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Managing peripheral artery disease in diabetic patients: a questionnaire survey from vascular centers of the Mediterranean Federation for the Advancing of Vascular Surgery (MeFAVS).

Umberto Marcello Bracale, Raffaele Pio Ammollo, Emad A. Hussein, Jamal J. Hoballah, Olivier Goeau-Brissoniere, Maurizio Taurino, Carlo Setacci, Felice Pecoraro, Giancarlo Bracale, on behalf of collaborators, Anna Maria Giribono, Liborio Ferrante, Gianmarco de Donato, Ettore Dinoto, Guido Bajardi, Maddalena Illario, Mohamed N. Bouayed, Ben R. Saleem, Raffaele Pulli, Bruno Gossetti, Bianca Pane, Patrizio Castelli, Matteo Tozzi, Tarek Sraieb, Francesco Setacci, Andrea Stella, Vincenzo De Luca

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1 TITLE

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3 centers of the Mediterranean Federation for the Advancing of Vascular Surgery (MeFAVS).

4 AUTHORS

5 Umberto Marcello Bracale¹, Raffaele Pio Ammollo¹, Emad A. Hussein², Jamal J. Hoballah³, Olivier
6 Goeau-Brissonniere⁴, Maurizio Taurino⁵, Carlo Setacci⁶, Felice Pecoraro⁷, Giancarlo Bracale¹ on
7 behalf of collaborators.

8 Collaborators

9 Anna Maria Giribono¹, Liborio Ferrante¹, Gianmarco de Donato⁶, Ettore Dinoto⁷, Guido Bajardi⁷,
10 Maddalena Illario⁸, Mohamed N. Bouayed⁹, Ben R. Saleem¹⁰, Raffaele Pulli¹¹, Bruno Gossetti¹²,
11 Bianca Pane¹³, Patrizio Castelli¹⁴, Matteo Tozzi¹⁴, Tarek Sraieb¹⁵, Francesco Setacci¹⁶, Andrea
12 Stella¹⁷, Vincenzo De Luca¹⁸.

13 Affiliations:

- 14 1. Vascular and Endovascular Surgery Unit, Department of Public Health, University Federico
15 II of Naples, Naples, Italy
- 16 2. Department of Vascular Surgery, Ain Shams University, Cairo, Egypt
- 17 3. Department of General Surgery, American University of Beirut Medical Center, Beirut,
18 Lebanon
- 19 4. Department of Vascular Surgery, Ambroise Paré Hospital, AP-HP, Boulogne-Billancourt,
20 France; Faculté de Médecine Paris Ile-de-France Ouest, Paris, France.
- 21 5. Unit of Vascular Surgery, Department of Clinical and Molecular Medicine, "Sapienza",
22 University of Rome, Sant'Andrea Hospital, Rome, Italy.
- 23 6. Vascular and Endovascular Surgery Unit, Department of Medicine, Surgery and
24 Neurological Sciences, Policlinico S. Maria alle Scotte, University of Siena, Italy
- 25 7. Department of Surgical Oncological and Oral Sciences (DICHIRONS), University of
26 Palermo, Vascular Surgery Unit, Palermo, Italy
- 27 8. Health Innovation Unit, Campania Region, Naples, Italy
- 28 9. Department of Vascular Surgery, EHU ORAN, Algeri, Algeria
- 29 10. Department of Surgery (Division of Vascular Surgery), University Medical Center
30 Groningen, Groningen, The Netherlands
- 31 11. Vascular Surgery, Department of Cardiothoracic Surgery, University of Bari, Bari, Italy.
- 32 12. Unit of Vascular Surgery, Department "Paride Stefanini", "Sapienza" University of Rome,
33 Rome, Italy.
- 34 13. Cardiovascular Surgery, IRCCS San Martino-IST University Hospital, Largo Rosanna
35 Benzi, 10, 16132, Genoa, Italy.

36 14. Research Centre for Vascular Surgery, Department of Medicine and Surgery, University of
37 Insubria, Italy.

38 15. Hannibal Médical Center, Tunis Berges du Lac Tunis

39 16. Unit of Vascular Surgery, Multimedica Institute for Research and Care, Milan, Italy

40 17. Vascular Surgery, Department of Experimental, Diagnostic and Specialty Medicine,
41 University of Bologna, Bologna, Italy.

42 18. Research and Development Unit, AOU "Federico II", Naples, Italy

43

44 Corresponding author:

45 Umberto Marcello Bracale

46 Associate Professor of Vascular Surgery

47 Department of Public Health

48 University Federico II of Naples

49 tel.: 00390817462629 fax.: 00390817462630

50 umbertomarcello.bracale@unina.it

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52

53 **ABSTRACT**

54 **Background:** The Mediterranean Federation for the Advancing of Vascular Surgery (MeFAVS)
55 was founded on October 1st 2018 to enhance cooperation amongst vascular professionals within
56 Mediterranean countries. Due to its prominent social and economic impact on national health
57 systems, diabetic arteriopathy has been selected as the very first topic to be investigated by the
58 Federation.

59 **Methods:** MeFAVS members were asked to reply to a questionnaire on the management of diabetic
60 ischemic foot. Results were collected and analyzed statistically. The questionnaire consisted of 15
61 multiple choice answers regarding diabetic foot diagnosis and treatment. The questionnaire was
62 submitted to 21 centers on April 20th, 2019.

63 **Results:** Response rate was 62%. The survey revealed that vascular surgeons, diabetologists and
64 wound care nurses made up the core of Diabetic Teams present in 76.9, 69.3 and 92.3% of the

65 centers, respectively. Diabetic Teams were most often led by vascular surgeons (53.8%) and
66 diabetologists (42.2%) but only in 7.9% of cases by nurses. Duplex ultrasonography (DUS) and
67 computed tomographic angiography (CTA) were the most commonly available tools used to assess
68 diabetic peripheral arterial disease (PAD). Surgical wound care was undertaken by vascular
69 surgeons in the majority of cases, and only in 46.2% of the cases to orthopedic or plastic surgeons
70 while non-surgical wound care was handled by specialized nurses (76.6%) and diabetologists
71 (53.8%). First-line revascularization was preferred over conservative treatment (61.5 vs. 53.8%) and
72 endovascular strategy (45.3%) over open (33.7%) or hybrid (21.0%) surgery. Vascular surgeons and
73 interventional radiologists were found to be the most common performers of endovascular
74 revascularization (92.3 and 53.8%, respectively). Amputations had an overall rate of 16.6% (range
75 4-30%) and a mean reintervention rate of 22.5% and were usually performed by vascular surgeons
76 for both minor and major interventions (84.6%) followed by orthopedic surgeons (15.4% minor,
77 30.8% major). The availability of a diabetic foot clinic (84.6%) and endovascular (53.8%) and open
78 surgery (46.2%) capabilities were considered fundamental in order to reduce amputation rates.

79 **Conclusions:** Especially since the introduction and spreading of new endovascular techniques for
80 the treatment of diabetic foot, it is a common consensus amongst vascular surgeons that a
81 standardized approach to the discipline is necessary in order to improve outcomes such as
82 amputation-free survival and mortality. In this perspective and purpose that transnational
83 cooperation amongst vascular professionals and residents in training are aiming for greater
84 proficiency in endovascular and open surgery.

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90 INTRODUCTION

91 Vascular Surgery has been experiencing a fundamental change since the introduction of
92 endovascular techniques. In the femoro-popliteal segment, minimally invasive interventions may be
93 life- and limb-saving, especially in diabetic patients where the progression of the disease
94 chronically impairs wound healing and endothelial function.

95 Driven by ever growing attention and investment from the medical industry, vascular device
96 technologies are exponentially increasing in number and variety and the development of new
97 techniques, as well as the training programs of residents, is of crucial importance for the
98 advancement of this specialty. One way to keep up with these changes has been through the
99 creation of an international vascular surgery network and with this aim MeFAVS, the
100 Mediterranean Federation for Advancing of Vascular Surgery, was founded on 1st October 2018
101 with the purpose of connecting University Professors, heads of Vascular Departments and
102 consultant surgeons for ongoing scientific, educational and clinical cooperation amongst the
103 Mediterranean basin countries of Italy, France, Spain, Portugal, Greece, Morocco, Algeria, Tunisia,
104 Egypt, Lebanon, Emirates, Albania, Croatia and Turkey. Current activities have been a series of
105 verbal information exchanges, meetings and surveys based on common topics of vascular
106 pathology, epidemiology, new treatments and materials for Vascular Surgery. The very first topic
107 which was chosen to be addressed amongst MeFAVS members was peripheral arterial disease in
108 diabetic patients; a serious, multi-level pathology, often with severe prognosis and a significant
109 incidence of major lower limb amputation due to ulcers and general impairment.

110 METHODS

111 We conducted a survey through an online questionnaire e-mailed to MeFAVS members, consisting
112 of 15 questions regarding surgical and endovascular approach to revascularization, amputation and

113 recurrence and diabetic foot team composition. Questions decided through several teleconferences
114 amongst MeFAVS founding members:

- 115 1) Diabetic foot center, members and chief of the team.
- 116 2) Diagnostic methods.
- 117 3) Diabetic foot ulcer/infection: first treatment.
- 118 4) Wound care: surgical or non-surgical approach.
- 119 5) Revascularization rate.
- 120 6) Endovascular revascularization: who is the performer?
- 121 7) Endovascular revascularization: type of access.
- 122 8) Do you follow an angiosome-oriented revascularization?
- 123 9) Minor and major amputation: who is the performer?
- 124 10) Rate of major amputation.
- 125 11) Prosthetic service options available for the diabetic lower limb amputees.
- 126 12) Rehabilitation of post lower limb amputees.
- 127 13) In order to reduce the amputation rate, what is more relevant?
- 128 14) Rate of reintervention.
- 129 15) Follow-up: times and modalities.

130

131 **RESULTS**

132 Of the 21 centers invited to participate in the Survey, 13 transmitted a completed questionnaire,
133 which was accepted, with a total response rate of 62%.

134 1. **Diabetic foot center** (Fig. 1) Vascular surgeons felt that they played a special role in the
135 management of DA, being almost always a part of the diabetic team (10/13, 76.9%) and most often
136 leading it (7/13, 53.8%). Of the other medical specialists, diabetologists were involved in the team,
137 either as members (9/13, 69.3%) or as heads (6/13, 46.2%). In some cases, more than one figure

138 was indicated as head of the team.

139 Amongst medical professionals, wound care nurses appear to have a core role in a multidisciplinary
140 team, being present in almost all the centers (12/13, 92.3%) but rarely as team leaders (1/13, 7.9%).

141 **2. Diagnostic methods** (Fig. 2). The most widely used tools to appraise pathology severity,
142 localization and type of lesion were DUS and CTA (13/13, 100%), followed by ABI (10/13,
143 76.9%), MRA (8/13, 61.6%) and TcPO₂ (7/13, 53.8%).

144 **3. Diabetic foot ulcer/infection: first treatment.** A conservative first-line regimen was preferred
145 in 7/13 (53.8%) cases while 8/13 (61.5%) acted with an initial revascularization. In 4 out of 13
146 cases (30.7%) both approaches were combined.

147 **4. Wound care** (Fig. 3). Surgical wound care was relegated to vascular surgeons in the totality of
148 cases (13/13, 100%), while non-surgical care was limited to only 3 out of 13 (23.1%). Both plastic
149 and orthopedic surgeons were dedicated to surgical wound care in 6/1 cases (46.2%), but were
150 almost never (1/13, 7.6%) or never involved in non-surgical care, respectively. Wound care nurses,
151 on the other hand, were committed almost exclusively to non-surgical (10/13, 76.9%), but seldom to
152 surgical (1/13, 7.7%) wound care.

153 **5. Revascularization rate** (Fig. 4). Frequency rates of open, endovascular and hybrid interventions
154 were between 3-70%, 20-95%, 2-60%, respectively amongst centers with a mean of 33.7, 45.3 and
155 21%, respectively.

156 **6. Endovascular revascularization** (Fig. 5). In 12/13 cases (92.3%) vascular surgeons were the
157 predominant medical professionals performing endovascular revascularizations, followed by
158 interventional radiologists (7/13, 53.8%) and angiologists (1/13, 7.9%).

159 **7. Endovascular revascularization access.** Retrograde contralateral access was preferred (13/13,
160 100%) over ipsilateral antegrade access (12/13, 92.3%). Ipsilateral retrograde popliteal or pedal

161 access and dual access resulted in being the least used (5/13, 38.5% and 4/13, 30.8%, respectively).

162 8. **Do you follow any angiosome-oriented revascularization?** Angiosome-oriented
163 revascularization was performed in 10/13 centers (76.9%) and none in 3/13 (23.1%).

164 9. **Amputation** (Fig. 6). Vascular surgeons appeared to be the most common performers of
165 amputations, both minor and major (11/13, 84.6%), while orthopedic surgeons were sometimes
166 dedicated to both minor (2/13, 15.4%) and major (4/13, 30.8%) amputations. Plastic surgeons were
167 called in to perform only minor amputations (4/13, 30.8%). In some cases, general surgeons acted
168 as minor (2/13, 15.4%) or major (1/13, 7.7%) amputation operators.

169 10. **Rate of major amputations.** Data on major amputation rates were not available in 1 case. The
170 mean rate among the remaining centers was 16.6%, ranging from 4% to 35%.

171 11. **Prosthetic service options available for the diabetic lower limb amputee.** Prosthetic services
172 for amputees were predominantly offered by both private or public (7/13, 53.8%) institutions
173 outside the hospitals participating in the survey, and only in 3 out of 13 centers (27.3%) were they
174 available within the hospital itself.

175 12. **Rehabilitation for post-lower limb amputees.** In 10/13 cases (76.9%) rehabilitation for
176 amputees was offered by public institutions external to the hospital; 8/13 (61.5%) centers had this
177 service inside the hospital, instead of 4/13 (30.8%) cases in which the service was offered in
178 private, outside the hospital institutions.

179 13. **In order to reduce the amputation rate, what is more relevant?** (Fig. 8). The most
180 important factor for reducing amputation rates was considered a dedicated diabetic foot clinic
181 (11/13, 84.6%), followed by endovascular (7/13, 53.8%) and open surgical skills (6/13, 46.2%). The
182 availability of endovascular devices, a dedicated amputation clinic or a hybrid room were deemed
183 less relevant.

184 14. **Rate of reintervention.** Data from this survey, unavailable from 2/13 responding centers,

185 revealed a mean rate of 22.5% (range: 10-40%) of reinterventions after any sort of revascularization
186 procedure.

187 15. **Follow-up.** From the data collected in our analysis it was not possible to define a shared
188 approach in controls regarding frequency of appointments nor type of examination however clinical
189 and DUS appeared to be the most common types of examination, usually performed regularly
190 together with higher frequency in the first year after revascularization.

191 **DISCUSSION**

192 Diabetes mellitus incidence and prevalence show an insidious, steady increase over time. According
193 to data released in the IDF Agenda, between the 18-99 year-old population in 2017, about 425
194 million people worldwide are estimated to have diabetes and if this trend continues, by 2045 almost
195 693 million people within the same age range will be diagnosed with diabetes.¹ DF has a mean
196 global prevalence of 6.4% out of the total population, is more frequent in males than in females and
197 type 2 is more prevalent than type 1 in diabetic foot patients. Moreover, patients with DF are older,
198 have a lower body mass index, longer diabetic duration and more hypertension, diabetic
199 retinopathy, and smoking history than patients without DF.²

200 Diabetes and DA, being multi-level diseases involving several organs, make it imperative to
201 properly assess each comorbidity and complication. This requires the collaboration of different
202 medical specialists and healthcare professionals in the diagnostic and therapeutic pathway. Despite
203 being this, in our experience, the first survey ever made in the frame of an established Federation of
204 Vascular Surgery centers of the Mediterranean basin, in which countries differ in terms of disease
205 prevalence, healthcare system structure and financial availabilities, and in which a well-defined
206 management of diabetes complications often lacks, this analysis tells us that vascular surgeons are
207 almost always part of the Diabetic Foot team often having a leading role in it. As stated in the ESVS
208 *Diabetic Foot* Guidelines, a vascular surgeon should be a systematically integrated member of a
209 diabetic team, with the important aim mandate to speed up the healing rate and avoid amputation.³

210 However, there is still lack of evidence, especially from randomized clinical trials, as to whether an
211 endovascular-first approach provides a benefit over conservative treatment and/or surgery of
212 diabetic foot ulcers in the *above-the-knee* district, while an endovascular-first strategy is confirmed
213 to have a prominent role in cases of *below-the-knee* disease. When compared to non-diabetic PAD,
214 diabetic arteriopathy has typical characteristics as it tends to be bilateral and infra-popliteal and
215 occlusions are more frequent than stenoses.⁵ In diabetic patients open surgery is often limited by a
216 patient's comorbidities, VGS graft availability and quality⁶ making endovascular interventions the
217 possibly favored approach. A recent meta-analysis concluded that at 1-year follow-up, open bypass
218 surgery or endovascular techniques were equally valid in producing diabetic foot ulcer healing.⁷

219 The most common complication of diabetic arteriopathy is undoubtedly amputation. Incidence of
220 all forms of lower extremity amputation ranges from 5.8–31 per 10⁵ in the general population to
221 46.1 to 9600 per 10⁵ in the diabetic population⁸ of which 85% of amputations follow an ulcer
222 complicated by gangrene and infection. Timing in revascularization ("*time is tissue*") is a crucial
223 aspect for patients' outcome: an early restoration of blood flow – coupled with an extensive surgical
224 debridement – lowers mortality, major amputation, and enhances foot healing.⁹

225 Costs of diabetic arteriopathies increase over time also because of prosthetic solutions and
226 rehabilitation, which require other, specialized professionals to participate in re-mobilizing the
227 amputee. The presence of the diabetic foot clinic, whose resources are focused on getting the best
228 results by reducing complications and hospitalization times, appears fundamental. As stated in the
229 recent GLASS Guidelines¹⁰, a successful limb salvage intervention is associated with low
230 postprocedural morbidity and mortality, preservation or restoration of independent ambulation,
231 improved quality of life for the patient and lower costs to the health care system. According to a
232 survey led by Spanos et al. in 2016,¹¹ in Mediterranean countries patients with diabetic foot are
233 usually managed by experienced vascular physicians in tertiary centers, but only few of them have a
234 structured DF team: a comprehensive reorganization of this service is of paramount importance in

235 the healthcare system of the Mediterranean countries.

236 Endovascular skills are also considered crucial in this perspective, calling on academic and teaching
237 hospitals to concentrate on residents' education. Despite the high societal needs of vascular surgery
238 treatments,¹¹ the specialty is reported to have lower appeal amongst medical residents over others.
239 Therefore, the offering of more specialized training in endovascular skills and/or integrating
240 vascular surgery with interventional radiology training programs¹² may lead to higher recruitment.¹³
241 Simulators, both open and endovascular, play an increasingly important role in training programs as
242 well as outreach programs for medical students.¹⁴

243 CONCLUSIONS

244 Transnational networks like the MeFAVS which foster essential collaboration, communication and
245 exchange is no doubt an effective strategy in promoting and advancing our vascular surgical
246 specialty which, given the growing need as a result of forecasted increased incidences of diabetes
247 over an ever-wider age span, will ensure that patients receive high standard care solutions coupled
248 with efficient healthcare costs, attract research and industry-supported development and generate
249 interest and the training of future generations of proficiently skilled professionals.

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285

286 Captions

287

288 Figure 1. Diabetic Foot Team, healthcare professionals (blue column). Diabetic Foot Team, Heads
289 of the Team (orange column).

290 Figure 2. Diagnostic assessment of PAD in diabetics.

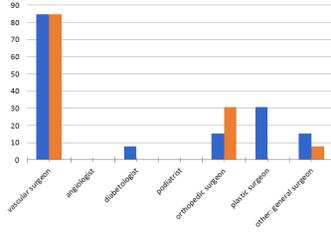
291 Figure 3. Surgical wound care according to healthcare professional (blue column). Non-surgical
292 wound care according to healthcare professional (orange column).

293 Figure 4. Revascularization rates for open, endovascular, hybrid and other surgery.

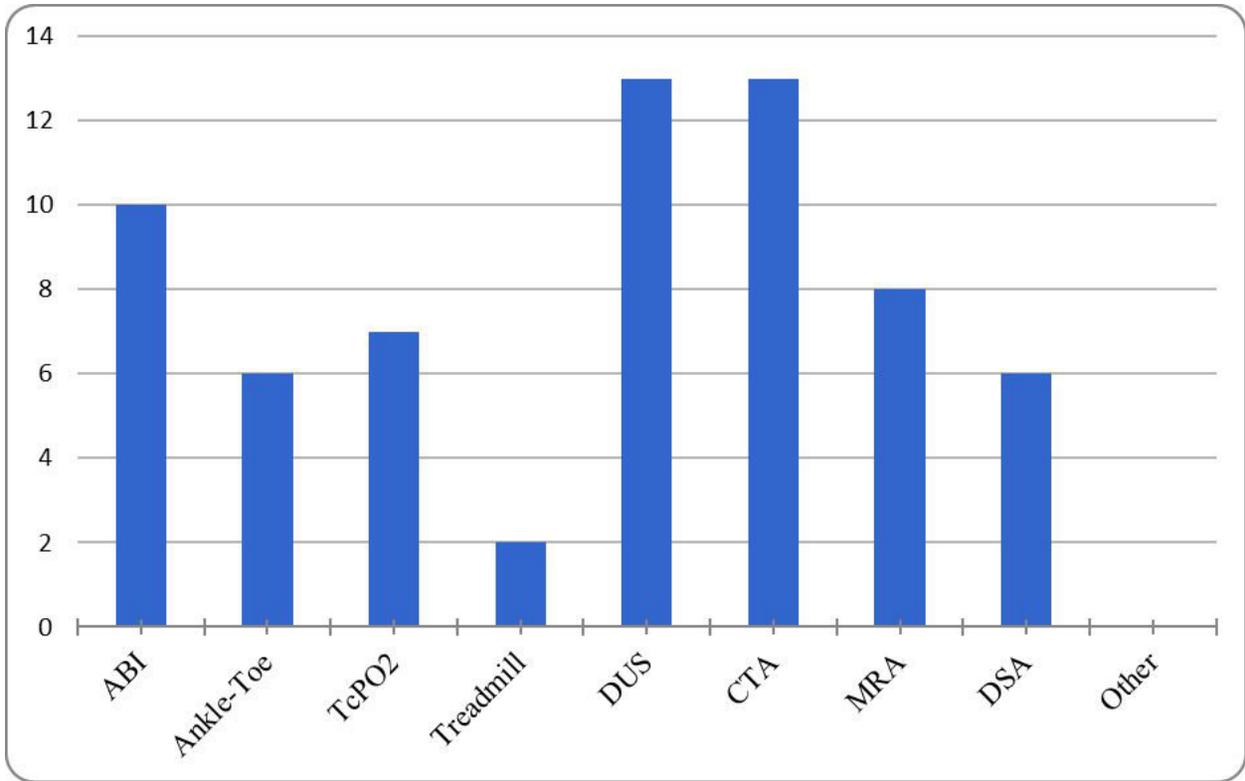
294 Figure 5. Endovascular revascularization according to medical specialist.

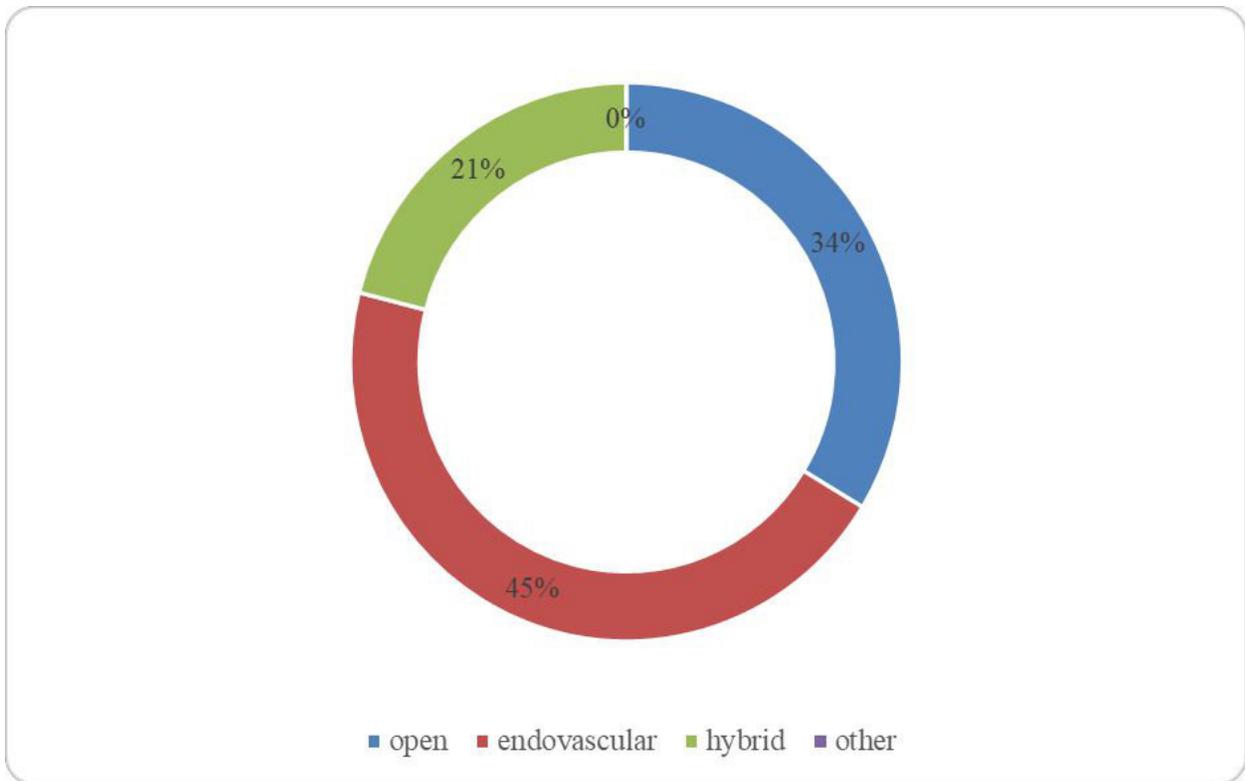
295 Figure 6. Minor (blue column) and major (orange column) amputation-performing medical
296 specialties.

297 Figure 7. Relevance of equipment and skills in order to reduce amputation rates.

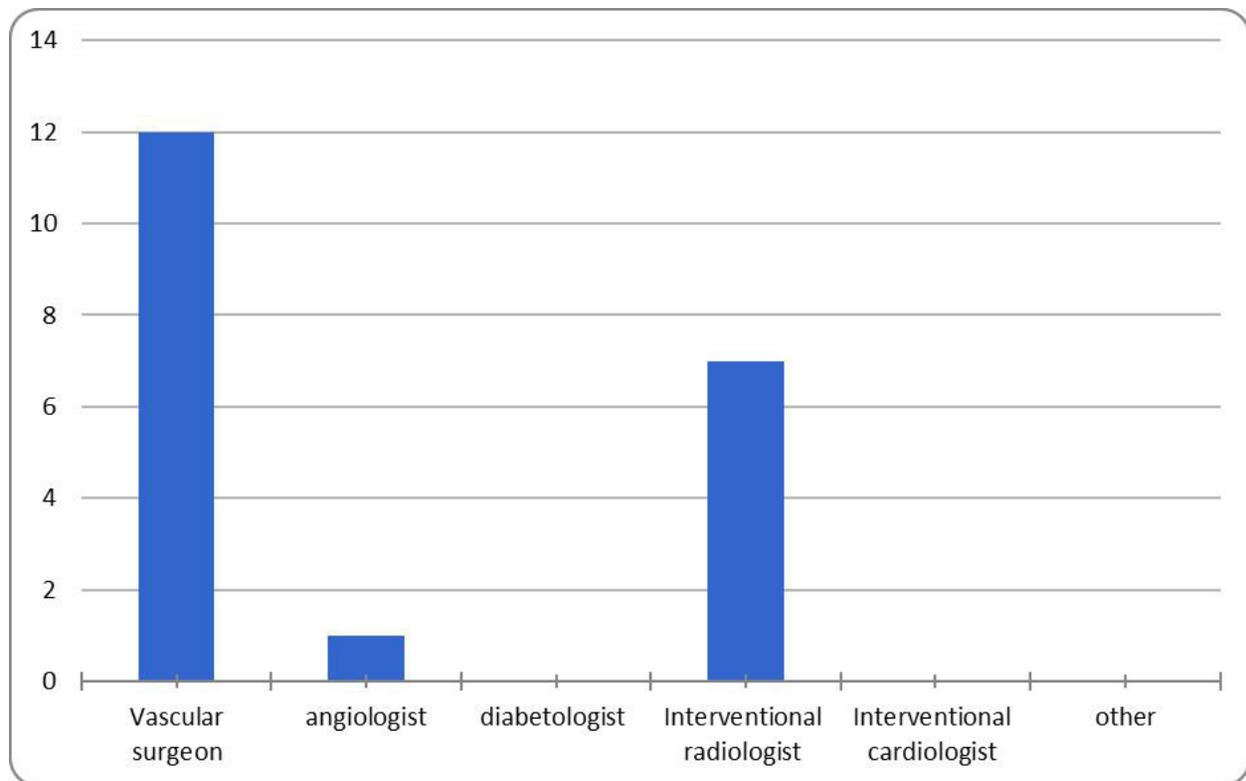


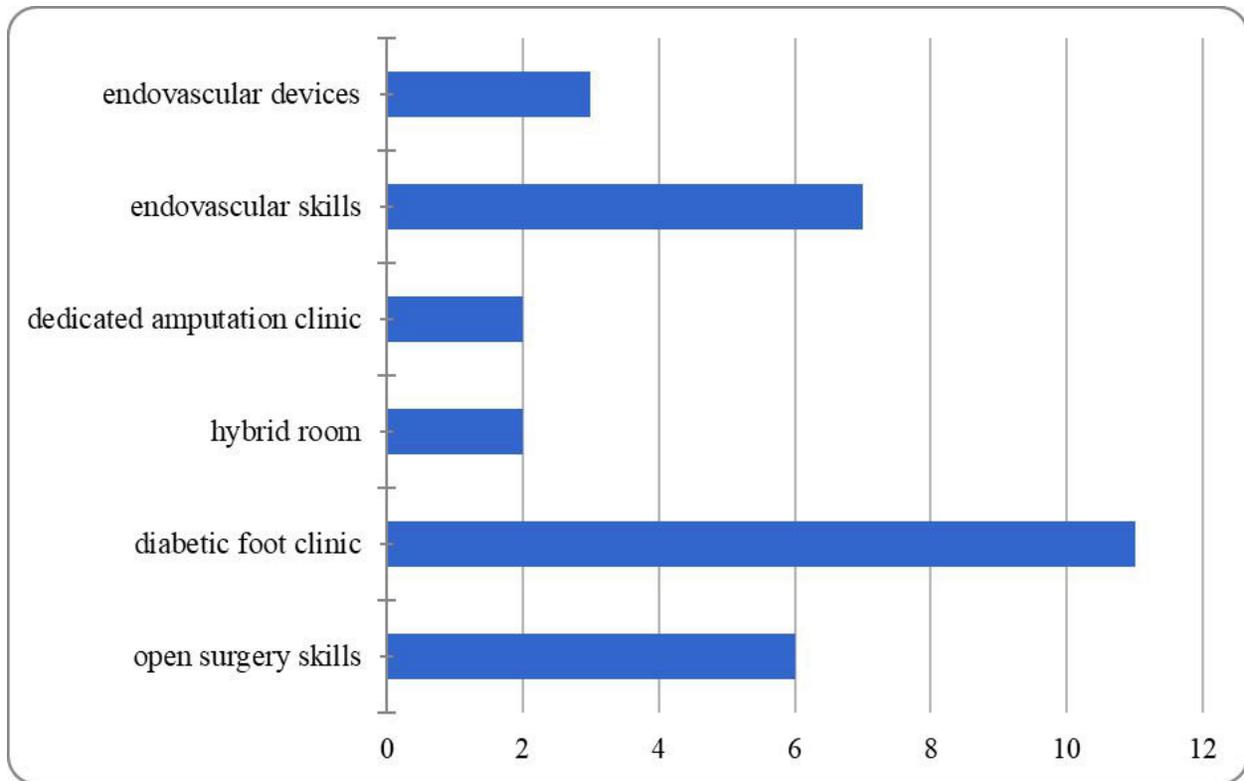
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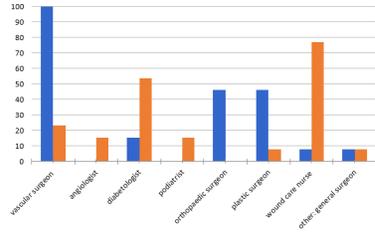




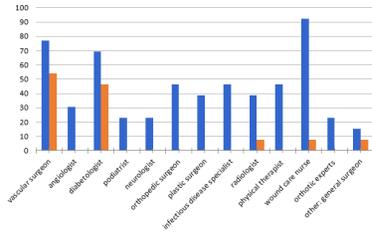
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