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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).

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## 1 TITLE

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

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52

### 53 **ABSTRACT**

54 **Background:** The Mediterranean Federation for the Advancing of Vascular Surgery (MeFAVS)  
55 was founded on October 1<sup>st</sup> 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 20<sup>th</sup>, 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 TcPO<sub>2</sub> (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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup>

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.<sup>5</sup> In diabetic patients open surgery is often limited by a  
216 patient's comorbidities, VGS graft availability and quality<sup>6</sup> 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.<sup>7</sup>

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 10<sup>5</sup> in the general population to  
221 46.1 to 9600 per 10<sup>5</sup> in the diabetic population<sup>8</sup> 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.<sup>9</sup>

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 Guidelines<sup>10</sup>, 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,<sup>11</sup> 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,<sup>11</sup> 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 programs<sup>12</sup> may lead to higher recruitment.<sup>13</sup>  
241 Simulators, both open and endovascular, play an increasingly important role in training programs as  
242 well as outreach programs for medical students.<sup>14</sup>

## 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.

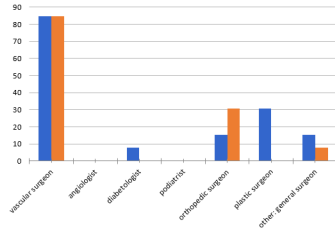
291 Figure 3. Surgical wound care according to healthcare professional (blue column). Non-surgical  
292 wound care according to healthcare professional (orange column).

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

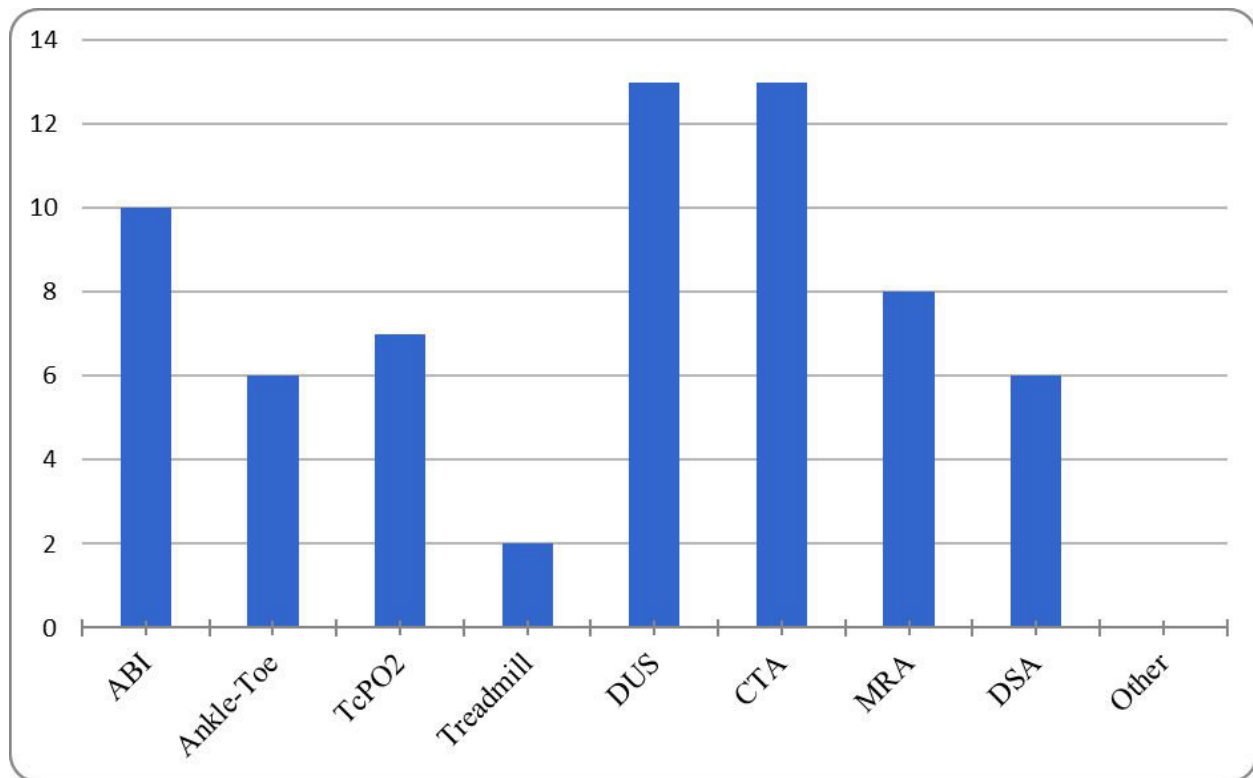
294 Figure 5. Endovascular revascularization according to medical specialist.

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

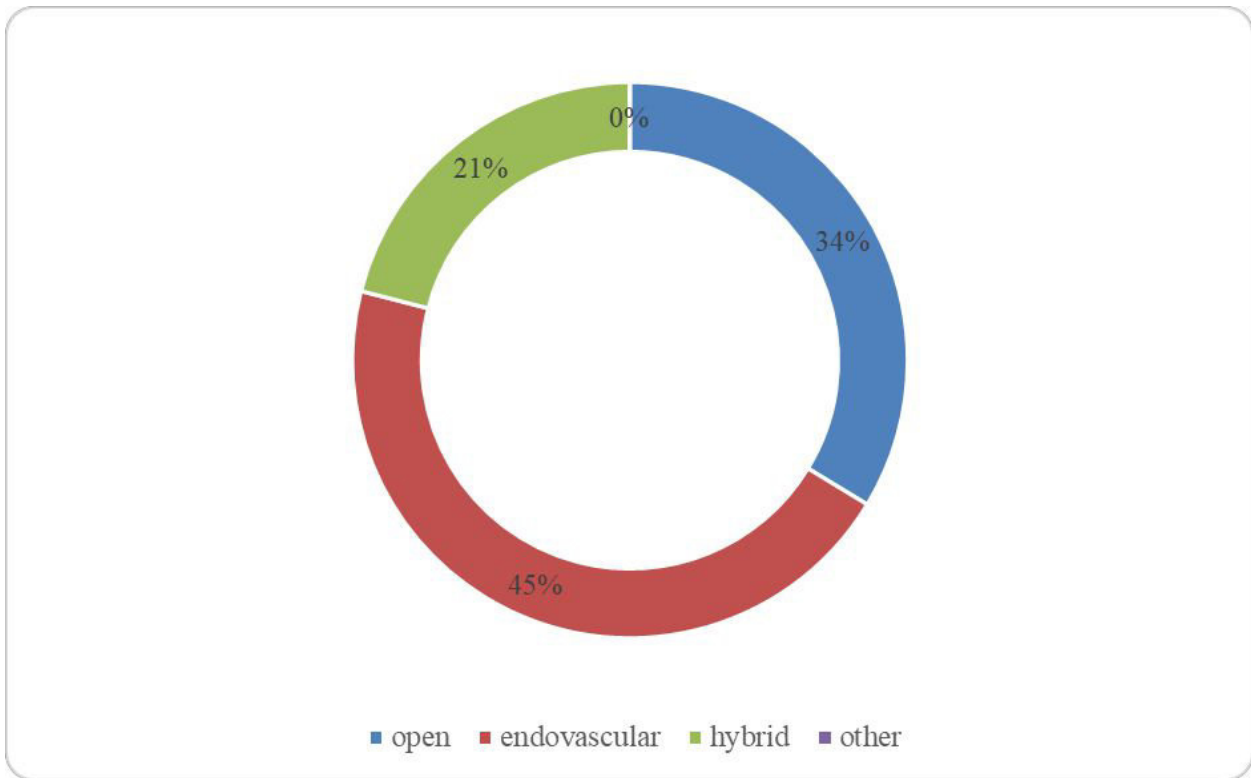
297 Figure 7. Relevance of equipment and skills in order to reduce amputation rates.



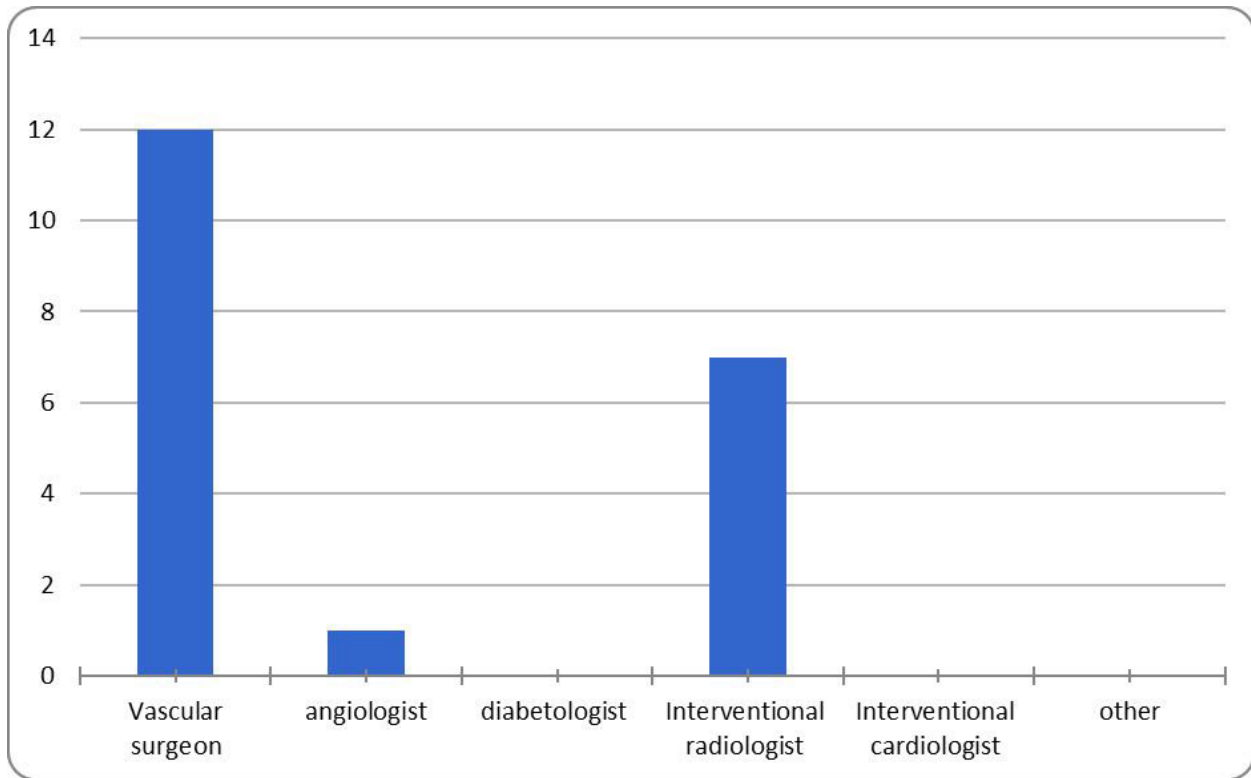
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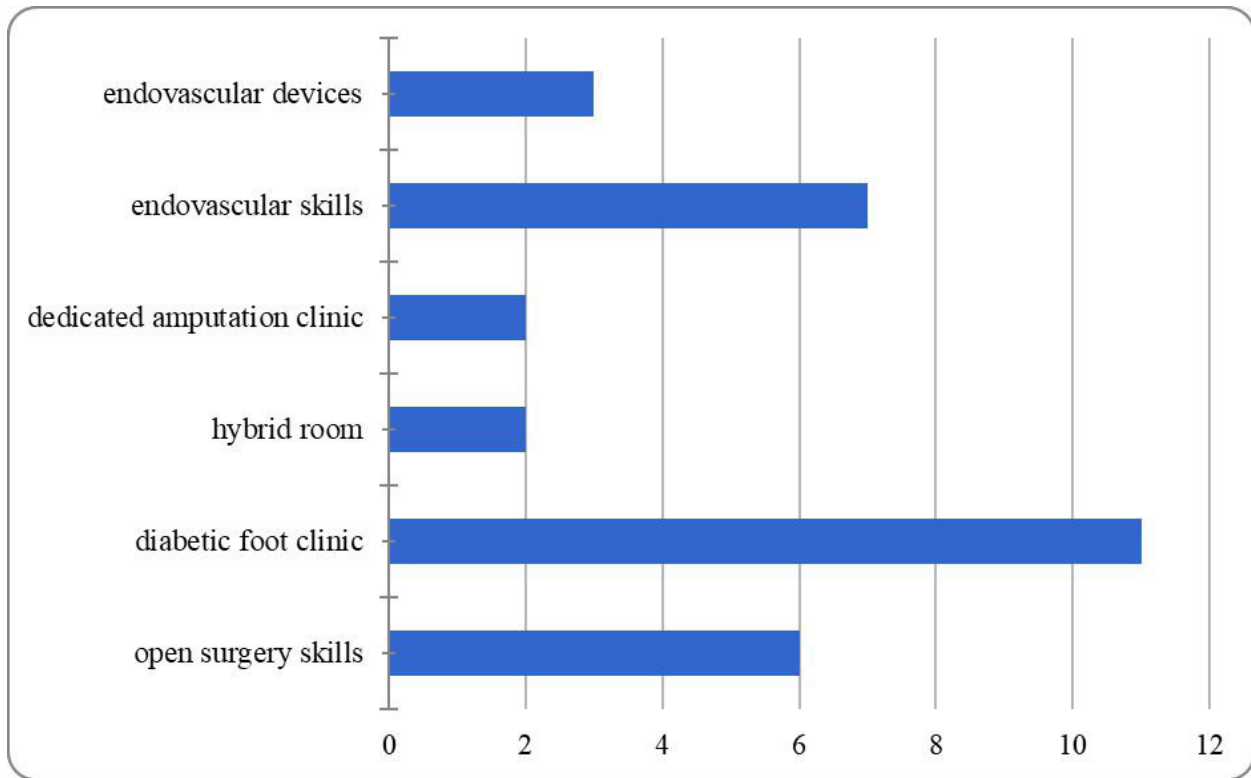


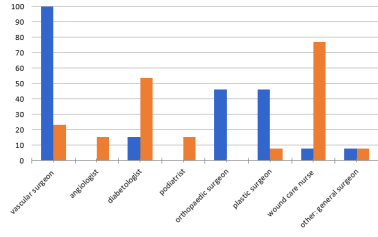




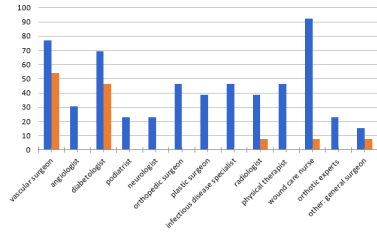
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