SAPHENOUS SPARING TREATMENTS ORIGINAL ARTICLE

Infrainguinal bypass using varicose veins with external scaffolding

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Abstract Background: Chronic limb-threatening ischemia (CLTI) is associated with high rates of mortality, amputation, and impaired quality of life. The great saphenous vein (GSV) is the first-choice material for surgical revascularization of the infrapopliteal arteries. It may occur that the autologous material is not of good quality, presenting varicosities and ectasias which can affect bypass patency. The long-term patency rate of these operations is still not clear and few evidences are still present in literature. The aim of our study is to report the technical feasibility and efficacy of infrainguinal bypasses performed with autologous ectatic or varicose vein and with the use of external vascular supports.

Materials and Methods: From September 2005 to January 2023, infrainguinal venous bypasses with autologous varicose or ectatic vein using an external vascular support were collected in the present study. The indication for surgery was the presence of CLTI with rest pain and/or gangrene. In case of localized dilatations of a segment of the GSV a partial bypass scaffolding (i.e. 10 to 15 cm) was used. Patients with a long segment of varicose vein underwent a completely covered ex situ vein bypass after a bench devalvulation. Follow-up was performed at 1, 3, 6 and 12 months and every 6 months thereafter, by clinical examination and color Doppler ultrasound. The outcome measures were technical success, 30-day and long-term primary and primary assisted bypass patency, as well as the limb salvage rate. External support infection rates upon reoperation for surgical wound infection as well as graft aneurysmal dilatation over time were also analyzed.

Results: 63 patients underwent infrainguinal bypass with autologous varicose or ectatic venous material. In 51 patients (80.9%) the GSV was used, in 3 cases (4.8%) the short saphenous vein (SSV) and in 9 cases (14.3%) a composition of both saphenous veins or with one arm vein. Technical success was achieved in all cases and the mean surgical time was 320±80 minutes. No intraoperative mortality was recorded. At 30 days the primary patency and limb salvage rate were 97.8%, due to two early bypass occlusions. No infections of the external vascular support were recorded. During a mean follow-up of 54.6±27.2 months 8 (13.1%) hemodynamic stenoses requiring reoperation and 3 (4.9%) thromboses of the bypass were found. The primary patency rate was 62.8%, assisted primary 76.3%, with a limb salvage rate of 78%.

Conclusion: In our experience, the great saphenous vein, even if ectatic or varicose, has proved to be a valuable conduit for the preparation of a infrainguinal bypasses in CLTI patients, with a satisfactory patency and limb salvage rates. In addition, composite vein graft also using arm vein, could be used in infrainguinal bypass with acceptable results. Also in the light of these results, a “saphenous sparing" surgical approach during corrective surgery for venous insufficiency of the lower limbs should be recommended, so as not to preclude future surgical treatments for limb salvage.

Keywords Chronic Limb-Threatening Ischemia, amputation, great saphenous vein, quality of life, varicose veins.

Introduction

Chronic limb-threatening ischemia (CLTI) is associated with high rates of mortality, amputation, and

impaired quality of life. Recently the Global guidelines have underlined how venous bypass is to be preferred for patients at acceptable surgical risk and with a high risk of limb amputation following an advanced extensive atherosclerotic pathology on the arterial axis of the lower limb; however, the optimal revascularization strategy is also influenced by the availability of autogenous vein for open bypass surgery[1,2].

As highlighted by several studies, the great saphenous vein (GSV) is the material of first choice for surgical revascularization of the infrapopliteal arteries both for the best long-term patency rates and for the lower risk of infection, compared to the prosthetic material[3,4].

When GVS is not available, other veins such as the short saphenous vein (SSV) and arm veins are considered a suitable alternative to bypass surgery, with satisfactory short- and long-term patency rates[5-7]. The same also applies when using an autogenous composite vein[8].

Despite the undoubted success and benefit of the use of autologous veins in infrainguinal bypasses, it may occur that the autologous material is not of good quality, presenting varicosities and ectasias that make the bypass more susceptible to aneurysm formation and subsequent graft failure. The long-term success of these operations is limited by the progressive thickening of the vein graft wall, which is caused by intimal hyperplasia and ultimately superimposed atherosclerosis[9-11]. These situations have historically been a contraindication to the use of autologous vein grafts[12].

The aim of our study is to report the technical feasibility and efficacy of infrainguinal bypasses performed with autologous ectatic or varicose vein and with the use of external vascular supports (Provena, Bbraun Aesculap, Tuttlingen, Germany and Frame ^{TM} , Vascular Graft Solutions LTD, Tel Aviv, Israel), in patients with CLTI during the latest 20 years.

Materials and Methods

From September 2005 to January 2023, infrainguinal venous bypasses with autologous varicose or ectatic vein, using an external vascular support were collected in the present study.

The indication for surgery was the presence of CLTI with rest pain and/or gangrene and consequent high risk of limb amputation. In all patients, the quality of the venous material was not "optimal" due to varices or ectatic dilatation. According to the respectively instruction for use of the external vascular support, FRAME^{TM} (Vascular Graft Solutions LTD, Tel Aviv, Israel) was used for an isolated section or for the entire vein with a diameter ≤ 4.5 and ≤ 8 mm (Fig 1), and up to 12 mm maximum diameter if Provena (Bbraun Aesculap, Tuttlingen, Germany) was placed (Fig 2).

All patients underwent a preoperative specialist examination, which included collection of the patient's clinical history, physical examination with evaluation of arterial pulses and the possible presence of ulcerative lesions and ultrasound arterial mapping.

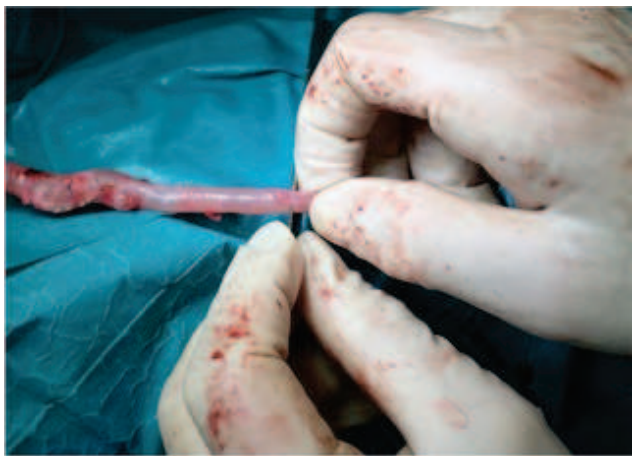

Fig. 1 Varicose Great Saphenous Vein diameter evaluation

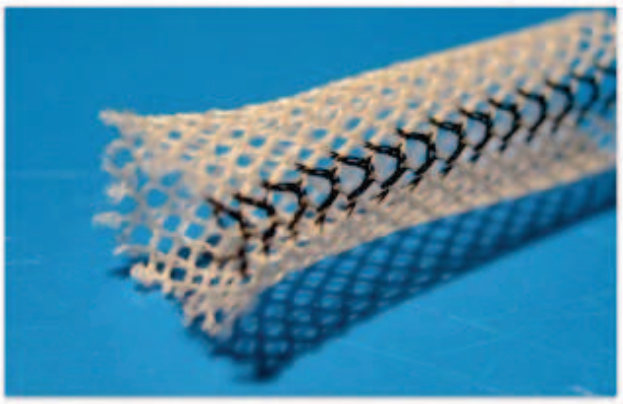

Fig. 2 Provena

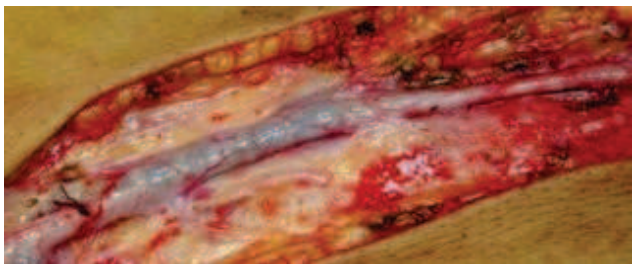

Fig. 3 Proximal segment Varicose Great Saphenous Vein

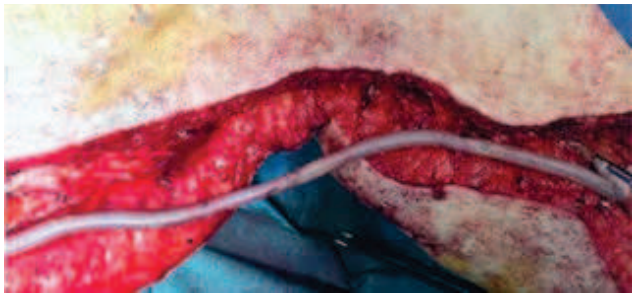

Fig. 4 Femoro-peroneal bypass with Frame™ and varicose Great Saphenous Vein

Fig. 5 Harvested varicose Great Saphenous Vein

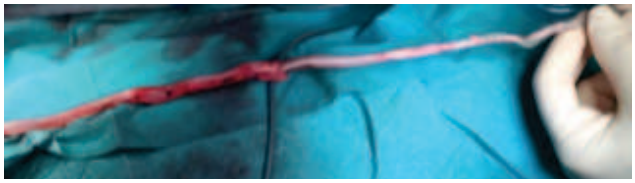

Fig. 6 Frame™ application along varicose Great Saphenous Vein

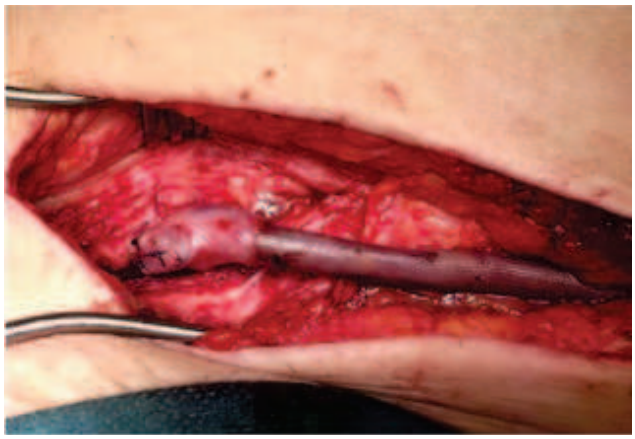

Fig. 7 Proximal anastomosis with Frame™ and varicose Great Saphenous Vein

Autologous veins were evaluated throughout the limb by measuring diameters in standing position for GSV and SSV. When necessary, the veins of the upper extremities (cephalic and basilic veins) were also evaluated. In addition, preoperative computed tomography angiography (CTA) or catheter angiography was performed in selected patients when necessary.

In case of localized dilatations of a segment of the GSV a partial bypass scaffolding (i.e. 10 to 15 cm) was used (Fig 3). Patients with a long segment of varicose vein underwent a completely covered ex situ vein bypass (Fig 4).

During surgery, once the varicose great saphenous vein was harvested (Fig 5), a gradual dilatation to evaluate the losses from the collateral branches and the effective quality of the autologous material was performed. Subsequently, a bench devalvulation of the vein was achieved using Chevalier valvulotome.

Vein devalvulation was performed to obtain an "in situ" vein bypass because the "in situ" conformation seem to offer the potential of grafting to smaller, more distal runoff vessels than was possible with reversed vein grafts. The vein was then marked every 10 cm to calculate its length and avoid twisting of the graft during the external support positioning.

At this point, the external support (Provena or FRAME™) was applied by sliding it along the vein (Fig 6). Once the external support was placed, the proximal anastomosis was performed and the exact length of the vein graft, and of the scaffolding, was in situ evaluated before the distal anastomosis suture (Fig 7-8).

Follow-up was performed at 1, 3, 6 and 12 months and every 6 months thereafter, by clinical examination and morphological evaluation of the bypass using color Doppler ultrasound (Fig 9).

The outcome measures were technical success, 30-day and long-term primary and primary assisted bypass patency, as well as the limb salvage rate. Technical success was defined as the correct positioning of the bypass with intraoperative patency.

Primary patency was defined as time (in months) from initial restoration of vessel patency (index procedure) to any secondary intervention to sustain bypass patency.

Primary-assisted patency was defined as time (in months) from initial procedure to impending failure of the bypass that was retreated during this time due to a significant stenosis but not full thrombosis or occlusion of the graft. External support infection rates upon reoperation for surgical wound infection as well as graft aneurysmal dilatation over time were also analyzed.

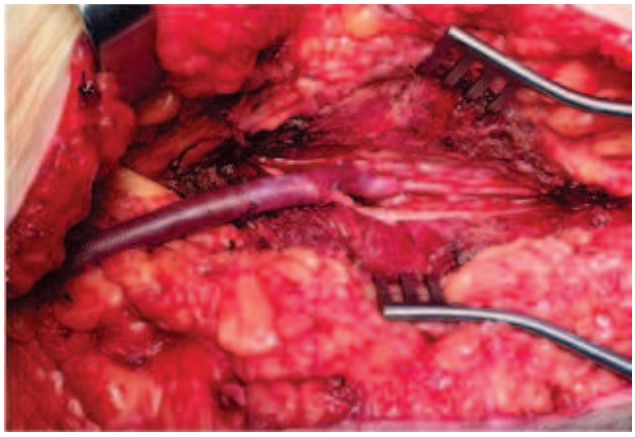

Fig. 8 Distal peroneal anastomosis with Frame™ and varicose Great Saphenous Vein

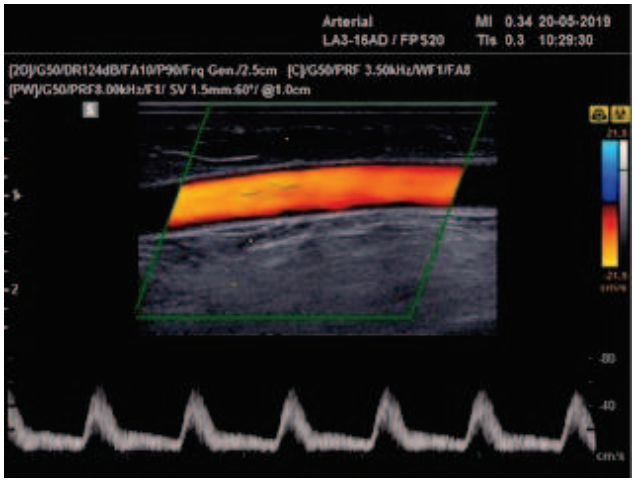

Fig. 9 1-month duplex ultrasound examination of femoro-peroneal bypass with Frame™ and varicose Great Saphenous Vein

Results

During the study period 63 patients underwent infrainguinal bypass with autologous varicose or ectatic venous material. Patient's clinical history and demographics data were reported in table I. In 51 patients (80.9%) the GSV was used, in 3 cases (4.8%) the SSV and in 9 cases (14.3%) a composition of both saphenous veins or with one arm vein. Fifteen (23.8%) patients received a combined anesthesia (i.e. general or spinal anesthesia plus ultrasound locoregional anesthesia with nerve blocks). (Table II). Technical success was achieved in all cases and the mean surgical time was 320±80 minutes. No intraoperative mortality was recorded.

At 30 days the primary patency and limb salvage rate were 97.8%, due to two early bypass occlusions. No infections of the external vascular support were recorded.

During a mean follow-up of 54.6±27.2 months, 8 (13.1%) hemodynamic stenoses requiring reoperation and 3 (4.9%) thromboses of the bypass were found. The primary patency rate was 62.8%, assisted primary 76.3%, with a limb salvage rate of 78%. (Table III)

During the same time, 11 cases without GSV availability were treated by means endovascular procedures. Six (54.5%), after previous coronary artery bypass graft surgery (CABG) and 5 (45.5%) after previous venous system operation as a stripping. In these cases, without GSV availability, the endovascular procedure wasn't the procedure of choice according to the extensive popliteal and infrapopliteal lesions; indeed, primary technical success, primary patency and limb salvage rate were 70.1%, 45.8%, 52% during long-term follow-up.

Table I

Age, median (range)	66	(42-91)
	n	%
Male	47	74.6
Smoking	49	77.7
Hypertension	51	80.9
Diabetes	26	41.3
Hyperlipidemia	29	46.0
Coronary Artery Disease	21	33.3
Renal Insufficiency	10	15.9
Dialysis	2	3.2
Ischemic rest pain	42	66.6
Tissue loss or gangrene	21	33.3
- Rutherford V	19	30.1
- Rutherford VI	2	3.2

Demographic Data and Risk Factors of the Patients

Discussion

Critical limb-threatening ischemia is considered the terminal evolution of chronic obliterating arterial disease and is associated with high rates of limb loss. In recent years it has again been highlighted that venous bypass, in the presence of a suitable great saphenous vein, is preferable to endovascular techniques for revascularization in patients complex arterial disease[1].

Table II

Anesthesia	n	%
GA	21	33.3
SA	41	65.0
LRA	16	25.4
Inflow Artery		
CFA	33	52.4
SFA	19	30.1
DFA	7	11.1
POP	4	6.4
Outflow Artery		
POP	3	4.8
PER	26	41.3
PTA	20	31.7
ATA	14	22.2
Vein Graft Details		
GSV	51	80.9
SSV	3	4.8
GSV+SSV or arm vein	9	14.3

GA=General Anesthesia; SA=Spinal Anesthesia; LRA=Loco Regional Anesthesia; CFA=Common Femoral Artery; SFA=Superficial Femoral Artery; DFA=Deep Femoral Artery; POP=Popliteal Artery; PER=Peroneal Artery; PTA=Posterior Tibial Artery; ATA=Anterior Tibial Artery; GSV=Great Saphenous Vein; SSV=Short Saphenous Vein.

However, there is few evidence regarding bypasses performed with ectatic or varicose venous material.

Starting from numerous studies conducted initially on animals, it was observed that the use of stents and synthetic sheaths for external scaffolding of the varicose vein, in addition to containing the graft avoiding its dilatation, prevent turbulence, thus improving its long-term patency. A stimulus to angiogenesis and the formation of vasa-vasorum was also observed, which significantly reduce the intimal hyperplasia[13-16].

Following this evidence, studies were also conducted on humans, involving the use of a polyester mesh (Provena, Bbraun), with satisfactory results[17-24]. Subsequently, in recent years other materials were produced and marketed as external support for varicose veins (kinking-resistant cobalt-chrome outer mesh-FRAME^{TM}, Vascular Graft Solutions LTD, Tel Aviv, Israel).

Our retrospective twenty-years study has demonstrated that in patients with autologous varicose material, in whom venous bypass surgery has represented a limb salvage treatment and often a life-saving procedure, it is possible to avoid the use of prosthetic material, which generally presents a greater infectious risk, while maintaining good long-term patency 76.3% and satisfactory limb salvage rate (78%), considering the severity of the underlying pathology. Furthermore, no dilatation or infection of the arterialized veins with external scaffolding were observed during the follow-up.

From this point of view, the preservation of the autologous venous material, albeit varicose, using a "saphenous sparing" surgical approach (such as CHIVA), is essential during corrective surgery for superficial venous insufficiency[25-27].

As highlighted by the latest Global international guidelines[1], composite venous bypasses, which also involve the use of autologous veins of the arm, can be a viable option in patients with CLTI and anatomy unfavorable to endovascular treatment or following endovascular failure; however, the results of this type of bypass are highly dependent on operator training and experience, as are bypasses with external scaffolding in case of ectatic or varicose vein material. In general, large single- and multi-center reports demonstrate that arm bypasses and composite venous bypasses perform better than non-autologous grafts on distal targets even though they are inferior to autologous GSV conduits[28,29]. as also reported in present series.

Table III

Primary patency	62.8%
Assisted primary patency	76.3%
Amputation-free survival	78.0%

Results during follow-up at 56 Months

Conclusion

In our experience, the great saphenous vein, even if ectatic or varicose, has proved to be a valuable conduit for the preparation of an infrainguinal bypasses in CLTI patients, with a satisfactory patency and limb salvage rates. In addition, composite vein graft also using arm vein, could be used in infrainguinal bypass with acceptable results.

Also in the light of these results, a "saphenous sparing" surgical approach during corrective surgery for venous insufficiency of the lower limbs should be recommended, so as not to preclude future surgical treatments for limb salvage.

References

1) Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. J Vasc Surg 2019;69:3-125.

2) Martelli E, Federici M. Venous distal bypass should be considered as the gold standard to finally attempt limb salvage in patients with severe critical limb ischemia and diabetic foot, or under dialysis. Acta Diabetol. 2020 Aug;57(8):1019-1020.

3) Klinkert P, Post PN, Breslau PJ, et al. Saphenous vein versus PTFE for above-knee femoropopliteal bypass. Areview of the literature Eur J Vasc Endovasc Surg 2004; 27:357.

4) Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007; 45(Suppl S): S5.

5) Faries PL, Arora S, Pomposelli FB Jr, et al. The use of arm vein in lower-extremity revascularization: Results of 520 procedures performed in eight years. J Vasc Surg 2000;31(1 Pt 1):50.

6) Calligaro KD, Syrek JR, Dougherty MJ, et al. Use of arm and lesser saphenous vein compared with prosthetic grafts for infrapopliteal arterial bypass: Are they worth the effort? J Vasc Surg 1997;26:919.

7) Gentile AT, Lee RW, Moneta GL, et al. Results of bypass to the popliteal and tibial arteries with alternative sources of autogenous vein. J Vasc Surg 1996;23:272.

8) Chew DK, Conte MS, Donaldson MC, et al. Autogenous composite vein bypass graft for infrainguinal arterial reconstruction. J Vasc Surg 2001;33:259.

9) Davies AH, Magee TR, Sheffield E, et al. The aetiology of vein graft stenoses. Eur J Vasc Surg 1994;8:389.

10) Van VR, Kruse RR, Fritschy WM, et al. Treatment of dilated venous bypass grafts with an expanded polytetrafluoroethylenecovered nitinol endoprosthesis. Vasc Endovasc Surg 2009;43:190.

11) Armstrong PA, Bandyk DF, Wilson JS, et al. Optimizing infrainguinal arm vein bypass patency with duplex ultrasound surveillance and endovascular therapy. J Vasc Surg 2004;40(4):724e30.

12) Panetta TF, Marin ML, Veith FJ, et al. Unsuspected preexisting saphenous vein disease: An unrecognized cause of vein bypass failure. J Vasc Surg 1992;15:102.

13) Jeremy JY, Gadsdon P, Shukla N, et al. On the biology of saphenous vein grafts fitted with external synthetic sheaths and stents. Biomaterials 2007;28:895.

14) Vijayan V, Smith FC, Angelini GD, et al. External supports and the prevention of neointima formation in vein grafts. Eur J Vasc Endovasc Surg 2002;24:13.

15) Violaris AG, Newby AC, Angelini GD, et al. Effects of external stenting on wall thickening in arteriovenous bypass grafts. Ann Thorac Surg 1993;55:667.

16) Dashwood MR, Angelini GD,Wan S, et al. Does external stenting reduce porcine vein graft occlusion via an action on vascular nerves. J Card Surg 2002;17(6):556e60.

17) Arvela E, Kauhanen P, Alback A, et al. Initial experience with a new method of external polyester scaffolding for infrainguinal vein grafts. Eur J Vasc Endovasc Surg 2009;38:456.

18) Moritz A, Grabenwoger F, Raderer F, et al. Mesh tube–Constricted varicose veins used as bypass grafts for infrainguinal arterial reconstruction. Arch Surg 1992;127:416.

19) Carella GS, Stilo F, Benedetto F, David A, Risitano DC, Buemi M, Spinelli F. Femoro-distal bypass with varicose veins covered by prosthetic mesh. J Surg Res 2011;168:189-94.

20) Achim Neufang, MD, PhD, Christine Espinola-Klein, MD, PhD, Savvas Savvidis, MD, et al. External polytetrafluoroethylene reinforcement of varicose autologous vein grafts in peripheral bypass surgery produces durable bypass function. J Vasc Surg 2018;67:1778-87.

21) Neufang A, Dorweiler B, Espinola-Klein C, et al. External reinforcement of varicose vein with PTFE prosthesis in infrainguinal bypass surgery e clinical results. Thorac Cardiov Surg 2003;51:62-6

22) Mellière D, Desgrange P, Allaire E, et al. Long term results of venous bypass for lower extremity arteries with selective short segment prosthetic reinforcement of varicose dilatations. Ann Vasc Surg 2007;21:45e9.

23) Mellière D, Le Chevillier B, Kovarsky S, et al. Wrapped autologous greater saphenous vein bypass for severe limb ischemia in patients with varicose veins. Preliminary report. J Cardiovasc Surg (Torino) 1995;36:117e20.

24) Moritz A, Grabenwoger F, Raderer F, et al. Use of varicose veins as arterial bypass grafts. Cardiovasc Surg 1993;1:508.

25) Franceschi C. Théorie et pratique de la cure conservatrice et hemodynamique de l'insuffisance veineuse en ambulatoire [Theory and practice of conservative and haemodynamic treatment of venous insufficiency in oupatients]. Precy-sous-Thil France Editions de l'Armançon 1988.

26) Zamboni P., Marcellino M. G., Cappelli M., Feo C. V., Bresadola V., Vasquez G., Liboni A. Saphenous vein sparing surgery: principles, techniques and results. The Journal of Cardiovascular Surgery 1998 April;39(2):151-62

27) Passariello F, Ermini S, Cappelli M, Delfrate R, Franceschi C. The office based CHIVA. Journal of Vascular Diagnostics 2013;1:13-20 DOI: 10.2147/JVD.S49637

28) Faries PL, LoGerfo FW, Arora S, Hook S, Pulling MC, Akbari CM, et al. A comparative study of alternative conduits for lower extremity revascularization: all-autogenous conduit versus pros- thetic grafts. J Vasc Surg 2000;32:1080e90.

29) Brochado Neto F, Sandri GA, Kalaf MJ, Matielo MF, Casella IB, Godoy MR, et al. Arm vein as an alternative autogenous conduit for infragenicular bypass in the treatment of critical limb ischaemia: a 15 year experience. Eur J Vasc Endovasc Surg 2014;47:609e14.