

Introducción: Las secuelas postraumáticas en los miembros son un cuadro de muy difícil abordaje por la gravedad de las lesiones, la falta de protocolos de tratamiento y especialmente por la elección de la mejor alternativa. El objetivo de este estudio fue analizar el resultado del tratamiento reconstructivo con un puntaje prequirúrgico diseñado para tal fin y evaluar su predictibilidad de resultado. **Materiales y Métodos:** Se realizó un análisis retrospectivo de tipo cohorte de los resultados del tratamiento con fijación externa en 32 pacientes con secuela traumática de la pierna en los últimos siete años que fueron estadificados con un puntaje preoperatorio elaborado para tal fin y comparado con el resultado obtenido con la tabla de resultados de la ASAMI con dos años de seguimiento mínimo. **Resultados:** Se obtuvo una relación directa entre la estadificación prequirúrgica y el resultado final. Dicha relación se ve reflejada en el alto porcentaje de excelentes resultados en pacientes de bajo riesgo (50%) y una tasa del 60% de malos resultados en pacientes de alto riesgo. **Conclusiones:** La evidencia actual es contradictoria y se discute cuál es la mejor opción de tratamiento. Los pacientes considerados de alto riesgo tienen un alto porcentaje de malos resultados y tal vez no se beneficien con la cirugía reconstructiva.
Palabras clave: Tibia; Ilizarov; secuela postraumática.
Nivel de Evidencia: IV

INTRODUCTION

Post-traumatic limb sequelae have become an endemic condition in our country. In 2014, the Pan American Health Organization reported that there had been 15,000 permanent injuries per year due to road traffic accidents in Argentina.[1] The publications on therapeutic alternatives for post-traumatic sequelae are very varied and, for the most part, have a low level of evidence (reports and case series).

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Numerous publications on serious injuries in acute patients evaluate the indications for amputation or reconstruction. Several decision-making scores have been designed to guide the treatment process of acute trauma patients, all of them with their strengths and weaknesses. The items most used in these scores are hemodynamic status, ischemia time, bone and muscle damage. However, a consensus has not yet been reached and they are not valid in cases of post-traumatic sequelae.[2,3] The Limb Lengthening Reconstruction Society (LLRS) designed the LLRS AIM Index to assess the level of complexity of the condition to be treated; however, it has not gained popularity over the years and its validity has not been fully evaluated.[4] It has not been related to end-of-treatment outcomes, either.

Reconstructive limb surgery is, in many cases, a great challenge in terms of the magnitude of the damage, its comorbidities, and the method applied for this purpose. External fixation as a method for the recovery of bone stock in patients with an infectious history or integumentary lesions not appropriate for internal osteosynthesis is the most widely used alternative in these circumstances.[5]

The objective of this study was to retrospectively evaluate the design of a preoperative risk score for post-traumatic leg sequelae according to the results obtained with the ASAMI classification and, in this way, obtain information that allows us to make more objective decisions in future cases and to be able to answer the following question: is salvage surgery with external fixation valid in high-risk patients?

MATERIALS AND METHODS

A retrospective analysis was carried out of patients >17 years of age who had post-traumatic leg sequelae with non-articular bone defects treated by external fixation in two institutions, by the same surgical team, during the last seven years, with a minimum follow-up of two years. Patients treated with an acute condition (<3 months since trauma) and those with misalignment and discrepancy of the lower limbs not associated with traumatic injuries were excluded. We decided to include only the lesions of the leg segment and those treated with external fixation to form a homogeneous population and reduce factors that influence the final result. For this study, a preoperative score was designed (Table 1) that evaluates the main problems faced by the surgeon in the treatment of this pathology, the purpose of which is to obtain a functional and pain-free limb during walking. The problems included as determinants of the outcome were: soft tissue involvement, infectious status, type and magnitude of the bone defect, joint damage, and general comorbidities of the patient (age >60 years, osteoarthritis or joint stiffness, multioperated segment, etc.).

During the design of this clinical assessment or scoring questionnaire, we attempted to cover all the characteristics of the higher-quality designs, such as content, criterion, and construct validity, internal consistency, floor and ceiling effect, and test-retest reliability.

Each item was given a numerical value based on the incidence of risk described in other publications[6-8] and on the experience of the surgical team. These values were added at the end of the evaluation of the patient and after it. Cut-off values were defined to classify patients by type of risk, where a value lower than 16 was considered low risk; between 16 and 30, medium risk; and >30, high risk.

The radiographic evaluation was performed using printed teleradiographs (radiographs taken at 3.05 m distance, compensating for the discrepancy to achieve leveling of the pelvis and patellae in front) and on digital measurement with the Phillips IntelliSpace Pacs program. The description of soft tissue quality, infectious status, joint involvement, comorbidities, etc. were obtained from the interrogation and physical examination in the first consultations.

Finally, once the treatment was concluded and after at least two years of follow-up, the final outcome was evaluated with the ASAMI score (Table 2).

RESULTS

The search yielded a total of 32 patients: 25 men and seven women with an average age of 38.3 years (range 19-63). All had a ≥1 cm discrepancy, deviations, or an infectious history that justified external fixation as the most appropriate option. We excluded patients who had been treated with other means and three other patients because they did not meet the long-term follow-up criteria. Table 3 details the characteristics of the sample.

The general results were included in a table with the score corresponding to that obtained in the preoperative period (Table 4). The final global results are detailed in Figure 1.

Table 1. Evaluation score*

Factors	Involvement	Score
Soft tissue	Normal coverage	0
	Vascularized flap	3
	Free flap	6
	Granulation tissue	8
	Soft tissue defect	10
Infection	Negative	0
	History of infection	3
	Positive for an antibiotic-sensitive germ	6
	Positive for two or more germs	10
	Positive for an antibiotic-resistant germ	15
Bone defect	No bone defect	0
	<10%	3
	11-20%	6
	20-30%	10
	>30%	15
Joint involvement	No obvious joint involvement	0
	Stiffness / contracture	5
	External popliteal sciatic nerve injury	8
	Mechanical bone or capsuloligamentary alteration	10
Comorbidities	No comorbidities	0
	Tobacco smoker (5 moderate; 10 severe)	
	Body mass index >30	5
	Post-traumatic osteoarthritis	5
	Age >60 years	5
	Diabetes >10 years	10
	Multiple previous surgeries (more than 5)	5
	Vascular or nervous compromise	10
Total		85

*The elements considered as determining factors for the final outcome are detailed.

Table 2. ASAMI score

Bone variable					
	Excellent	Good	Good	Fair	Poor
Consolidation without infection	Yes	Yes	Yes	Yes	No
Residual deformity	<7° mm	<7° mm	>7° mm	>7° mm	
Length discrepancy	<2.5 cm	> 2.5 cm	<2.5 cm	> 2.5 cm	
Functional variable					
	Weakness	Equinus stiffness	Soft tissue dystrophy	Pain	Work inactivity
Excellent	No	No	No	No	No
Good	2 out of 5	variable			
Fair	3 or 4 out of 5	variable			
Poor	Yes	Yes	Yes	Yes	Yes

Table 3. Patient characteristics (n = 31)

Age and average	37 years (61- 19)
Male:Female	14:7
Right:left	9:12
Bone defect: mean and range	4.9 cm(0.5- 14)
Signs of active / negative infection	14/22
Soft tissue defects	5/22
Delay until treatment	16.6 months (5-32)

Table 4. Pre-treatment and post-treatment outcomes (minimum follow-up of 2 years)

Patient	Age	Segment	Sex	Risk score	Final score	Side	Active infection	Bone defect	Delay (months)
1	29	Leg	M	49	Good	L	Yes	14	5
2	29	Leg	M	8	Excellent	L	No	7	5
3	45	Leg	M	26	Good	L	Yes	8	10
4	25	Leg	M	3	Excellent	R	No	3	23
5	41	Leg	F	44	Poor	L	Yes	10	6
6	33	Leg	M	30	Excellent	L	Yes	6	18
7	37	Leg	M	25	Excellent	L	No	8	13
8	42	Leg	M	16	Fair	L	Yes	6	43
9	52	Leg	M	24	Good	R	No	2	16
10	53	Leg	F	29	Excellent	R	Yes	2	21
11	42	Leg	M	11	Excellent	L	No	3	35
12	44	Leg	M	26	Good	L	Yes	6	19
13	34	Leg	M	8	Excellent	R	No	5	13
14	46	Leg	M	8	Good	L	No	2	9
15	30	Leg	M	17	Excellent	L	No	3	23
16	48	Leg	F	6	Excellent	R	No	3	14
17	39	Leg	M	34	Poor	R	Yes	2	27
18	53	Leg	M	57	Fair		Yes	7	4
19	27	Leg	M	17	Good	L	No	4	11
20	48	Leg	M	14	Good	L	No	4	25
21	19	Leg	F	21	Fair	L	Yes	11	14
22	24	Leg	M	29	Excellent	L	Yes	1	5
23	19	Leg	F	17	Fair	L	No	5	7
24	27	Leg	M	16	Good	R	No	5	27
25	29	Leg	M	6	Excellent	L	No	1	14
26	63	Leg	F	27	Good	R	Yes	4	32
27	42	Leg	M	6	Excellent	L	No	0	13
28	23	Leg	M	3	Excellent	R	No	0	9
29	30	Leg	M	50	Good	L	Yes	11	7
30	46	Leg	M	30	Good	L	No	6	28
31	54	Leg	F	61	Poor	L	Yes	4	20
32	53	Leg	M	21	Excellent	L	No	3	9
	38.313			23.09				4.88	16.41

M = male, F = female, L = left, R = right.

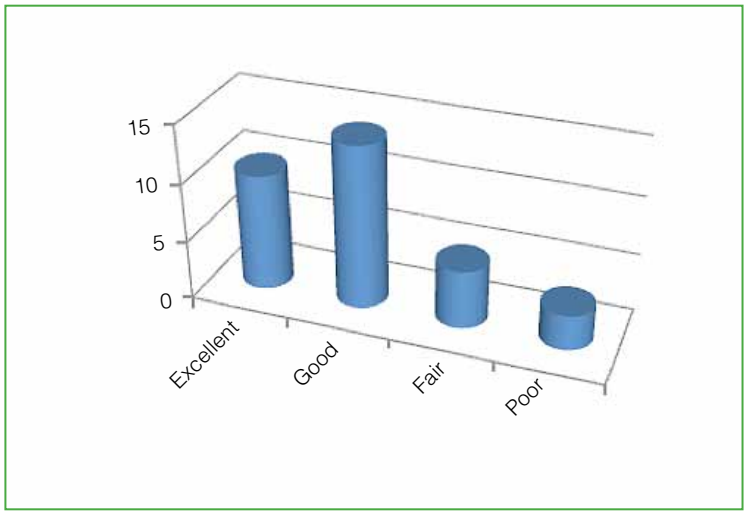

Figure 1. Global post-treatment outcomes (n = 32).

The data were then crossed to observe the relationship between the result obtained from the preoperative evaluation and the final outcome of the patient (Table 5, Figure 2).

Table 5. Outcomes versus risk

Risk of complications	Excellent	Good	Fair	Poor
Low	8	2	0	0
Moderate	6	7	3	0
High	0	1	2	3
Total	14	10	5	3

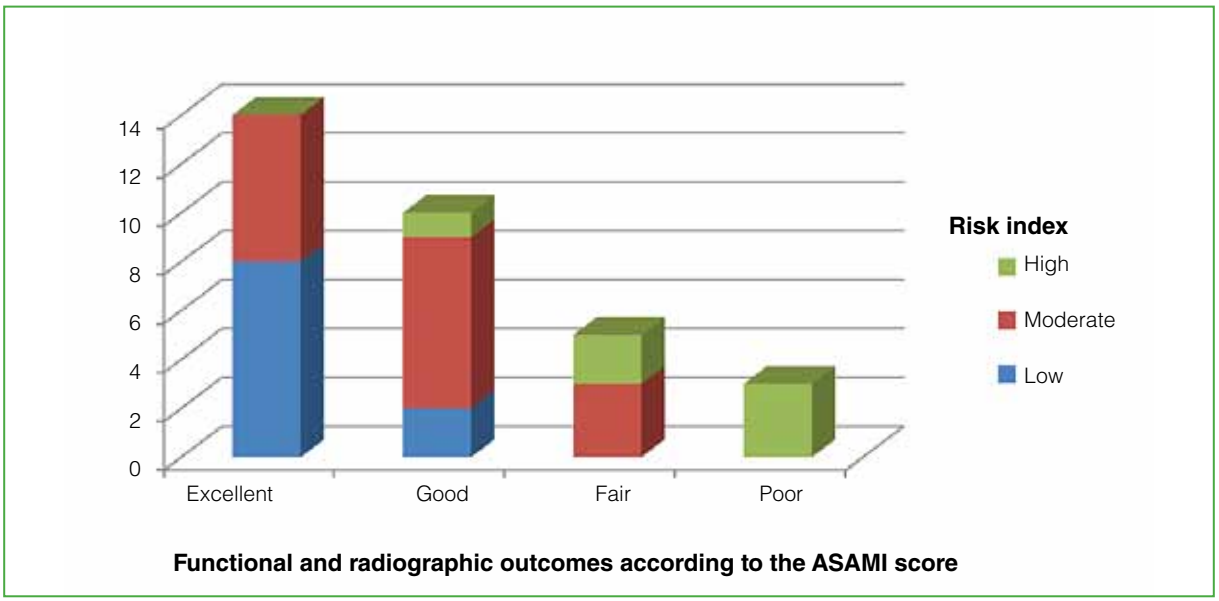

Figure 2. Relationship between the patient's risk and the final outcome. A direct relationship was observed between the risk and the final outcome (n = 31).

The results obtained show a direct relationship between the risk rate analyzed in the preoperative evaluation and the final outcome value. This relationship is reflected in the high percentage of excellent outcomes in low-risk patients (60%), while, in high-risk patients, the rate of poor outcomes reached 60%.

All patients had good adherence to treatment and a continent family, so this was not taken into account in the result analysis. Three of 32 patients obtained a bad outcome (9.3%), all of them were high-risk (60% of the total).

DISCUSSION

In the current literature, we have not found evidence of a pre-surgical protocol with similar characteristics that analyzes the factors that influence the final outcomes of the treatment of post-traumatic limb sequelae. Most publications on bone reconstruction in serious limb injuries are level 4 (case reports or series).

Today, the decision of bone reconstruction or amputation in post-traumatic sequelae is very subjective, as it is based on the experience of the surgeon because the scientific evidence is not conclusive in this regard. This is because there are no scores or treatment algorithms for this sequelae pathology. Three publications are the product of the Lower Extremity Assessment Project (LEAP) cohort study, where the impact of the disease on the quality of life of amputees and those who underwent bone reconstruction was evaluated in 613 cases. The first of them, published by Bosse et al. in 2002, did not find statistically significant differences in the domains of functions or in the psychological aspect.[9] The second publication was by Mackenzie et al. in 2005, who reviewed the patients again with a minimum of seven years of follow-up and, despite not finding statistically significant differences, detected functional and psychological deterioration with both treatment options.[10] The factors determined as risk markers for this decrease were: smoking, poverty, previous health status, and lack of family support.[11] Finally, in the third report, Harris et al. evaluated the complications of patients in the LEAP cohort with a minimum follow-up of two years and highlighted as relevant that surgical site infection was the most frequent in amputees and that the non-union rate was 31.5% in patients who had undergone limb salvage surgery. Although in the first six months the most critical patients are those who undergo amputation, the authors concluded that those who undergo bone reconstruction should expect a high complication rate.6

From another point of view, some reports from rehabilitation specialists conclude that, despite improving the quality of life by 30% after amputation, the final outcomes are still poor.[12,13]

Another important point to take into account when making decisions is the magnitude of the damage to be repaired and the deterioration of the limb. In the vast majority of reports, the maximum amount of lengthening or transport is not determined, but some publications state that lengthening more than 20-25% of the total length of the affected segment in a single event can lead to a greater incidence of complications. The total duration of external fixation in femoral bone lengthening ranges from 24 to 90 weeks per event, with an average time/length index of 6.23 weeks for each centimeter of lengthening, although some authors have published much longer periods depending on the extent of osteogenesis.[14,15] The need to prolong the use of the device can be considered a risk factor for more complications.

In 2005, Capomassi et al. published a series of 24 type B cases according to Paley's classification; the rate of good and excellent outcomes was 83%. The authors concluded that distraction osteogenesis is a valid method for treating severe osteocutaneous limb defects.[16]

In 2016, the Ministry of Health and Social Protection of Colombia and the University of Antioquia developed an evidence-based clinical practice guideline on reconstructive surgery compared to amputation in patients suffering from severe lower limb injuries. Despite not being conclusive due to its low level of evidence, the authors suggest reconstruction in patients >16 years of age with severe trauma in order to reduce costs and improve long-term function. Additionally, this publication revealed three interesting variables that modify the final outcomes: whether the study population is civilian or military, whether the amputation is carried out early (<90 days) or late, and whether the level of amputation is above or below the knee. Studies in military personnel found favorable amputation results, reported less post-traumatic stress, less chronic pain, and a lower complication rate. Regarding the level of reconstruction, the outcome was better when the damage compromised the leg, while the damage to the femur caused a higher complication rate and the outcomes were better with amputation.[17]

The weaknesses of our study are the partially subjective numerical values of the score, that is, that the construct validity and the internal validity could not be evaluated due to a low casuistry and a medium and short-term follow-up. As for strengths, we consider that the test has good content validity, test-retest and interobserver reliability, sensitivity to change, and possible validation and translation.

CONCLUSIONS

The predictive risk score is a useful tool and its goal is to give objectivity in future decision-making, especially when reconstructive surgery and amputation do not have a clear indication. In addition, the score will show unresolved complications at the end of the treatment (sensitivity to change) and the values obtained can be seen quantitatively. Therefore, and based on the results of this study, patients with a high risk of complications have a high incidence of poor functional and radiographic outcomes, and reconstructive surgery with the method analyzed would not be recommended.

Conflict of interest: The author has no conflicts of interest to declare.

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