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Title: Operative treatment and clinical outcomes in peripheral vascular trauma. The combined experience of two centres in the endovascular era.

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Abstract: Background. Arterial traumas of the extremities are quite rare in civilian records; nevertheless, patients with trauma of limbs are admitted daily in emergency departments worldwide. The up-to-date information about epidemiology and treatment (open vs endovascular surgery) comes from war records and it is not always easy getting data on mortality and morbidity in these patients. The aim of this study is to analyse the approach (open or endovascular) and the outcome of patients with vascular trauma of upper limbs (from the subclavian artery) and/or lower limbs (distal to the inguinal ligament), in the greater Milan area. **Patients and methods.** A retrospective analysis was conducted on data recorded by the emergency departments of two hospitals of the greater Milan between 2009-2017. We collected all patients with arterial injuries of the limbs in terms of demography, injury patterns, clinical status at admission, therapy (open or endovascular approach) and outcomes in terms of limb salvage and survival.

Results. We studied 52 patients with vascular trauma of extremities. The main mechanism of trauma was road accident (48.1%), followed by criminal acts (32.7%), self-endangering behaviour (13.5%), work (3.8%) and sport accidents (1.9%). Associated lesions (orthopaedic, neurological and/or venous lesions of the limbs) were present in 39 patients (75%). All patients underwent emergency surgery, forty six patients (88,5%) by open repair (PTFE or greater saphenous vein bypass grafts, arterial suture or ligation) while endovascular approach was used only in 6 patients (11.5%), all treated with embolization. The overall post-operative mortality rate was 5.7% (3 patients). Among survivors, we report 5 major amputations of the lower limbs, 3 of them after bypass graft infection and 2 after graft failure. The rate of limbs salvage was 90.4%.

Conclusions Isolated arterial trauma of the extremities are rare, usually they occur in the setting of multiple trauma patients. Despite progresses in surgical techniques, there are still controversies in diagnosis and treatment of these patients. We treated the majority of cases with open surgery (n=46), choosing endovascular approach (embolization performed mainly by interventional radiologists) in difficult anatomic districts. We believe that, during decision making of the surgical strategy, it is important to consider the anatomical site of lesions and the general

condition of the patients. Moreover, in case of multiple trauma, we suggest a multidisciplinary approach in order to provide the best medical care to the victims.

Suggested Reviewers:

To T.M. Sullivan,
Editor-in-Chief

Annals of Vascular Surgery

Dear Editor

Please find enclosed the manuscript “Operative treatment and clinical outcomes in peripheral vascular trauma. The combined experience of two centres in the endovascular era.” which we have revised, according to Reviewer’s suggestions, and we would like to submit for publication in Annals of Vascular Surgery.

Our aim was to analyze retrospectively the treatment and the outcomes of vascular traumas of the extremities in the greater Milan area, between 2009-2017. We performed an analysis of data collected by two Milanese Institutes: ASST Ospedale Metropolitano Niguarda Ca’ Granda and IRCCS Fondazione Ca’ Granda Policlinico, the first of which with high flux trauma center.

Vascular injuries of upper and lower limbs are rare in civilian records, but despite their low epidemiologic impact, they could be life threatening lesions. We well know that the treatment of these lesions still remains a controversial filed. In the last years endovascular treatment is emerging and surely represents a valid approach, but we shouldn’t forgot that often the majority of patients are multiple-injured and needed of emergency treatment for associated lesions. In this setting, the mini-invasive endovascular approach often remains confined to penetrating injuries in the treatment of areas with a difficult anatomic access or in injuries that can be treated not in an emergency setting.

All authors have read and approved the submitted manuscript and it has never been submitted nor published elsewhere in whole or in part. They do not have any conflict of interest in drugs, materials, or devices or financial disclosures and the study here presented does not violate any ethical principle.

We hope therefore you will consider our contribute for publication.

Sincerely yours

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REVIEW OF THE PAPER

Ref. No.: AVS-D-19-00349

Title: A two centers experience for extremity vascular trauma treatment: which is the real role of the endovascular repair?

Dear Editor,

The reviewers have recommended some revisions to our manuscript and we present our answer to their valuable questions.

Reviewer 1

English must be thoroughly revised because of many incorrect sentences and rough expressions

We have revised the entire manuscript, correcting typo and syntax errors.

Title: The title must definitely be modified because it doesn't reflect the content of the manuscript. One could expect that the main topic of the study is the role of endovascular therapy in the management of arterial trauma while the paper is much more descriptive and reporting global presentation and management of vascular trauma

We perfectly agree with Reviewer's observation and consequently we have changed the title trying to accord to the real object of this paper. The new title is: "Operative treatment and clinical outcomes in peripheral vascular trauma. The combined experience of two centres in the endovascular era"

Line 39-42 Abstract - Background: At the end of this subsection, the study objective must be stated

Done

Line 44 Abstract - Patients and Methods: "n=52" is a Result.

We agree. We have corrected this mistake

Line 46 Abstract - Patients and Methods: All the cited criteria are global items but no specific evaluation or judgement criterion is dedicated to endovascular treatment, as it would be expected when reading the title. Is this epidemiologic observational or comparative regarding two ways of managing trauma?

We agree with Reviewer's observation. The paper has an epidemiological-observational print. Our centers don't have preliminary criteria to assign patients to open surgery or embolization procedure. The decision making, in an emergency setting, is usually done considering the site of lesion and the general status of the patients.

Line 52-53 Abstract - Results: "largely" limited to embolization. This doesn't have a precise meaning.

According to Reviewer's observation we have rephrase that.

Abstract - Conclusion: The conclusion doesn't match the objective and methods. "Covered stents" for example were never mentioned earlier,...etc

We agree and we thank for this observation. According to Reviewer's comment we have rewritten the conclusion in order to be consistent with the object of the paper

Line 82 Introduction: PTFE: The acronym must be explained when it is used for the first time

Done

Line 85-87 Introduction: The objective is not focusing on the role of endovascular techniques...

Thanks to reviewer's observations we have chosen to redraft some issues of this paper. It's more correct to state that our aim was given an epidemiological-observational view of our experience and not comparative study regarding two ways of managing trauma. Analyzing our experience we chosen to deepen the surgical approach that was used to treat our patient, including a focus on open and endovascular techniques

Line 91 Materials and methods: "52 patients" is a result. The number of included patients must be stated in the Results section.

Done

Line 95-96 Materials and methods: "Autochtonous or newly arrived immigrants". Is this truly relevant? Only if the aim of the paper is to describe social context of vascular trauma... Otherwise this criterion must be removed. Specially that the corresponding result is not cited further..

We agree and we apologize for this typo. It was included in the first draft of this paper with the aim of describing a social context, but we have decided to not include this analysis in the final version.

Line 118 Materials and methods: "Tab 1" is a Result and must be cited in the Results section.

Done

Line 107-109 Materials and methods: In my opinion the description of the statistical analysis is dispensable because the analyzed and compared outcomes are very few: Only one value is analyzed in all the manuscript, which is the association of lesions. It is not worth describing and performing the student test.

We agree. We have corrected according to reviewer's suggestion.

Line 122 Results: Succession of many numbers and percentages makes the paragraph difficult to read. It is better to incorporate to Figure 1.

Done. We have re-elaborate the graphic in figure 1 and we have incorporated the data both in the figure and in the caption

Line 160-164 Results: Describe the initial lesions that lead to amputation or death.

Done

Line 234-237 Discussion: risk factors for amputation. Please do the same analysis of your personal data. Discuss those, in the light of similar literature

Done

The conclusion is fine, but not is not keeping with the majority of the manuscript.

According to the Reviewer's suggestions we re-discussed the manuscript's conclusions, trying to be more adherent to the aim of the paper.

Reviewer 2

Line 150-153 I think it' s necessary to explain the reason of the most frequent option for the arterial reconstruction of the lower limb is a graft

Thank you for your interesting observation. We have performed more frequently graft reconstruction because we didn't have much healthy arterial tissue, for direct suture We know that termino-terminal suture is ideal in complete traumatic transections, but in many cases this approach was impossible. We also know that bypass, using an inverted saphenous vein is the best revascularization technique in case of extensive arterial injury but, unfortunately, the ipsilateral vein was often not available due to associated venous injury and the harvest of the contralateral would have lengthened the operating time in patients with critical impairment.

Editor

Please present your references according to Vancouver rules

Done. We have followed the instructions for authors oh your homepage

Anyway, we would thank the Referees for having appreciated our work and for their remarkable suggestions and comments, which have been taken into account to improve the original paper.

We hope that the present form the paper may be considered for publication.

With our best regards,

Ilenia D'Alessio, on the behalf of all the authors.

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1 **Operative treatment and clinical outcomes in peripheral vascular trauma. The**
2 **combined experience of two centres in the endovascular era.**

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26 **Disclosure** The authors have no personal, financial, or institutional interest in any of the drugs,
27 materials, or devices described in this article.

28

29 **KEYWORDS** vascular trauma, extremities, open surgery, endovascular surgery

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31 **Words count 3547**

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35 **ABSTRACT**

36 **Background.** Arterial traumas of the extremities are quite rare in civilian records; nevertheless,
37 patients with trauma of limbs are admitted daily in emergency departments worldwide. The up-to-
38 date information about epidemiology and treatment (open vs endovascular surgery) comes from war
39 records and it is not always easy getting data on mortality and morbidity in these patients. The aim
40 of this study is to analyse the approach (open or endovascular) and the outcome of patients with
41 vascular trauma of upper limbs (from the subclavian artery) and/or lower limbs (distal to the
42 inguinal ligament), in the greater Milan area.

43 **Patients and methods.** A retrospective analysis was conducted on data recorded by the emergency
44 departments of two hospitals of the greater Milan between 2009-2017. We collected all patients
45 with arterial injuries of the limbs in terms of demography, injury patterns, clinical status at
46 admission, therapy (open or endovascular approach) and outcomes in terms of limb salvage and
47 survival.

48 **Results.** We studied 52 patients with vascular trauma of extremities. The main mechanism of
49 trauma was road accident (48.1%), followed by criminal acts (32.7%), self-endangering behaviour
50 (13.5%), work (3.8%) and sport accidents (1.9%). Associated lesions (orthopaedic, neurological
51 and/or venous lesions of the limbs) were present in 39 patients (75%). All patients underwent
52 emergency surgery, forty six patients (88,5%) by open repair (PTFE or greater saphenous vein
53 bypass grafts, arterial suture or ligation) while endovascular approach was used only in 6 patients
54 (11.5%), all treated with embolization. The overall post-operative mortality rate was 5.7% (3
55 patients). Among survivors, we report 5 major amputations of the lower limbs, 3 of them after
56 bypass graft infection and 2 after graft failure. The rate of limbs salvage was 90.4%.

57 **Conclusions** Isolated arterial trauma of the extremities are rare, usually they occur in the setting of
58 multiple trauma patients. Despite progresses in surgical techniques, there are still controversies in
59 diagnosis and treatment of these patients. We treated the majority of cases with open surgery (n=46),
60 choosing endovascular approach (embolization performed mainly by interventional radiologists) in
61 difficult anatomic districts. We believe that, during decision making of the surgical strategy, it is
62 important to consider the anatomical site of lesions and the general condition of the patients.
63 Moreover, in case of multiple trauma, we suggest a multidisciplinary approach in order to provide
64 the best medical care to the victims.

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70 **Manuscript**

71

72 **INTRODUCTION**

73

74 Arterial traumas of the upper and lower extremities represent 3% [1] of all civilian trauma and
75 include both blunt and penetrating injuries. The former usually are caused by car or motorcycle
76 accidents and are the most frequent in civilian records, the latter mainly being related to criminal
77 acts. While the majority of isolated injuries from penetrating trauma are successfully treated, blunt
78 trauma lesions have poorer outcomes particularly in polytraumatized patients [2].

79 Despite the benefits achieved with the introduction of computed tomographic angiography (CTA) in
80 the diagnostic process [3] the choice of the best treatment option, still remains unclear. Since the
81 beginning of vascular surgery, open surgery has been the only option in treating arterial trauma for
82 many decades. Several approaches, from direct suture of the injured vessel to bypass grafting using
83 inverted saphenous vein, polytetrafluoroethylene (PTFE) or Dacron, have been performed.
84 Nevertheless, more data are needed to properly select the optimal management for patients with
85 arterial trauma of the extremities [4].

86 The aim of this retrospective study is to analyse the management and outcome of peripheral arterial
87 trauma, merging the experience of two Institutions of the metropolitan area of Milan, with particular
88 focus on the role of techniques (open or endovascular) used in our experience.

89

90 **MATERIALS AND METHODS**

91

92 The present study enrolled all patients with arterial traumas of the upper and lower extremities
93 admitted between January 1st, 2009 and December 31st, 2017 to level 1 trauma center ASST
94 Ospedale Metropolitano Niguarda and to IRCCS Fondazione Cà Granda Policlinico, both located in
95 Milan.

96 We have retrospectively collected data taken from emergency departments database of the two
97 Institutions, reporting age, gender, trauma's mechanism and nature (criminal, self-inflicted, road,
98 sport and work accidents), Glasgow Coma (GCS(S)), heart rate (HR(S)) and systolic blood pressure
99 (SBP(S)) on the scene(S). Moreover, Emergency Department (ED) evaluation of Glasgow Coma
100 scale (GCS(ED)), heart rate (HR(ED)) and systolic blood pressure (SBP(ED)) were analysed.
101 Lactates, the need of emergency surgery, the presence of injuries in other anatomic districts (head,
102 chest and abdomen), the association with orthopaedic, neurological and venous lesions of limbs, the

103 Injury Severity Score (ISS), the total length of stay and outcomes were also evaluated. We limited
104 our analysis only to the extremities, from subclavian artery for the upper limbs and from the
105 inguinal ligament for the lower limbs. We excluded from our analysis vascular trauma of the neck,
106 chest and abdomen, iatrogenic lesions, complete sections of limbs and chronic lesions, such as
107 pseudo-aneurysm in drug-addicted patients. The ISS threshold to define major trauma was 15.
108 Statistical analysis was performed using JMP 11.2.0 (SAS Institute Cary, NC). Data were presented
109 in a descriptive form. Ordinal and nominal variables were reported as patients' percentage.
110 Continuous variables were reported as average \pm standard deviation

111

112 **RESULTS**

113

114 During the study period, 52 patients with vascular injuries of limbs, 45 males (86.6%) and 7
115 females (13.4%) with mean age 37 ± 18 years, were analysed. In addition, parameters reported in
116 Tab. 1, have been taken into account.

117 Five types of causes of injuries were found: road (25 patients, 48%), criminal (17 patients, 32,7%),
118 inflicted self-endangering behavior (7 patients, 13,4%), work (2 patients, 3,8%) and sport (1 patient,
119 1,9%) accidents.

120 We also examined traumas depending on the anatomical site. We had 29 patients (55.8%) with
121 lesions distal to common femoral artery, 20 patients (38.5%) with lesions below subclavian artery
122 and 3 patients (5.7%) with involvement of both anatomic districts. The relationship between
123 mechanism of injury and type of lesions (blunt or penetrating) are showed in Fig. 1. Penetrating
124 trauma occurred more frequently in upper extremities (55.0%), while blunt trauma resulted more
125 common in lower extremities lesions (55.0%).

126 Since the majority of patients had multiple traumas, we evaluated several clinical parameters as
127 reported in Tab. 1 with the purpose of giving a complete clinical grading. The majority of patients
128 needed emergency surgery for vascular lesions (86.5%), while the remains underwent other surgical
129 procedures according to damage control strategy.

130 Many patients reported concomitant lesions in other anatomic districts: 2 patients (3.8%) suffered
131 head injuries, in 14 (26.9%) chest was involved, while 12 (23.0%) presented abdominal injuries.
132 We also have analysed the presence of orthopaedic, neurological and venous lesions of limbs (Tab.
133 2). Orthopaedic lesions were the most frequent injuries associated with the vascular ones both for
134 upper and lower extremities (12 and 17 patients respectively, 59.2% of the study population), while
135 venous lesions occurred more frequently in lower extremities traumas compared to upper limbs (6

136 vs 2 patients). Six patients (12.2%) were affected by two types of lesion in the same limb, while 5
137 (10.2%) experienced venous, neurological and orthopaedic lesions in the same limb.

138 Regarding the type of artery involved, we reported 3 (10.3%) lesions of the common femoral artery,
139 9 (31.0%) of the superficial femoral artery, 4 (13.7%) of the profunda femoris artery, 6 of popliteal
140 artery, 3 (10.3%) of anterior tibial artery, 2 (6.8%) of posterior tibial artery, 1(3.4%) of peroneal
141 artery and 1 (3.4%) with concomitant involvement of the common femoral artery and anterior tibial
142 artery.

143 In upper limb traumas, 3 (15%) cases involved the axillary artery, 9 (45%) the brachial artery, 5
144 (25%) the radial artery, 1 (5%) the ulnar artery and 2 (10%) both ulnar and radial arteries.

145 Three patients reported lesions of the common femoral artery associated to lesion of axillary,
146 brachial and radial arteries. (Tab 3).

147 All patient underwent diagnostic CTA before treatment, and among them 8 (15.3%) had
148 angiography. The majority of patients underwent open surgery (n=46/52, 88.5%), while
149 endovascular approach has been performed only in 6 patients (11.5%).

150 In the group with lower limbs lesions we performed: 12 bypass grafts (41.3%), 8 arterial sutures
151 (27.5%), 4 arterial ligations (13.7%), 3 coil embolization (10.3%), 1 arterial thrombectomy (3.4%)
152 and 1 thigh amputation (3.4%). We performed more frequently graft reconstruction since direct
153 suture was not possible due to unhealthy arterial tissue. PTFE bypass was the most used technique
154 since the ipsilateral saphenous was often injured and the harvest of the contralateral saphenous vein
155 would have required more operating time in patients in critical conditions. In the group with lesions
156 of upper limbs we carried out 10 direct suture (50.0%), 4 bypass grafts (20.0%), 2 coil embolization
157 (10.0%), 1 arterial ligation (5.0%), 1 amputation (5.0%), 1 arterial thrombectomy (5.0%). One
158 patient (5.0%) died before reaching operating room because of associated lesions. In the group of
159 patients with injuries in both (upper and lower) limbs, multiple direct sutures have been performed,
160 associated in 1 patient to embolization procedure (Tab. 4).

161 The total length of stay in the hospital was 34 ± 31 days because the majority of patients suffered
162 multiple traumas. The overall post-operative mortality rate was 5.7% (3 patients). Two patients died
163 because of Multiple Organ Failure, 1 died because of cerebral haemorrhage in the first week after
164 limb revascularization. Among survivors, we reported 5 major amputations of the lower limbs, 1 in
165 the operating room, 2 after bypass infections and 2 after graft failure, 7 days and 32 days
166 respectively after the first attempt of limb salvage.

167

168 **DISCUSSION**

169

170 Arterial traumas of the peripheral arteries of the extremities are a rare observation in patients
171 admitted to the emergency department. Among civilians, ER evaluations are prevalently related to
172 road accidents, criminal attacks and, less frequently, to self-harming behaviours, work and or sport
173 traumatisms. [2,5]

174 As stated above, most patients with blunt trauma were poly-traumatized. In these cases, patients'
175 life is the first priority, followed by limb salvage. The outcome in these patients is strictly
176 influenced by co-morbidities and associated lesions. Multiple trauma patients are expected to
177 present a higher risk of mortality than those with single injuries, being the overall mortality of
178 multiple lesions significantly higher than mortality rates of single lesions. [6] Literature reports an
179 association with bony injury in 35.1% of cases, nerve injury in 7.6%, and injuries affecting the
180 head, chest, or abdomen in 3.6%. [7]

181 Regarding vascular injuries of limbs, it is important to differentiate minor arterial trauma, due to
182 low speed agents, from major arterial trauma. In the first case, neither active bleeding is detected at
183 CTA scan nor ischemia at physical examination. Therapeutic chooses usually consists in monitoring
184 the patient during follow up, by means of physical examination and ultrasound scan. In case of
185 major arterial trauma, with active bleeding and/or ischemia, the patient needs to be treated in the
186 emergency room with basic and advanced life support.

187 Diagnostic imaging provides a valid support in identifying vascular injuries. Nowadays, delays in
188 diagnosis and treatment are usually uncommon in patients with multiple injuries, due to the
189 introduction of total-body CT scan, which allows a complete screening of severely injured patients
190 with blunt multiple-trauma, determining whether surgical or angiographic intervention is needed.
191 [7-8]

192 After diagnosis, a critical aspect in managing vascular injuries of limbs is constituted by treatment
193 decision-making process.

194 Data regarding the management of complex extremity trauma lesions are conflicting and
195 randomized controlled studies are not reported. The absence of Level 1 and 2 evidence studies is
196 not surprising because of the complexity of the topic. In fact, there are frequently concomitant
197 injuries, multiple traumas and heterogeneity of treatment. Moreover, the relative rarity of such
198 lesions contributes to complicate the analysis and to reach a consensus on their treatment.

199 For decades the classic approach to vascular lesions of extremities has been open surgery, though
200 the growing interest in endovascular treatment has developed in the last years. [9-10]

201 Piffaretti et al [11], reported treatment of lesions amenable to endovascular repair in 10 cases over
202 81 (12.0%) of arterial trauma lesions, represented mainly by pseudoaneurysms, dissections and

203 arterio-venous fistulas with only one case of expanding hematoma. Immediate success was obtained
204 in all procedures.

205 Desai et al [12], in a 8 years retrospective analysis, reported 28 endovascular repair in 21 (75.0%)
206 penetrating injuries and 7 (25.0%) blunt trauma including pseudoaneurysm, extravasations,
207 occlusions and arteriovenous fistulas, without any further distinction about localization. Patients
208 were selected for endovascular treatment in case of no pulsatile bleeding from the wound and a
209 suitable access site with a lesion amenable to stent graft repair at preoperative imaging. They
210 reported a 100% of immediate technical success with the use of covered stent, a mean length of stay
211 of 18 ± 22.9 days. The overall limb salvage rate was 92% at 45 days and 79% at 93 days.

212 Ganapathy et al [4] collected 68 patients with 70 total arterial injuries. Endovascular approach was
213 performed in 20 patients. Compared to open repair (n=50), endovascular less commonly required
214 fasciotomy (15% vs. 46%, p=0.03) and transfusion (50% vs. 77%, p=0.06). Analysed outcomes
215 between groups were trending higher in the endovascular group with respect to limb salvage rates at
216 discharge (94% vs. 89%), median length of stay (14days vs. 9), and median follow-up (288days vs.
217 92) compared to the open group, but the data were not statistically significant. There was increasing
218 utilization of endovascular repair over time (7% of total procedures in 2009; 50% in 2014).

219 Tresson et al [13] reported endovascular treatment limited to the embolization of pelvic arteries in a
220 series of 20 patients injured after Paris Terrorist Attack in 2015. They did not report the use of
221 covered stents because of the devastating wounds associated, requiring always a surgical
222 exploration.

223 In our cohort, endovascular treatment has been limited to 6 patients (11.5%). Nearly 80% of our
224 patients were either hemodynamically unstable or had multiple vessels injured on arrival to the ER.
225 These conditions have made endovascular repair less suitable, limiting its use only in case of
226 pseudoaneurysms [14] and/or arteriovenous fistulas, though rather uncommon in civilian trauma
227 patients.

228 Despite all efforts, the prognosis of patients with arterial trauma is influenced by several factors,
229 first and foremost by the degree of general impairment evaluated using ISS; second by the kind of
230 trauma. Blunt trauma has a poorest prognosis compared to penetrating injuries that have an
231 amputation rate three times greater. [15]. In our cohort, we have reported 6 cases of amputation, 5
232 among survivors and 1 in a deceased patient, with, in most cases, lesions of the popliteal artery.
233 Furthermore, independent risk factors for amputation, including occluded graft, combined above-
234 and below-knee injury, compartmental syndrome, arterial transection, lack of intra or immediately
235 postoperative anticoagulation and associated compound fracture, play a fundamental role in the
236 clinical course[5,16].

237 In our study, as reported previously (see: Results section), we had 5 major amputations of the lower
238 limbs: 1 in the OR (operating room) for a devastating lesion above the popliteal artery, 2 after graft
239 infections with septic embolism and 2 after bypass failure for the lack of postoperative
240 anticoagulation because of concomitant brain bleeding.

241

242 **CONCLUSIONS**

243

244 In our experience, surgical treatment of peripheral vascular injuries is always a challenging issue,
245 especially in complicated multiple trauma patients.

246 Although we are all aware of the revolutionary impact of the endovascular approach in many fields,
247 open surgery still has a role in the management of vascular trauma of the extremities mainly in
248 patients with severe concomitant lesions.

249 In these cases, the high frequency of devastating injuries and the frequent need for orthopaedic
250 and/or neurological repair, make endovascular surgery scarcely suitable.

251 On the contrary, endovascular surgery may result fundamental for the treatment of penetrating
252 injuries in areas of difficult anatomic access, such as the abdominal and pelvic area, the shoulder
253 and the neck or, in case of more peripheral lesions whose treatment can be postponed [11,17].

254 To avoid any misleading generalization on the issue of arterial trauma repair, we strongly believe
255 that, for each patient, it is necessary to consider the anatomical locations of the vascular injury and
256 the degree of general impairment. Moreover, a multidisciplinary approach is essential in treating
257 these complex patients. Cooperation among different surgical specialists (vascular, orthopaedic,
258 thoracic and neurosurgeons) and interventional radiologists is the key to obtain the best clinical
259 results.

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Table's legend

Tab. 1. Parameters on the scene and at the arrival in the Emergency Department. SBPs= systolic blood pressure on the scene of trauma. HRs=heart rate on the scene of trauma. GCSs=Glasgow coma scale on the scene of trauma. SPBed= systolic blood pressure at the arrival at emergency department. HRed= heart rate at the arrival at emergency department. GCSs= Glasgow Coma Scale at the arrival at emergency department. Lactates=lactates at the arrival at emergency department. ISS=Injury Severity Score.

Tab. 2. Associated lesions related to localization of vascular injury at lower, upper or both limbs
N = number of patients.

Tab. 3. Detailed analysis of the arteries injured related to localization at lower, upper or both limbs.
N = number of patient.

Tab. 4. Kind of treatment related to localization of vascular injury (lower, upper or both limbs) N =
number of patient.

Figure's legend

Figure 1 Relationship between mechanism of injuries and localization at upper, lower or both limbs:
W = work accidents, C = criminal acts, R = road accidents, A = self-inflicted acts, S = sport accidents. Among patients with lesions in the lower limbs we reported 16 R (55.2%), 7 C (24.1%) 4 A (13.8%), 1 W (3.4%) and 1 S (3.4%). Among patients with lesions distal to the subclavian artery we reported 7 R (35.0%), 9 C (45.0%), 3 A (15.0%) and 1 W (5.0%). In the group of patients with involvement of both locations (upper and lower limbs) we reported 2 R and 1 C.

1 **Operative treatment and clinical outcomes in peripheral vascular trauma. The**
2 **combined experience of two centres in the endovascular era.**
3 **~~A two-centers experience for extremity vascular trauma treatment: which is the~~**
4 **~~real role of the endovascular repair?~~**

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6
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29 materials, or devices described in this article.

30
31 **KEYWORDS** vascular trauma, extremities, open surgery, endovascular surgery

32
33 **Words count 3573**

34 **ABSTRACT**

35 **Background.** Arterial traumas of the extremities are quite rare in civilian records, nevertheless
36 patients with trauma of limbs are admitted daily in emergency departments worldwide. The up-to-
37 date information about epidemiology and treatment (open vs endovascular surgery) comes from war
38 records and it is not always easy getting data on mortality and morbidity in these patients. The aim
39 of this study is to analyse approach (open or endovascular) and the outcome of patients with
40 vascular trauma of upper limbs (from the subclavian artery) and/or lower limbs (distal to the
41 inguinal ligament), in the greater Milan area.

42 **Patients and methods.** A retrospective analysis was conducted on data recorded by the emergency
43 departments of two hospitals of the greater Milan between 2009-2017. We studied all patients (~~n=~~
44 ~~52~~) with arterial injuries of the limbs in terms of demography, injury patterns, clinical status at
45 admission, therapy (open or endovascular approach) and outcomes in terms of limb salvage and
46 survival.

47 **Results.** We studied 52 patients with vascular trauma of extremities. The main ~~principal~~ mechanism
48 of trauma was road accident (48.1%), followed by criminal acts (32.7%), self-inflicted lesions
49 ~~endangering behavior related traumas~~ (13.5%), work (3.8%) and sport accidents (1.9%). Associated
50 lesions (orthopedic, neurological and/or ~~superficial~~ venous lesions of the limbs) were present in 39
51 patients (75%). All patients ~~were operated-~~ underwent emergency surgery, forty six patients
52 (88,5%) by open repair (PTFE or greater saphenous vein bypass grafts, arterial suture or ligation)
53 while endovascular approach was used only in 6 patients (11.5%), all treated-with embolization.
54 procedure and was largely limited to embolization.

55 The overall post-operative mortality rate was 5.7% (3 patients). Among survivors, we report 5
56 major amputations of the lower limbs, 3 of them after bypass graft infection and 2 after graft failure.
57 ~~The overall mortality rate was 5.8%.~~ The rate of limbs salvage was 90.4%.

58 **Conclusions** Isolated arterial trauma of the extremities are rare, usually they occur in the setting of
59 multiple trauma patients. Despite progresses in surgical techniques, there are still controversies in
60 diagnosis and treatment of these patients. We treated the majority of cases with open surgery (n=46),
61 choosing to resort to endovascular ~~treatment~~ approach (embolization performed mainly by
62 interventional radiologists) ~~in all cases of single vascular lesions; this approach is useful~~ in difficult
63 anatomic districts. ~~Covered stents are mostly not suitable to treat polytraumatized patients with~~
64 ~~associated wounds requiring a surgical exploration.~~ We believe that, during decision making of the
65 surgical strategy, it is important to consider the anatomical site of lesions and the general condition
66 of the patients. Moreover, in case of multiple trauma, we suggest a multidisciplinary approach in
67 order to provide the best medical care to the victims.

68 **Manuscript**

69

70 **INTRODUCTION**

71

72 Arterial traumas of the upper and lower extremities represent 3% [1] of all civilian trauma and
73 include either blunt and penetrating injuries. The former usually are caused by car or motorcycle
74 accidents and are the most frequent in civilian records, ~~being~~ the latter ~~mainly being~~ related to
75 criminal acts. While the majority of isolated injuries from penetrating trauma are successfully
76 treated, blunt trauma lesions have poorer outcomes particularly in polytraumatized patients.[2]¹

77 Despite the benefits achieved with the introduction of computed tomographic angiography (CTA) in
78 the diagnostic process[3] ²the choice of the best treatment option, still remains unclear. Since the
79 beginning of vascular surgery, open surgery ~~has been the only option in treating arterial trauma~~
80 ~~preferred therapeutic option for the treatment of arterial trauma~~ for many decades. Several
81 approaches, from direct suture of the injured vessel to bypass grafting using inverted saphenous
82 vein, ~~polytetrafluoroethylene (PTFE) or Dacron~~, have been performed. Nevertheless, more data are
83 needed to properly select the optimal management for patients with arterial trauma of the
84 extremities.[4]

85 The aim of this retrospective ~~study analysis~~ is to ~~evaluate analyse~~ the management and outcome of
86 peripheral arterial trauma incidence and the short term results of the surgical interventions
87 performed for arterial traumas of the extremities, merging the experience of two Institutions of the
88 metropolitan area of Milan, with particular focus on the role of techniques (open or endovascular)
89 used in our experience.

90

91 **MATERIALS AND METHODS**

92

93 The present study enrolled ~~all~~ ~~52~~ patients with arterial traumas of the upper and lower extremities
94 admitted between January 1st, 2009 and December 31st, 2017 to ~~tertiary~~ level 1 trauma center
95 ASST Ospedale Metropolitano Niguarda and to IRCCS Fondazione Cà Granda Policlinico, both
96 located in Milan.

97 We have retrospectively collected data taken from emergency departments database of the two
98 Institutions, reporting age, gender, ~~autochthonous or newly arrived immigrants from European or~~
99 ~~extra European countries~~, ~~the~~ trauma's mechanism and nature (criminal, self-inflicted, road, sport
100 and work accidents), Glasgow Coma (GCS(S)), heart rate (HR(S)) and systolic blood pressure
101 (SBP(S)) on the scene(S). Moreover, Emergency Department (ED) evaluation of Glasgow Coma

102 scale (GCS(ED)), heart rate (HR(ED)) and systolic blood pressure (SBP(ED)) were analysed.
103 Lactates, the need of emergency surgery, ~~the surgery choice~~, the presence of injuries in other
104 anatomic districts (head, chest, and abdomen), the association with orthopedic, neurological and
105 venous lesions of limbs, the Injury Severity Score (ISS), the total length of stay and ~~clinical and~~
106 ~~surgical~~ outcomes were also evaluated. (Tab 1)
107 We limited our analysis only to the extremities, ~~whose threshold was the distal segment of the from~~
108 subclavian artery for the upper limbs and the inguinal ligament for the lower limbs. We excluded
109 from our analysis vascular trauma of the neck, chest and abdomen, iatrogenic lesions, complete
110 sections of limbs ~~total traumatic amputation~~ and chronic lesions, such as pseudo-aneurysm in drug-
111 addicted patients. The ISS threshold to define major trauma was 15.
112 Statistical analysis was performed using JMP 11.2.0 (SAS Institute Cary, NC). ~~Student t test was~~
113 ~~used to rate statistically significant differences between two independent means of sampled data.~~
114 Data were presented in a descriptive form. Ordinal and nominal variables were reported as patients'
115 percentage. Continuous variables were reported as average \pm standard deviation
116

117 RESULTS

118
119 During the study period, 52 patients with vascular injuries of limbs, 45 males (86.6%) and 7
120 females (13.4%) with mean age 37 ± 18 years, were analysed. In addition, parameters reported in
121 Tab. 1, have been taken into account.

122 Five types of causes of injuries were found: road (25 patients, 48%), criminal (17 patients, 32,7%),
123 inflicted self-endangering behavior (7 patients, 13,4%), work (2 patients, 3,8%) and sport (1 patient,
124 1,9%) accidents.

125 We also examined traumas depending on the anatomical site. We had 29 patients (55.8%) with
126 lesions distal to common femoral artery, 20 patients (38.5%) with lesions below subclavian artery
127 and 3 patients (5.7%) with involvement of both anatomic districts. The relationship between
128 mechanism of injury and type of lesions are showed in Fig. 1. Among patients with lesions in the
129 lower limbs we reported 16 road accidents (55.2%), 7 criminal acts (24.1%) 4 self inflicted acts
130 (13.8%), 1 work accident (3.4%) and 1 sport accident (3.4%). Among patients with lesions distal to
131 the subelavian artery we reported 7 road accidents (35.0%), 9 criminal acts (45.0%), 3 self-inflicted
132 acts (15.0%) and 1 work accident (5.0%). In the group of patients with involvement of both
133 locations (upper and lower limbs) we reported 2 road accidents and 1 criminal act. (Fig 1)

134 Penetrating trauma occurred more frequently in among upper extremities lesions (55.0%), while
135 blunt trauma resulted more common in lower extremities lesions occurred (55.0%). (Tab 2)

136 Since the majority of patients ~~had multiple traumas poly-traumatized~~, we ~~have~~ evaluated several
137 clinical parameters as reported in tab 1 with the purpose of giving a complete clinical grading. The
138 majority of patients needed emergency surgery for vascular lesions (86.5%), while the remains
139 underwent other surgical procedures according to damage control strategy.

140 Many patients reported concomitant lesions in other anatomic districts: 2 patients (3.8%) suffered
141 head injuries, in 14 (26.9%) chest was involved ~~and, among them, 6 patients reported two different~~
142 ~~kind of chest lesions~~, while 12 (23.0%) presented abdominal injuries, ~~5 of whose reported two or~~
143 ~~more abdominal lesions~~.

144 We also have analysed the presence of orthopedic, neurological and venous lesions of limbs (Tab. 2
145). Orthopedic lesions were the most frequent injuries associated with the vascular ones both for
146 upper and lower extremities (12 and 17 patients respectively, 59.2% of the study population), while
147 venous lesions occurred more frequently in lower extremities traumas compared to upper limbs (6
148 vs 2 patients). Six patients (12.2%) were affected by two types of lesion in the same limb, while 5
149 (10.2%) experienced all venous, neurological and orthopedic lesions in the same limb.

150 Regarding the type of artery involved, we reported 3 (10.3%) lesions of the common femoral artery,
151 9 (31.0%) of the superficial femoral artery, 4 (13.7%) of the profunda femoris artery, 6 of popliteal
152 artery, 3 (10.3%) of anterior tibial artery, 2 (6.8%) of posterior tibial artery, 1(3.4%) of peroneal
153 artery and 1 (3.4%) with concomitant involvement of the common femoral artery and anterior tibial
154 artery.

155 In upper limb traumas, 3 (15%) cases involved the axillary artery, 9 (45%) the brachial artery, 5
156 (25%) the radial artery, 1 (5%) the ulnar artery and 2 (10%) both ulnar and radial arteries.

157 Three patients reported lesions of the common femoral artery associated to lesion of axillary,
158 brachial and radial arteries. (Tab 3).

159 All patient underwent diagnostic CTA before treatment, and among them 8 (15.3%) had
160 angiography. The majority of patients underwent open surgery (n=46/52, 88.5%), while
161 endovascular approach has been performed only in 6 patients (11.5%).

162 In the group with lower limbs lesions we performed: 12 bypass grafts (41.3%), 8 arterial sutures
163 ~~raffias~~ (27.5%), 4 arterial ligations (13.7%), 3 coil embolization (10.3%), 1 arterial thrombectomy
164 (3.4%) and 1 thigh amputation (3.4%). We performed more frequently graft reconstruction because
165 direct suture was not possible due to unhealthy arterial tissue. PTFE bypass was the most used
166 technique since the ipsilateral saphenous was often injured and the harvest of the contralateral
167 saphenous vein would have required more operating time in patients in critical conditions. In the
168 group with lesions of upper limbs we carried out 10 direct suture (50.0%), 4 bypass grafts (20.0%),
169 2 coil embolization (10.0%), 1 arterial ligation (5.0%), 1 amputation (5.0%), 1 arterial

170 thrombectomy (5.0%). One patient (5.0%) died before reaching operating room because of
171 associated lesions. In the group of patients with injuries in both (upper and lower) limbs, multiple
172 direct sutures have been performed, associated in 1 patient to embolization procedure (Tab. 4).
173 The total length of stay in the hospital was 34±31 days because the majority of patients suffered
174 multiple traumas. The overall post-operative mortality rate was 5.7% (3 patients). Two patients died
175 because of Multiple Organ Failure, 1 died because of cerebral hemorrhage three days after limb
176 revascularization. Among survivors we reported 5 major amputations of the lower limbs, 1 in the
177 operating room, 2 after bypass infections and 2 after graft failure, 7 days and 32 days respectively
178 after the first attempt of limb salvage.

179

180 **DISCUSSION**

181

182 Arterial traumas of the peripheral arteries of the extremities are a rare observation in patients
183 admitted to the emergency department. Among civilians, ER evaluations are prevalently related to
184 road accidents, criminal attacks and, less frequently, to self-harming behaviors, work and or sport
185 traumatism. [2,5]

186 As stated above, most patients with blunt trauma were poly-traumatized. In these cases, patients'
187 life is the first priority, followed by limb salvage. The outcome in these patients is strictly
188 influenced by co-morbidities and associated lesions. Multiple trauma patients are expected to
189 present a higher risk of mortality than those with single injuries, being the overall mortality of
190 multiple lesions significantly higher than mortality rates of single lesions. [6] Literature reports an
191 association with bony injury in 35.1% of cases, nerve injury in 7.6%, and injuries affecting the
192 head, chest, or abdomen in 3.6%. [7]

193 Regarding vascular injuries of limbs, it is important to differentiate minor arterial trauma, due to
194 low speed agents, from major arterial trauma. In the first case, neither active bleeding is detected at
195 CTA scan nor ischemia at physical examination. Therapeutic chooses usually consists in monitoring
196 the patient during follow up, by means of physical examination and ultrasound scan. In case of
197 major arterial trauma, with active bleeding and/or ischemia, the patient needs to be treated in the
198 emergency room with basic and advanced life support.

199 Diagnostic imaging provides a valid support in identifying vascular injuries. Nowadays, delays in
200 diagnosis and treatment are usually uncommon in patients with multiple injuries, due to the
201 introduction of total-body CT scan, which allows a complete screening of severely injured patients
202 with blunt multiple-trauma, determining whether surgical or angiographic intervention is needed.
203 [7,8]

204 After diagnosis, a critical aspect in managing vascular injuries of limbs is constituted by treatment
205 decision-making process.

206 Data regarding the management of complex extremity trauma lesions are conflicting and
207 randomized controlled studies are not reported. The absence of Level 1 and 2 evidence studies is
208 not surprising because of the complexity of the topic. In fact, there are frequently concomitant
209 injuries, multiple traumas and heterogenicity of treatment. Moreover, the relative rarity of such
210 lesions contributes to complicate the analysis and to reach a consensus on their treatment.

211 For decades the classic approach to vascular lesions of extremities has been open surgery, though
212 the growing interest in endovascular treatment has developed in the last years. [9,10]

213 Piffaretti et al[11], reported treatment of lesions amenable to endovascular repair in 10 cases over
214 81 (12.0%) of arterial trauma lesions, represented mainly by pseudoaneurysms, dissections and
215 arterio-venous fistulas with only one case of expanding hematoma. Immediate success was obtained
216 in all procedures.

217 Desai et al [12], in a 8 years retrospective analysis, reported 28 endovascular repair in 21 (75.0%)
218 penetrating injuries and 7 (25.0%) blunt trauma including pseudoaneurysm, extravasations,
219 occlusions and arteriovenous fistulas, without any further distinction about localization. Patients
220 were selected for endovascular treatment in case of no pulsatile bleeding from the wound and a
221 suitable access site with a lesion amenable to stent graft repair at preoperative imaging, a suitable
222 access site, and available imaging indicated a lesion amenable to stent graft repair. They reported a
223 100% of immediate technical success with the use of covered stent, a mean length of stay of $18 \pm$
224 22.9 days. The overall limb salvage rate was 92% at 45 days and 79% at 93 days.

225 Ganapathy et al collected 68 patients with 70 total arterial injuries. Endovascular approach was
226 performed in 20 patients. Compared to open repair (n=50) endovascular less commonly required
227 fasciotomy (15% vs. 46%, $p=0.03$) and transfusion (50% vs. 77%, $p=0.06$). Analysed outcomes
228 between groups were trending higher in the endovascular group with respect to limb salvage rates at
229 discharge (94% vs. 89%), median length of stay (14days vs. 9), and median follow-up (288days vs.
230 92) compared to the open group, but the data were not statistically significant. There was increasing
231 utilization of endovascular repair over time (7% of total procedures in 2009; 50% in 2014).[4]

232 Tresson et al[13] reported endovascular treatment limited to the embolization of pelvic arteries in a
233 series of 20 patients injured after Paris Terrorist Attack in 2015. They did not report the use of
234 covered stents because of the devastating wounds associated, requiring always a surgical
235 exploration.

236 In our cohort, endovascular treatment has been limited to 6 patients (11.5%). Nearly 80% of our
237 patients were either hemodynamically unstable or had multiple vessels injured on arrival to the ER.

238 These conditions have made endovascular repair less suitable, limiting its use only in case of
239 pseudoaneurysms [14] and/or arteriovenous fistulas, though rather uncommon in civilian trauma
240 patients.

241 Despite all efforts, the prognosis of patients with arterial trauma is influenced by several factors,
242 first and foremost by the degree of general impairment evaluated using ISS; second by the kind of
243 trauma. Blunt trauma has a poorest prognosis compared to penetrating injuries that have an
244 amputation rate three times greater ~~Amputation rate is at least three times greater than penetrating~~
245 ~~injury~~. [15]. In our cohort, we have reported 6 cases of amputation, 5 among survivors and 1 in a
246 deceased patient, with, in most cases, lesions of the popliteal artery. Furthermore, independent risk
247 factors for amputation, including occluded graft, combined above- and below-knee injury,
248 compartmental syndrome, arterial transection, lack of intra or immediately postoperative
249 anticoagulation and associated compound fracture, play a fundamental role in the clinical
250 course. [5,16]

251 In our study, as reported previously (see: Results section), we had 5 major amputations of the lower
252 limbs: 1 in the OR (operating room) for a devastating lesion above the popliteal artery, 2 after graft
253 infections with septic embolism and 2 after bypass failure for the lack of postoperative
254 anticoagulation because of concomitant brain bleeding.

255

256 CONCLUSIONS

257

258 In our experience, surgical treatment of peripheral vascular injuries is always a challenging issue,
259 especially in complicated multiple trauma patients.

260 Although we are all, ~~acknowledge~~ aware of the revolutionary impact of the endovascular approach
261 in many fields, open surgery still has a role in the management of vascular trauma of the extremities
262 mainly in patients with severe concomitant lesions.

263 In these cases, the high frequency of devastating injuries and the frequent need for orthopaedic
264 and/or neurological repair, make endovascular surgery scarcely suitable.

265 On the contrary, endovascular surgery may result fundamental for the treatment of penetrating
266 injuries in areas of difficult anatomic access, such as the abdominal and pelvic area, the shoulder
267 and the neck or, in case of more peripheral lesions whose treatment can be postponed. [11,17]

268 To avoid any misleading generalization on the issue of arterial trauma repair, we strongly believe
269 that, for each patient, it is necessary to consider the anatomical locations of the vascular injury and
270 the degree of general impairment. Moreover, a multidisciplinary approach is essential in treating
271 these complex patients. Cooperation among different surgical specialists (vascular, orthopedic,

272 thoracic and neurosurgeons) and interventional radiologists is the key to obtain the best clinical
273 results.

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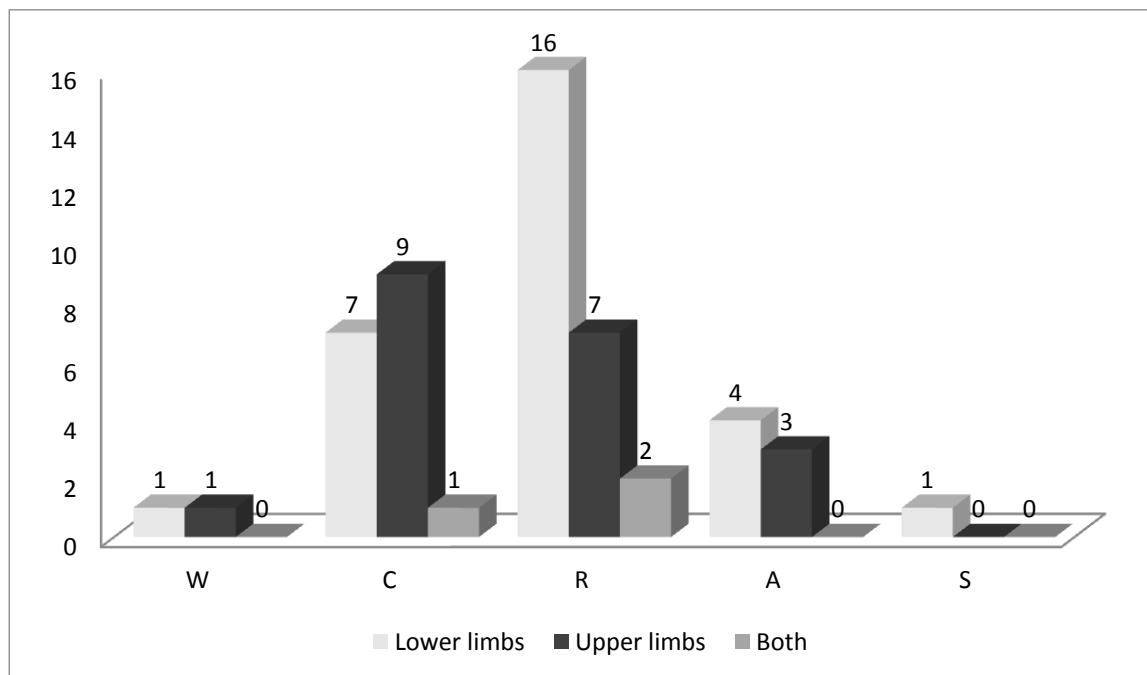
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320
321

Figure 1



Tables

Tab. 1

PARAMETERS ON THE SCENE AND AT THE ARRIVAL IN THE EMERGENCY DEPARTMENT	
SBPs	109 ± 3 mmHg
HRs	89 ± 28 bpm
GCSs	13 ± 3
SBPed	101 ± 45 mmHg
HRed	94 ± 34 bpm
GCSed	11 ± 5
Lactates	4 ± 3 mmol/l
ISS	22 ± 18
Need of emergency surgery	47 (90.3%)

Tab. 2

VASCULAR INJURY	NUMBER OF PATIENTS	ASSOCIATED LESIONS	N (%)
LOWER LIMBS	29	orthopedic lesions neurological lesions venous lesions	17 (58.6%) 6 (20.6%) 6 (20.6%)
UPPER LIMBS	20	orthopedic lesions neurological lesions venous lesions	12 (60.0%) 6 (30.0%) 2 (10.0%)
BOTH	3	orthopedic lesions neurological lesions venous lesions	2 (66.6%) 1 (33.3%) 1 (33.3%)

Tab. 3

VASCULAR INJURY	NUMBER OF PATIENTS	ARTERY INJURED	N (%)
LOWER LIMBS	29	Common femoral artery Superfial femoral artery Profunda femoris artery Popliteal artery Anterior tibial artery Posterior tibial artery Peroneal artery Common femoral artery and anterior tibial artery	3 (10.3%) 9 (31%) 4 (13.7%) 6 (30%) 3 (10.3%) 2 (6.8%) 1 (3.4%) 1 (3.4%)
UPPER LIMBS	20	Axillary artery Brachial artery Radial artery Ulnar artery Radial and Ulnar artery	3 (15.0%) 9 (45.0%) 5 (25.0%) 1 (5.0%) 2 (10.0%)
BOTH	3	Common femoral artery and brachial artery Common femoral artery and radial artery	1 (33.3%) 2 (66.6%)

Tab. 4

	NUMBER OF PATIENTS	KIND OF TREATMENT	N (%)
LOWER LIMBS	29	Bypass PTFE femoro popliteal graft Saphenous femoro popliteal graft femoro-femoral graft femoro-anterior tibial graft Direct suture Arterial Ligature Embolization Thromboembolectomy Amputation	12 (41.3%) 8 (66.6%) 2 (16.6%) 1 (8.3%) 1 (8.3%) 8 (27.5%) 4 (13.7%) 3 (10.3%) 1 (3.4%) 1 (3.4%)
UPPER LIMBS	20	Direct suture Bypass omero-radial omero-omeral Embolization Arterial Ligature Amputation Thromboembolectomy No procedure (death)	10 (50%) 4 (20%) 2 (50%) 2 (50%) 2 (10%) 1(5%) 1 (5%) 1 (5%) 1 (5%)
BOTH	3	Direct suture Direct suture and embolization	2 (66.6%) 1(33.3%)