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Predictive Factors of Amputation in Infra Inguinal Vascular Injuries

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1. Abstract

1.1. Background

Infra-inguinal vascular injuries (IIVI) are emergencies involving both functional and vital prognosis. The choice between saving the limb or doing a first-line amputation is difficult even for an experienced surgeon. The aims of this work are to analyze early outcomes in our center and to identify predictive factors for amputation.

1.2. Methods

Between 2010 and 2017, we reviewed retrospectively patients with IIVI. The main criteria for judgement were: primary, secondary and overall amputation. Two groups of potential risk factors of amputation were analyzed: Those related to the patient: age, shock, ISS score; those related to the lesion: mechanism, above or below the knee, bone lesions, venous lesions and skin decay. A univariate and multivariate analysis were performed to determine the risk factor(s) independently associated with the occurrence of amputation.

1.3. Results

57 IIVI were found in 54 patients. The mean ISS was 32,3 ± 21. A primary amputation was performed in 19%, and secondary in 14% of cases. Overall amputation rate was 35% (n=19). Multivariate analysis reveals that the ISS is the only predictor of primary (p=0.009; OR:1.07; CI:1.01-1.12) and global (p=0.04; OR:1.07; IC:1.02-1.13) amputation. A threshold value of 41 was selected as a primary amputation risk factor with a negative predictive value of 97%.

1.4. Conclusion

The ISS is a good predictor of the risk of amputation in IIVI. A threshold of 41 is an objective criterion helping to decide for a first-line amputation. Advanced age and hemodynamic instability should not be important in the decision tree.

2. Introduction

Nowadays, with the growth number of urban violence and road traffic injuries, we are assisting to an increasing prevalence of peripheral vascular injuries (PVI). Currently this prevalence is estimated between 4 to 6% of all injuries [1,2]**.** Patients can present three types of clinical features: hemorrhagic, ischemic or both. The diagnosis is often made by physical examination, helped by imaging, particularly CT angiography. PVIs are medico-surgical emergencies that involve, not only the functional prognosis of the limbs by the ischemia, but also the vital prognosis by the hemorrhagic shock [3]**.** They can lead to death in more than 20% of cases [4,5], and can be responsible of major amputation in 6 to 18% of them [6]. The choice between saving the limb or doing a first-line amputation is difficult even for an experienced surgeon. The benefice of an enthusiastic decision to preserve a limb with very severe injuries is uncertain due to the difficulty to predict its functional future. Also, if the decision is late it can lead to serious consequences.

That's why, having objective prognostic criteria for the risk of amputation, could be of considerable help in this decision. In addition to that, it will improve the morbidity and mortality associated with these traumas. Some criteria have been reported in the literature, but their prognostic value remains controversial [7-9]. Risk scores were also established in the 1990s, but their low validity makes their interest in clinical practice obsolete. With the evolution of surgical management techniques, including soft tissue reconstruction, bone stabilization and the development of the endovascular approach, the rescue of certain limbs formerly dedicated to amputation is now possible. For all these reasons, an update of these prognostic factors is interesting to improve our practices. Through the results of managing these PVIs in our regional trauma center, this study aims to identify the predictive risk factors of primary, secondary and global amputation.

3. Materials and Methods

3.1. Study Population and Data Collection

Between January 2010 and December 2017, we retrospectively reviewed all the patients operated for a non-aortic vascular injury. Among this population, only those admitted for infra-inguinal trauma were analyzed. We excluded patients with:

- Iatrogenic vascular injuries
- Electively chronic vascular lesions
- Normal surgical explorations
- Unusable files.

Demographic and clinical data (comorbidity, the mechanism of the injury, the ISS (Injury Severity Score), injury assessment), surgical data (revascularization procedure, primary amputation) and early outcomes (secondary amputation and mortality) were collected.

The ISS [10,11] is an anatomo-clinical score for evaluating the severity of the trauma. The injuries are divided into six body regions: head and neck, face, chest, abdominal or pelvic contents, extremities or pelvic bones and the skin. For each region a score is assigned from 0 to 6 (Table I). The ISS is the sum of the three highest square scores. This score varies from 0 to 75.

Amputation is called primary, if it is carried out immediately without a revascularization's gesture. Il is called secondary if il is performed following a failure of the limb revascularization, during the same hospitalization.

Table I : ISS Score [10,11].

Body region	Score and injury severity
Head and neck Face Thorax Abdomen or pelvic contents Extrimity or pelvic bone Skin	0 : aucune 1 : mineur 2 : modéré 3 : grave (sans risque vital) 4 : sévère (risque vital mais survie probable) 5 : Critique (Survie incertaine) 6 : non viable

3.2. Management and Surgical Techniques

The diagnosis of a PVI was clinical and helped by CT-angiography. An initial physical examination to check vitals is first done in the emergency room, allowing to assess the hemodynamic, respiratory and neurological state. Whenever possible, a full-body scanner with contrast injection is performed to identify both vascular and non-vascular lesions.

The prioritization of injuries is made in a multidisciplinary manner in the presence of vascular, visceral, orthopedic, neuro surgeons and the reanimating doctor.

For patients with high hemodynamic instability, exploration is performed directly in the operating room by angiography after performing a fast-echo and a standard chest and pelvis x-ray. In this case, a CT-angiography is performed immediately after surgery, for the rest of the lesion assessment.

The management of the vascular lesion is done by a surgical or endovascular approach. For conventional surgery, a vascular control upstream and downstream the lesion is performed. Depending on the hemostasis balance, a dose of 50UI/Kg heparin may or may not be administered prior the vascular clamping. In case of partial or total cross-section with clear limits, vascular repair by simple suture or end-to-end anastomosis is carried out. In case of complex vascular lesions, careful debridement of both ends of the artery is performed before performing an autologous venous graft bypass. In some cases when the patient's management exceeds 6 hours with significant ischemia of the limb, a Sundt shunt is set up quickly while waiting for the venous graft to be taken. A prosthetic bypass is performed only if the saphenous vein is unusual. A thrombectomy with the Fogarty catheter is systematically performed before the bypass. The revascularization is systematically assessed by an arteriography at the end of the procedure.

Primary amputation indications are: severe muscular and cutaneous decay and uncontrollable hemodynamic instability. Hemostatic amputation is then performed.

In case of both arterial and venous lesion on the femoral or popliteal level, venous restoration is performed whenever the hemodynamic state allows it. Otherwise, a simple ligature of the vein is preferred.

The nerve repair and/or the cover gesture is performed depending on the case, either during the same surgical time or a few days after.

A fasciotomy discharge is carried out according to the assessment of the surgeon, either at the end of the procedure, or secondary if occurrence of compartment syndrome.

Endovascular treatment is carried out in the presence of hemorrhagic lesion or an intimo-medial arterial lesion without loss of continuity of the artery wall. Bare or covered stents are deployed in this case.

3.3. Factors Analyzed

Two groups of amputation risk factors were analyzed:

- Those related to the patient: age, shock and ISS
- Those related to the lesion: lesion mechanism, location, bone damage, skin decay and associated venous lesions

3.4. Statistical Analysis

Data were analyzed using SPSS software version 23.0. The data are reported in frequencies and percentages for qualitative variables, and in mean and standard deviations for quantitative variables. The comparison of continuous variables is carried out by Student or Mann-Whitney tests, while for qualitative variables chi-square or exact Fisher tests are used.

All potential prognostic factors were examined by a univariate analysis. Those associated with amputation ($p < 0.05$) in the univariate analysis, and those considered relevant clinically or in literature data, were included in the multivariate logistic model. Odds ratios (OR) are presented with their confidence intervals to assess the degree of association between the variable and the occurrence of amputation.

4. Results

During the study period, there were 106 non aortic vascular injuries in 100 patients. More than half of these lesions were in the lower limbs (54%) and 35.8% were in the supra-aortic trunks and upper limbs. The lesions were mostly isolated arterial (73.6%).

4.1. Patients

Among these non-aortic vascular traumas, we analyzed the infra-inguinal located ones: 57 lesions occurred in 54 patients, which is our study population.

The mean age was 30.7 ± 12 years [15-61 years], with a male predominance (91%).

Vascular trauma is penetrating in 37 cases (65%): a gunshot wound in 11 patients (20.4%) and a stabbing wound in 16 patients (29.6%).

The average ISS score was 32.3 ± 21 [6 - 75]. It was above 15 in 96% of patients. Hemodynamic instability is found in 37% of cases.

Preoperative CT-angiography was performed in 68% (n=39). In 32% (n=15) of cases the diagnosis was made in intraoperative.

The location of the lesions was above the knee in 55.6% of cases (n=30): common femoral (n=2), superficial femoral (n=25) and deep femoral artery (n=3). Lesions were below the knee in 44.4% of cases (n=27): popliteal artery (n=17) and arterial leg axes (n=10).

Three patients had two simultaneous vascular wounds: one involved the superficial femoral and the popliteal arteries, and the other involved the superficial and the deep femoral arteries.

4.2. Early Results

Open surgery was performed in 86% of cases (n=49):

- 23 bypasses including one prosthetic
- 10 vascular repairs without bypass including 6 end-to-end anastomosis and 4 repairs with simple vascular sutures
- 5 vascular ligations: 3 arterial and 2 venous
- 11 primary amputations (19%): 2 trans-tibial and 9 trans-femoral amputations.

Endovascular treatment was performed in 14 % of cases (n=8): 3 overed stents (5.3%), bare stents (7%) and coil embolization (1.7%)

We reported one early death (1.9%) due to respiratory and neurological distress.

The morbidity rate was 19% (n=11): 5 post-operative infections, 2 of which led to vascular anastomotic disruption then to secondary amputation; 6 other secondary amputations due to bypass thrombosis.

In total, the overall amputation rate was 35% (n=19): 11 primary and 8 secondary amputations.

4.3. Predictive Factors

Univariate analysis shows that shock, ISS and below the knee location are significantly associated with the risk of primary amputation (p=0.001, p=0.001, p=0.040 respectively) **(Table II)**.

For secondary amputation, only popliteal location (p=0.040) and skin decay (p=0.040) are significant.

Factors associated with overall amputation risk include shock (p=0.007), ISS score (p=0.001), blunt trauma (p=0.050), associated bone injury (p=0.050) and skin decay (p=0.030).

In the multivariate analysis the ISS was the only predictive factor independently associated with the risk of primary amputation **(Table III).**

For secondary amputation, we added to the multivariate model, in addition to significant factors of the univariate analysis, others that are clinically relevant but not significant in our study **(Table IV).**

Multivariate analysis concerning the risk of overall amputation shows that the ISS was the only independent predictive factor **(Table V).**

For primary amputations, we identified a threshold value of 41 for the ISS, with 90% of sensibility, 93% of specificity and 97% of negative protective value **(Figure 1)**. Note that in our series, whenever the ISS was greater than 41, the vascular lesion was one of the three most serious lesions used to calculate this score.

For global amputations, we identified an ISS threshold value of 34 with a sensitivity of 68%, a specificity of 94% and a negative predictive value of 84.6% **(Figure 2).**

Table II: Univariate analysis of lower limb vascular injury amputation predictors.

	Primary amputation	Secondary amputation	Global amputation
Mean age (years)	32,4 (*p*=0,607)	32,3 (*p*=0,709)	32,37(*p*=0,476)
Shock (%)	81,8 (*p*=0,001)	37,5 (*p*=1)	63,2 (*p*=0,007)
Mean ISS	61,2 (*p*=0,001)	35,4 (*p*=0,574)	50,3 (*p*=0,001)
Mechanism (%)			
-fire wound	0 (*p*=0,095)	18,2 (*p*=1)	18,2 (*p*=0,292)
-stab wound	31,2 (*p*=0,27)	0 (*p*=0,088)	31,2 (*p*=0,764)
-blunt trauma	35,7 (*p*=0,129)	21,4 (*p*=0,41)	57,1 (*p*=0,05)
Localization (%)			
-Popliteal	6,2(*p*=0,144)	31,2 (*p*=0,041)	37,5 (*p*=1)
-below the knee	18,2 (*p*=0,04)	24 (*p*=0,125)	32 (*p*=0,77)
Associated lesions (%)			
-Multiple arterial lesions	0 (*p*=0,6)	33,3 (*p*=0,388)	33,3 (*p*=1)
-Venous lesions	19 (*p*=1)	14,3 (*p*=1)	33,3 (*p*=1)
-Bones fractures	25 (*p*=0,51)	25 (*p*=0,12)	50 (*p*=0,05)
-Skin decay	27,3 (*p*=0,67)	36,4 (*p*=0,04)	63,6 (*p*=0,03)

Table III: Multivariate analysis of primary amputation predictors.

Risk factor	*p*	Odds Ratio	95% Confidence Interval
Shock	0,52	2,46	0,15-38,3
ISS	0,009	1,07	1,01-1,12
Blunt trauma	0,9	4,5	0
Popliteal lesion	0,13	0,1	0-1,9
Associated bone lesion	0,9	7,9	0
Skin decay	0,45	0,3	0-7

Table IV: Multivariate analysis of secondary amputation predictors.

Risk factor	*p*	Odds Ratio	95% Confidence Interval
Shock	-	-	-
ISS	-	-	-
Skin decay	0,041	12,32	1,10-137,7
Popliteal lesion	0,028	14,5	1,32-158,8
Blunt trauma	0,474	2,15	0,26-17,5
Multiple arterial lesions	0,40	0,85	0,01-41

Table Y: Multivariate analysis of overall amputation predictors**.**

Risk factor	*p*	Odds Ratio	95% Confidence interval
Shock	0,5	1,97	0,26-14,5
ISS	0,04	1,07	1,02-1,13
Blunt trauma	0,9	8	0
Popliteal lesion	0,5	1,73	0,27-10,9
Associated bone lesion	0,9	3,29	0
Skin decay	0,44	2,14	0,3-15
Multiple arterial lesion	0,614	2,36	2-36

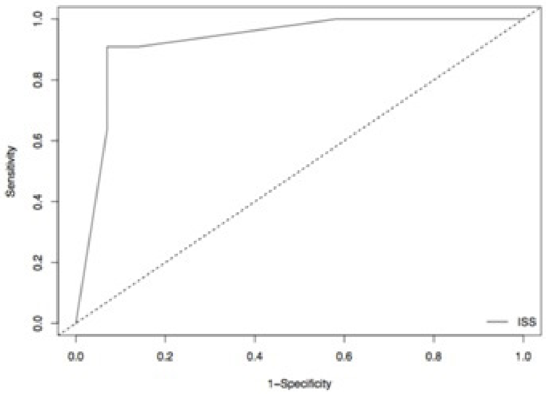

Figure 1: ISS ROC curve for primary amputations.

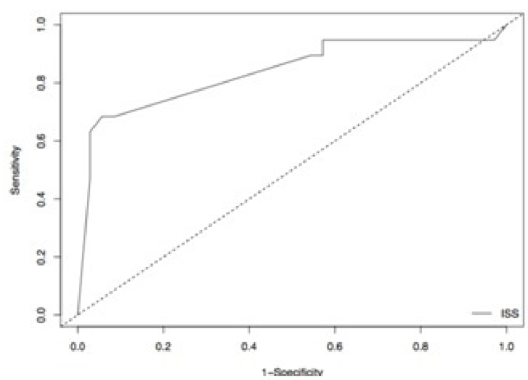

Figure 2: ISS ROC curve for overall amputations.

5. Discussion

Vascular trauma in the lower limb can lead to amputation that can be primary, secondary or late. The amputation risk rate can reach 18% [12]**.** In our series, the secondary amputation rate of 14% is substantially similar to that of the literature. However, the primary amputation rate is relatively high 19%, but with a low mortality rate of 1.9%. This rate is lower than that of the other series of the literature [13-15]**,** despite the severity of our traumas, as evidenced by the high ISS >15 in 96% of cases. Although the direct link between this reduction in mortality and the increase in the primary amputation rate cannot be formally established, it is highly likely that primary amputation prevented a number of deaths.

Amputation provides a significant morbidity for these patients, mostly young as we have seen in our series. Thereby the dilemma between carrying out a primary amputation, and saving the limb by taking both vital and failure risk due to a second resort to an amputation, remains a topical debate. The choice between these two decisions is difficult. Improving our understanding of the prognostic factors of amputation, will thus help the physician for the decision tree and give to the patient and his family precise and objective elements when informing on the risk of amputation.

Many factors have been reported in the literature [14-45] as potentially associated with a significant increase in the risk of amputation: the mechanism of the injury, the location of the arterial lesion, multiple arterial injuries, associated bone lesions, skin and/or soft parts decay, the length of the treatment, associated compartment syndrome and the surgical repair method. Some authors proposed risk scores [7,9,46]. The Mangled Extremity Severity Score (MESS), the Limb Salvage Index (LSV), the Predictive Salvage Index (PSI). Unfortunately to date, the level of relevance of our knowledge to these prognostic factors remains low and insufficient.

This low level of knowledge is also reflected in the low performance of risk scores as shown by the low sensitivity rate of the three MESS, LSI and PSI scores demonstrated in the Bosse et al study [46]. Bonanni et al [7] went so far as to name their study: “The futility of predictive scoring of mangled lower extremities”. None of these three scores have a negative predictive value of 100%. Therefore, these scores cannot in anyway replace the practitioner’s clinical assessment and experience.

The reasons given for controversies about the value of prognostic factors in the literature are first, that no distinction is made between primary and secondary amputation in some studies. Second, the data are from retrospective series with small population size. Thirdly, the disparity of series resulting from both civilian and military traumas or sometimes mixing the two populations. For all these reasons, an update of these prognostic factors is interesting to improve our practices. It is in this context that we elaborate this work.

In our study, we considered the primary, secondary and global amputation events, for which we analyzed separately the predictive factors of occurrence. The risk of late amputation could not be studied due to insufficient follow-up.

To our knowledge, there is no work in the literature focused in predicting the risk of primary amputation. In the multivariate analysis, in our series, the ISS was the only independent predictor of primary amputation (*p*=0,009; OR :1,07; IC :1,01-1,12). We could therefore suggest that, in the presence of serious vascular injury, an ISS>41 score would direct us to the indication of primary amputation. It is obviously necessary to validate this threshold value of ISS on another series with larger numbers.

Concernig the risk of secondary amputation, in a recent meta-analysis of 45 studies, Perkins et al [16] have highlighted 6 prognostic factors of secondary amputation but with a variable level of significance: muscle and skin decay (26% vs 8% if absent; OR:5.8), compartment syndrome (28% vs 6% if absent; OR:5.11), multiple arterial lesions (18% vs9% if absent; OR:4.85), management delay greater than 6 hours (24% vs 5% if absent; OR:4.4) and the blunt trauma (19% vs 5% if penetrating trauma; OR:1.88). Thus, in case of muscle and skin decay or compartment syndrome, the risk of secondary amputation is 5 times more important. The importance of tissue decay is a marker of trauma severity, since it is the direct consequence of energy transfer during the lesion. In our series, among all these factors, only popliteal injury and skin decay were significant in univariate analysis. The presence or absence of compartment syndrome and time of management could not be investigated due to lack of data.

The risk of global amputation includes primary and secondary amputations. Only three series in the literature in our knowledge, analyzed prognostic factors for global amputation [15, 35, 47]. Hafez et al [12] identified 3 predictive factors: the combined lesion above and below the knee (*p*=0,01; OR :4.4; IC :1.4-14), multiple bone fractures (*p*=0.003; OR :2.7; IC :1.6-5.2) and compartment syndrome (*p*<0.001; OR :4.1; IC :2.2-7.8). In addition to these factors, Topal et al [37] identified the skin decay (*p*=0.01; OR :1.74; IC :1.15-2.62) as an additional factor associated with the risk of amputation. In one of the largest civilian trauma series analyzing a national database of 651 patients, Kauvar et al [47] identified multiple arterial lesions (*p*=0.003; OR :5.2; IC :1.7-15.6) and associated bone fractures (*p*=0.02; OR :2.2; IC :1.1-42) as prognostic factors of amputation. In our series bones damages and skin decay have also been significantly associated with the risk of amputation in the univariate analysis. But in the multivariate analysis only the ISS was independently associated with this risk. The ISS is indeed a marker of trauma severity that is directly correlated with morbidity and mortality after the injury. The non-significancy of other factors, such as muscular and cutaneous decay, associated bones damages and multiple arterial lesions can be explained by the inter-correlation between these factors and the ISS. Against all expectations, the associated venous lesions do not appear as a significant prognostic factor for neither primary amputation, nor overall amputation nor even secondary amputation. This corroborates the results of the meta-analysis of Pekins et al [16] for secondary amputations, and those of Kauvar et al [47], Hafez et al [12] and Topal et al [35] for overall amputations. Venous repair remains controversial. Some authors [48,49] have shown a correlation between arterial lesions associated with venous lesions; they recommend the repair of proximal venous lesions. Other authors [50] found no correlation between simple ligature and limb rescue. Moreover, venous ligature is one of the means recommended for the damage control. Among the patient-related factors studied in our series, neither age nor hemodynamic status is significant. This is consistent with literature data, including the meta-analysis of Perkins et al [16]. Thus, the advanced age of the patients and the hemodynamic shock at admission, should not be factors on which must be based the decision to carry out or not the act of amputation. This is an important element that will allow us to change our practice and decision tree for primary amputations.

5.1. Study Limitations

- The retrospective nature of our work creates the usual biases of this type of study, particularly in terms of collecting missing data. As such, a certain number of data (time to management, lodge syndrome) could not be analyzed.
- The study population is small
- The Lack of medium-term follow-up to assess late amputation rates.

6. Conclusion

This study provides some insight into the management of peripheral vascular injuries. The first reflection is about our low mortality rate which contrasts with a high primary amputation rate. This allows us to comfort the choice, which is certainly difficult, to carry out a saving amputation gesture rather than a too enthusiastic revascularization that leads to the death of the patient or to the preservation of an inoperative limb. It remains to define the prognostic factors that help to indicate a first line amputation, and this is the main object of this work. The link between the high ISS and the risk of mortality and morbidity, is well demonstrated in the literature. Our study reveals for the first time the close relation between ISS and risk of amputation. Thus, an ISS >41 predicts the risk of primary amputation with a negative predictive value close to 100%. This is our second point of reflection that helps the surgeon in the presence of a serious polytrauma, to consider the possibility of carrying out an amputation using this objective criterion. Finally, the last thought is about the lack of link between the risk of amputation and the age in the one hand, and the hemodynamic state on the other hand. This leads us to eliminate the advanced age and the hemodynamic instability at the admission of the list of factors on which is based the decision to perform a primary amputation.

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