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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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TITLE

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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ABSTRACT

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

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

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

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

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

INTRODUCTION

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

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

METHODS

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

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

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

RESULTS

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

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

was indicated as head of the team.

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

2. **Diagnostic methods** (Fig. 2). The most widely used tools to appraise pathology severity, localization and type of lesion were DUS and CTA (13/13, 100%), followed by ABI (10/13, 76.9%), MRA (8/13, 61.6%) and $TcPO_2$ (7/13, 53.8%).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DISCUSSION

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

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

However, there is still lack of evidence, especially from randomized clinical trials, as to whether an endovascular-first approach provides a benefit over conservative treatment and/or surgery of diabetic foot ulcers in the *above-the-knee* district, while an endovascular-first strategy is confirmed to have a prominent role in cases of *below-the-knee* disease. When compared to non-diabetic PAD, diabetic arteriopathy has typical characteristics as it tends to be bilateral and infra-popliteal and occlusions are more frequent than stenoses.[5] In diabetic patients open surgery is often limited by a patient's comorbidities, VGS graft availability and quality[6] making endovascular interventions the possibly favored approach. A recent meta-analysis concluded that at 1-year follow-up, open bypass surgery or endovascular techniques were equally valid in producing diabetic foot ulcer healing.[7]

The most common complication of diabetic arteriopathy is undoubtedly amputation. Incidence of all forms of lower extremity amputation ranges from 5.8–31 per 10^5 in the general population to 46.1 to 9600 per 10^5 in the diabetic population[8] of which 85% of amputations follow an ulcer complicated by gangrene and infection. Timing in revascularization ("*time is tissue*") is a crucial aspect for patients' outcome: an early restoration of blood flow – coupled with an extensive surgical debridement – lowers mortality, major amputation, and enhances foot healing.[9]

Costs of diabetic arteriopathies increase over time also because of prosthetic solutions and rehabilitation, which require other, specialized professionals to participate in re-mobilizing the amputee. The presence of the diabetic foot clinic, whose resources are focused on getting the best results by reducing complications and hospitalization times, appears fundamental. As stated in the recent GLASS Guidelines[10], a successful limb salvage intervention is associated with low postprocedural morbidity and mortality, preservation or restoration of independent ambulation, improved quality of life for the patient and lower costs to the health care system. According to a survey led by Spanos et al. in 2016,[11] in Mediterranean countries patients with diabetic foot are usually managed by experienced vascular physicians in tertiary centers, but only few of them have a structured DF team: a comprehensive reorganization of this service is of paramount importance in

the healthcare system of the Mediterranean countries.

Endovascular skills are also considered crucial in this perspective, calling on academic and teaching hospitals to concentrate on residents' education. Despite the high societal needs of vascular surgery treatments, [11] the specialty is reported to have lower appeal amongst medical residents over others. Therefore, the offering of more specialized training in endovascular skills and/or integrating vascular surgery with interventional radiology training programs[12] may lead to higher recruitment.[13] Simulators, both open and endovascular, play an increasingly important role in training programs as well as outreach programs for medical students.[14]

CONCLUSIONS

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

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286 Captions

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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.