

Stenosis of reverse great saphenous vein graft in infrainguinal arterial revascularization

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SUMMARY

Objective: The aim of this study was to evaluate the prevalence of hemodynamically significant infrainguinal bypasses stenosis using reverse great saphenous vein graft. **Methods:** From March of 2008 to March of 2009, 56 infrainguinal bypasses were performed with reverse great saphenous vein graft in 56 patients. On the 30th post-operative day, 32 out of 56 patients were submitted to vascular ultrasonography. The prevalence of significant graft stenosis was determined. In addition, the diagnosis of stenosis was related to the clinical and surgical characteristics of the patients. The variables analyzed at the moment of diagnosis were the localization of the graft stenosis, the risk factors associated with stenosis and the association of vascular ultrasonography findings with ankle-brachial pressure index (ABI). **Results:** The overall prevalence of significant graft stenosis was 48.4%. Out of the total number of observed stenosis, 19.4% were considered severe, and 29% mild or moderate. There was no significant association between the presence of significant stenosis and the following variables: gender, diabetes, hypertension, smoking, hipercholesterolemia, graft diameter, site of the distal anastomosis, and graft composition. There was a weak agreement between ABI and vascular ultrasonography in detecting stenosis in general ($K = 0.30$; $CL95\% 0.232 - 0.473$; $p = 0.018$). However, there was a substantial agreement in detecting severe stenosis ($K = 0.75$; $CL95\% 0.655 - 0.811$; $p = 0.0001$). **Conclusion:** There was a high prevalence of stenosis on the 30th post-operative day, mostly localized in the proximal half of the vein graft. There was no significant association of stenosis with clinical and surgical factors analyzed. ABI and vascular ultrasonography had weak agreement with the diagnosis of stenosis in general and an important agreement for the diagnosis of severe stenosis.

Keywords: Color Doppler ultrasonography; Pulsed Doppler ultrasound; vascular graft occlusion; angiography; vascular patency.

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INTRODUCTION

The bypass using the great saphenous vein to treat critical lower limb ischemia is a time-honored therapeutic option, showing reduced surgical mortality ratios and good success rates in preserving the ischemic limb¹. This operation, however, is subject to frequent graft stenosis both in anastomoses and in the great saphenous vein body resulting from myointimal hyperplasia and/or technical matters, mainly over the first postoperative year. These stenoses can progress to a great saphenous vein thrombosis and cause the procedure failure².

The development of the vascular ultrasonography enabled noninvasive hemodynamic monitoring after lower limb bypasses. Many studies³ showed the method accuracy in diagnosing significant stenoses and thus surgical interventions to treat stenoses threatening the vein patency could be carried out before thrombosis occurrence. Vascular ultrasonography also enabled prevalence and natural history of venous graft stenoses to be known. The stenoses occurring earlier progress more rapidly to critical stenosis, compared with later stenoses, thus stressing the ultrasonography importance in early postoperative period⁴. The best way to follow-up the patients postoperatively remains controversial, and routine ultrasound surveillance has not been recommended by the TASC II consensus, based on an European multicenter study results⁵.

International reports have showed ultrasonography benefit in the early diagnosis of stenoses, but there are no similar studies in Brazil. Thus, this study purpose is to know the prevalence of stenoses in great saphenous vein infrainguinal bypasses, their distribution along the graft, as well as the associated risk factors. An additional purpose was to study the concurrence between the ABI⁶ and vascular ultrasonography in diagnosing stenoses.

METHODS

This study was approved by the Ethics Research Committee at *Universidade Federal de Minas Gerais* (protocol ETIC 339/07). In this study, patients undergoing infrainguinal bypass with reverse great saphenous vein graft at the Hospital Tolentino Neves (Belo Horizonte, MG) from March 2008 to March 2009 were included. All patients had lower limb obstructive arterial disease that was atherosclerotic in origin and showed severe ischemia grade (trophic lesion or pain at rest). Patients who died over the postoperative period, who had saphenous vein thrombosis before the ultrasonography, those undergoing lower limb bypass using conduits other than the great saphenous vein, those who did not attend for the postoperative ultrasonography and those who did not adhere to the protocol were excluded from the study.

Data regarding the surgical procedure, such as graft extension, diameter of the vein and the venous segments,

and ABI measurement at the hospital discharge, were collected and commented about at the questionnaire used in this study.

After hospital discharge, the patients were instructed to come to a follow-up visit on the postoperative 30th day for clinical reevaluation, ABI measurement and a revascularized limb ultrasonography. The patients were examined in the supine position with light hip joint abduction and light knee flexion. Ultrasound examinations were carried out using the ultrasound machine GE Vivid 6 (GE, USA), by a single examiner and using a linear transducer with the frequency ranging from 5 MHz to 10 MHz. The color Doppler box was angulated 60 degrees. The ultrasound examination followed the sequence below:

- Initially, the whole venous graft track was covered by the ultrasound linear transducer in the color mode, with increased focal velocity being observed.
- The peak systolic velocity (PSV) recorded in the donor artery, in the proximal anastomosis, in proximal, middle, and distal thirds of the venous graft, in the distal anastomosis and in the recipient artery was obtained.

The anastomoses and the graft were characterized for the presence of stenoses⁷ by using the arterial blood flow velocity criteria for stenosis classification. The peak systolic velocity (PSV) and the velocity ratio (VR) were considered. The severe stenoses were classified as those with a PSV higher than 300 cm/s and VR higher than 3.5; moderate stenoses were those with PSV 180 to 300 cm/s e VR 2 to 3.5; absent stenosis was shown when PVS was lower than 180 cm/s and VR was lower than 2.

The patients with mild to moderate stenosis were assigned to clinical examination and serial ultrasonographies. Those with severe stenosis or a graft body velocity lower than 45 cm/s and/or ABI fall higher than 0.15, compared to the hospital charge examination, were assigned to an arteriography and a new surgical procedure, in case the stenosis was confirmed⁸.

STATISTICAL ANALYSIS

The qualitative variables analyzed were clinical features, gender, diabetes, smoking, hypertension, great saphenous vein diameter, distal anastomosis site, ABI variation.

The quantitative variables analyzed were age and blood flow velocity in bypass segments. The analysis was done by minimum and maximum value observed and by calculating the means and standard deviations. For qualitative analysis, absolute and relative frequencies were calculated.

The agreement between stenosis diagnosis by vascular ultrasonography and the ABI was tested through the kappa index of agreement. This index ranges from zero to 1.0. A K value < 0.45 indicates low reproducibility (agreement) between the methods compared; K values between 0.45 and 0.75 indicate good reproducibility; K values > 0.75 indicate optimal reproducibility between the methods compared⁹.

Fisher's exact test was used to test the association between qualitative variables and stenosis presence for expected frequencies lower than 5 or the chi-square test was used when frequencies were expected to be higher. The significance level used for the tests was 5%.

RESULTS

Out of 56 infrainguinal bypasses using reverse great saphenous vein, five patients experienced early occlusion from bypass thrombosis, three died, and 16 did not show up on the 30th day to undergo an ultrasonography.

The group who came to the follow-up consisted of 32 patients (21 males, 61.6%), representing 57.1% of operated patients. The clinical features of patients are listed in Table 1. In one patient, the ultrasonography could not be performed because of a technical difficulty. He was obese and had an infected dehiscent wound, precluding the graft full extension view. Thus, in 31 patients (55.4%), the ultrasonography and the achievement of the used data were possible in this study analysis.

After the vascular ultrasonography, the patients were classified into three groups, according to stenoses found in the grafts: no stenosis, 16 patients (51.6%); mild/moderate stenosis, nine patients (29%); marked stenosis, six patients (19.4%).

The patients with severe stenosis were assigned to arteriography and underwent stenosis repair after the diagnosis was confirmed. Out of six patients assigned to arteriography, one had a graft occlusion and five patients had stenoses repaired by endovascular treatment. All these stenoses were found at the graft proximal segment. The patients with a mild to moderate stenosis were instructed on the need to undergo serial sonographic assessments and those without a stenosis were recommended a quarterly sonographic assessment over the first year. The association among clinical

and demographic variables, graft composition and the presence of stenoses was studied. In the current study, there was no significant association between the variables studied and the presence of bypass stenoses (Table 2).

Table 3 shows there was an agreement between the ABI and vascular ultrasonography in 67.74% of patients whose outcome was significant ($p = 0.018$). Upon assessing the agreement grade by the Kappa index, a weak agreement was observed (Kappa index < 0.45). Upon diagnosing severe stenoses, an agreement between the ABI and vascular ultrasonography was found in 91.30% of patients, a significant result ($p = 0.0001$). Upon assessing the agreement grade by the Kappa index, the agreement was fair (Kappa index 0.75).

DISCUSSION

The current study found a high rate of stenoses in grafts¹⁰. All patients studied had critical ischemia as a surgery indication and 2/3 bypasses were infrapopliteal. This finding is substantially different from the cited papers reporting significant intermittent claudication and a lower obstructive arterial disease intensity in lower limbs, reflected by the high percentage of femoropopliteal revascularizations. It must be underscored that six patients with a severe stenosis were referred to surgical treatment, stressing the need of an earlier sonography. The treatment of lower limb critical ischemia by revascularizations using the great saphenous vein needs a preoperative planning to select the bypass configuration and the postoperative clinical and sonographic surveillance strategy to reach the long-term required patency rates.

In 1973, Szilagyi *et al.*¹¹ demonstrated by postoperative follow-up arteriography that one-third of infrainguinal bypasses with great saphenous vein developed stenoses requiring surgical repair within the first postoperative year. More recent studies confirmed prior findings¹² and identified myointimal hyperplasia as the mechanism responsible for stenosis appearance¹³, making postoperative follow-up of patients a requirement.

The ultrasonography on the 30th day aims at identifying severe stenoses that should be repaired and mild to moderate stenoses that need continued surveillance, as their natural history is unfavorable compared with stenosis-free bypasses. By ultrasonography, it is possible to assess the venous graft adaptation to the arterial flow and the myointimal hyperplasia pattern developed by each saphenous bypass, while predicting the graft biological behavior, their trend to stenosis appearing and consequent occlusion risk.

Stenoses in venous grafts in early postoperative period have a poor clinical course. Wilson *et al.*¹⁴ assessed 123 patients undergoing lower limb revascularization by means of vascular ultrasonography performed at the hospital discharge and found a 37% stenosis prevalence. In 26 (57%) patients with stenoses, there was a worsening,

Table 1 – Clinical characteristics of patients

Clinical characteristics	Total (%)
Males	21 (61.6%)
Diabetes mellitus	9 (29%)
Kidney failure	1 (3.2%)
Hypertension	18 (58.1%)
Hypercholesterolemia	21 (67.7%)
Smoking	18 (58.1%)
Intermittent claudication	0 (0.0%)
Pain at rest	4 (12.9%)
Trophic lesion	27 (87.1%)
Supragenicular femoropopliteal bypass	5 (16.1%)
Infragenicular femoropopliteal bypass	5 (16.1%)
Distal femoral	21 (67.7%)
Great saphenous vein diameter > 3 mm	27 (87.1%)
Composite graft*	05 (16.1%)

*Graft consisting of 2 great saphenous vein segments joined by an end-to-end anastomosis.

Table 2 – Statistical analysis of the variables associated with stenosis prevalence in 31 infrainguinal bypasses using the great saphenous vein

Variable	Odds Ratio	95%CI	p Value
Gender	2.57	0.52 – 12.72	0.2485
Diabetes mellitus	0.50	0.10 – 2.52	0.4013
Smoking	1.60	0.38 – 6.82	0.5252
Hypertension	0.55	0.13 – 2.31	0.4109
Hypercholesterolemia	1.36	0.30 – 6.28	0.6907
Distal femoral bypass	1.36	0.30 – 6.28	0.6907
*Diameter < 3 mm	0.36	0.03 – 3.90	0.4000
**Composite graft	0.78	0.11 – 5.46	0.8004

*Great saphenous vein graft diameter assessed by vascular ultrasonography. **Graft consisting of 3 2 great saphenous vein segments.

Table 3 – Ankle-brachial index and vascular ultrasonography compared for diagnosing overall stenoses and severe stenoses

Methods compared	N concurrent cases (%)	K	95%CI	p
Ankle-brachial index with vascular ultrasonography in overall stenoses	67.74	0.305	0.232 a 0.473	0.018
Ankle-brachial index with vascular ultrasonography in severe stenoses	91.30	0.7473	0.655 a 0.811	—0.0001

with impaired hemodynamics requiring a surgical intervention. Nielsen¹⁵, by following 42 patients, demonstrated poor clinical course in early stenoses compared with late stenoses (one-year patency 51% vs. 92%, $p = 0.03$). Ferris *et al.*¹⁶ reviewed 224 lower limb revascularizations and identified a 26% stenosis prevalence in ultrasonography imaging performed within the first six weeks. The group of patients with stenosis showed a five-year patency lower than the stenosis-free group (77 vs. 83, $p = 0.05$), even with sonographic surveillance, having demonstrated partially limited interventions in extending the graft survival.

The quality of the venous graft used in bypasses is a determinant factor for stenosis development; among the graft characteristics, its diameter is increasingly considered by surgeons. In the current study, the influence of the graft diameter on stenosis appearing is reviewed. The majority of grafts (27 grafts/87.1%) reviewed had a diameter > 3 mm, a fact that can be explained by the preoperative selection or by the higher early thrombosis incidence in reduced diameter grafts which would not be a part of the sample studied on the 30th postoperative day. In this sample, a significant relationship between graft diameter and stenosis could not be identified. Idu *et al.*¹⁷ reviewed 300 bypasses with autologous grafts to identify risk factors associated with stenoses. After multiple regression analysis in which several factors were considered, such as graft extension, proximal and distal anastomosis sites, venovenous anastomoses at the graft body, technique used (*in situ* or reverse) and atherosclerosis risk factors, the only independent factor predicting stenosis was a graft diameter lower than 3.5 mm. The great saphenous

vein grafts with a diameter < 3.5 mm showed lower patency compared with alternative grafts constructed from arm veins or the small saphenous vein and, according to the authors, the former should not be used when the latter is available.

Another aspect to be considered when reviewing the venous graft quality and its proneness to developing stenoses is the venovenous anastomoses at the graft body joining non-adjacent segments of the great saphenous vein. This technique is used when great saphenous vein segments show macroscopic changes indicating that segment is inappropriate, such as no dilatation when prepared or wall thickening secondarily to prior inflammatory processes. In settings with insufficient extension of the available great saphenous vein, the construction of the venovenous anastomosis with a contralateral great saphenous vein segment or alternative venous grafts is required. The stenoses could appear in anastomosis sites or in vein segments with microscopic changes. In the current study, five saphenous bypasses (16.1%) were constructed from composite grafts: two (40%) with stenoses on the early sonographic imaging and a prevalence similar to that found in other bypasses (odds ratio [OR]: 0.36; $p = 0.4$). A multicenter study with patients from the PREVENT III study pointed out technical aspects associated with the graft thrombosis. One of the aspects studied was the composite graft patency (with venovenous anastomoses)¹⁸. In that study, 15% of grafts were composite grafts, with a reduced one-year primary patency compared with grafts consisting of a single great saphenous vein segment (OR: 1.47; 95% confidence interval [95%CI]: 1.18-1.84).

The graft extension and the distal anastomosis site can determine the stenosis arising, depending on the blood flow velocity, as reduced velocities stimulate myointimal hyperplasia¹⁹. The bypasses with distal anastomoses located at the popliteal artery have higher flow velocity compared with infrapopliteal bypasses because of the difference in blood outflow found²⁰. In the present paper, 67.7% of reviewed bypasses had a distal anastomosis at infrapopliteal arteries, reflecting clinical picture severity in these patients. There was no significant differences in prevalence for stenoses between femoropopliteal and infrapopliteal bypasses (40% vs. 47.6%, $p = 0.445$).

In this series, most stenoses were at the bypass proximal segment (proximal anastomosis, proximal and middle thirds in the venous graft). One of the explanations for this fact is the reverse great saphenous vein use, whose segment with the largest diameter and the least sensitive to stenoses in the great saphenous vein corresponds to the bypass distal third. A similar distribution is found in the literature²¹. No papers reviewing the different stenosis locations when the bypass was constructed with the great saphenous vein in a *in situ* position were found; if it is adopted, the anastomosis diameter will be gradually reduced from proximal to distal.

The clinical significance of stenoses located at the proximal artery and at the proximal anastomosis and their prognostic importance has been debated. Some authors²² demonstrated the stenoses located at that segment are poorly symptomatic, compared with those located at the bypass distal segments. Others debate the prognostic significance of stenosis located at the proximal anastomosis, as well as their repair benefit²³. The increased flow velocity at the proximal anastomosis is frequently found on routine sonographic imaging and may not be related to the stenosis. At this location, the blood flow undergoes hemodynamic changes secondary to a caliber and thickness mismatching between the artery and vein anastomosed, which is not observed when the blood flow is assessed at the venous graft body. Maybe velocity criteria are not either valid as an indication of graft body stenosis or they do not have the same prognostic value when applied to flow analysis at the proximal anastomosis.

The main reason for using vascular ultrasonography in postoperative follow-up in lower limb revascularizations is the feasibility of identifying stenoses that would increase the graft occlusion risk even if they are not identified by a clinical evaluation. The clinical evaluation is based on a reduced ABI. The ABI measurement and its comparison with the prior examination can indicate graft stenoses when there is a fall higher than 0.15. In the investigation sample, four patients with an ABI fall were identified, all of them with a severe stenosis found by ultrasonography. Despite the good agreement observed between the ABI and ultrasonography to diagnose severe stenoses ($k = 0.7473$),

the ABI did not identify two patients with severe stenoses and nine with mild to moderate stenoses, all of them detected by ultrasonography. Thus, the postoperative surveillance strategy based only on the ABI measurement may not screen patients with severe stenoses requiring immediate interventions. In addition, it would not identify mild to moderate stenosis grafts requiring continued surveillance in view of a possible stenosis progression.

Bandyk *et al.*²⁴ stressed that about 20% to 40% of patients having a stenosis with hemodynamic impact identified by vascular ultrasonography did not experience symptoms or a ABI fall. Papanicolaou *et al.*²⁵ pointed out there is no correlation between the ABI variations and peak systolic velocity variations in stenoses measured by vascular ultrasonography. Green *et al.*²⁶, in a prospective study, compared both postoperative graft surveillance methods. Patients with ABI fall and with ultrasound evidence of mild to moderate stenosis along the graft had 4% of acute graft thrombosis. In those with an ABI fall higher than 0.10 associated with ultrasound diagnosis of hemodynamically significant stenosis, the graft thrombosis risk was 66%, showing the importance of the ABI fall in identifying thrombosis risk in grafts.

STUDY LIMITATIONS

The current study is limited by the reduced sample size, thus precluding stenosis-related risk factors to be identified. Developing a logistic regression model with several risk factors and a larger sample of patients is desirable for future associations. Another limitation regards the lost to follow-up patients compared to the early cases. This fact occurred because of the early graft occlusion and because of patients' non-attendance to postoperative surveillance examination. These latter patients could have grafts with a different stenosis prevalence compared to the sample studied, changing the outcome. A hypothesis that would warrant non-attendance could be attributed to a course with no stenosis and consequently a successful operation. Several measures are required to reduce the graft early occlusion: observation of the operation quality during surgery via imaging; identification of patients with thrombophilias to start systemic anticoagulation early and surgical team training to reduce occlusion resulting from technical failures. The patients' adherence to regular postoperative surveillance should be encouraged by the health team and those who drop out should be encouraged to return.

CONCLUSION

This paper indicates that, as a result of the high graft stenosis prevalence and the recognizedly poor outcomes, especially in early stenoses, vascular ultrasonography should be routinely performed as a part of the follow-up on the 30th postoperative day. After the sonography is performed, different postoperative follow-up strategies can be estab-

lished for patients with early graft stenoses. These patients could be benefited by ultrasound surveillance added to the clinical examination. However, the ultrasound surveillance strategy restricted only to early stenosis patients was not tested in the current study. Further prospective studies are required to prove this approach relevance and efficacy.

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