Three-year outcome of the heparin-bonded Viabahn for superficial femoral artery occlusive disease

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Objective: **Self-expanding covered stents for superficial femoral artery (SFA) occlusive disease have undergone an evolution during the years. Early results of the latest generation, the heparin-bonded Viabahn (W. L. Gore & Associates, Flagstaff, Ariz) with a contoured proximal edge, were promising, with reported 1-year primary patency rates of 73% to 78% in long lesions. The aim of this study was to present the 3-year outcome of the heparin-bonded Viabahn for SFA occlusive disease.**

Methods: **All patients treated with a heparin-bonded Viabahn in three centers between April 2009 and December 2011 were included in the study and retrospectively analyzed. Clinical state in Rutherford category, ankle-brachial indexes, and duplex ultrasound scans were the features of follow-up at 6 weeks and 6, 12, 24, and 36 months. Primary end points of the study were the 3-year primary, primary assisted, and secondary patency rates.**

Results: **A total of 73 SFAs in 70 patients were treated with a heparin-bonded Viabahn and included in the study. Fifty-four patients were male (77%), and the mean age was 70.0 ± 9.1 years. The mean lesion length was 17.4 ± 7.0 cm, and 84% were classified TransAtlantic Inter-Society Consensus II types C and D. The median follow-up was 25 months (range, 2-55 months). The 3-year primary, primary assisted, and secondary patency rates were 59%, 71%, and 82%, respectively, with a 3-year freedom from amputation of 100%.**

Conclusions: **The use of a heparin-bonded Viabahn for SFA occlusive disease is related to patency rates within limits of surgical reconstruction. The procedure is related to low morbidity and amputation rates. (J Vasc Surg 2015;62:984-9.)**

Plain balloon angioplasty and bare-metal stenting yield good results for short occlusive and stenotic lesions in the superficial femoral artery (SFA). Results, however, tend to decrease with lesion length. For that reason, alternative strategies have been developed, including atherectomy, paclitaxel-based technologies, and use of covered stents. Initially, the use of covered stents was related to mixed results, likely to be due to a variety of patient and lesion characteristics, treatment protocols, and improvements of the covered stent.[1,2] The latest generation Viabahn (W. L. Gore & Associates, Flagstaff, Ariz) has incorporated the heparin-bonding technology, and the proximal edge has been reshaped toward a contoured edge to prevent infolding in case of oversizing. Moreover, longer stents are now available, reducing the number of overlap zones. Initial 1-year results of three case series and one randomized trial have demonstrated a primary patency rate of 67% to 78%.[3-6] The randomized VIASTAR trial (Viabahn endoprosthesis with Propaten bioactive surface vs bare nitinol stent in the treatment of long lesions in SFA occlusive disease) comparing the heparin-bonded Viabahn with bare-metal stents proved the superiority of the Viabahn over bare-metal stents at 24 months.[7] There was, however, no significant impact on clinical outcome and target revascularization rate. Recently, the performance and safety of the 25-cm-long heparin-bonded Viabahn were assessed in TransAtlantic Inter-Society Consensus II (TASC II) type C and D lesions, showing 1-year primary and secondary patency rates of 67.0% and 96.9%, respectively.[6]

In the previously published 1-year results of our two-center cohort[3] of 56 limbs treated with the heparin-bonded Viabahn, the primary patency at 1 year was 76%, with a primary assisted rate and a secondary patency rate of 82% and 89%, respectively. As patency rates may decrease over time, it is essential to assess a prolonged follow-up. The aim of this study was to assess the 3-year

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outcome of the heparin-bonded Viabahn in the treatment of SFA occlusive disease. To increase the sample size, a third center was added to the cohort.

METHODS

Patient population. All patients treated with a heparin-bonded Viabahn between April 2009 and December 2011 in one of the three participating hospitals (Rijnstate Hospital, Arnhem; Isala Clinics, Zwolle; and St. Antonius Hospital, Sneek, The Netherlands) were gathered in a database and retrospectively analyzed. The initiation time of the randomized SUrgical vs PERcutaneous Bypass (SuperB) trial, comparing the heparin-bonded Viabahn with the venous femoropopliteal bypass, was the end date of inclusion in the present study.[8] Patients of this cohort may also have been included in other subanalyses.[3,9-12] Data were retrospectively collected and anonymously analyzed. Retrospective research of patients' charts is not in the scope of the Dutch Law on research with human participants, and therefore neither formal approval of the Central Committee on Research Involving Human Subjects nor patient consent was required.

Indication for intervention included disabling claudication and critical limb ischemia. In all patients, secondary risk prevention was performed according to national guidelines, and patients with disabling claudication were primarily treated with supervised walking exercise. The choice for endovascular treatment with a covered stent was based on anatomic suitability and preferences of the patient and interventionalist. Interventions were performed by vascular surgeons and interventional radiologists.

Patient characteristics, medical history, clinical state, and demographics were retrieved. Clinical state was classified by the Rutherford system,[13] cardiovascular risk factors according to the Society for Vascular Surgery and American Association for Vascular Surgery medical comorbidity grading system, and lesion characteristics according to the TASC II criteria.[14] Procedural aspects and postprocedural data were retrieved from the case files. Standard follow-up consisted of clinical assessment, ankle-brachial index measurements, and duplex ultrasound examination at 6 weeks, 6 months, and 12 months and annually afterward.

Treatment protocol. The treatment protocol has been described before.[3] In summary, the common femoral artery was approached either percutaneously or by surgical cutdown. In case of a concomitant lesion in the common or deep femoral artery, an endarterectomy was performed. The stenotic section was passed with a Terumo wire (Terumo Medical Corporation, Elkton, Md) and a catheter, and a distal re-entry was made. The diseased segment was dilated, and endografts (Viabahn endoprostheses) were placed from distal to proximal with minimal oversizing. The entire diseased segment was covered with endografts, which were postdilated with an angioplasty balloon of the same size as the endograft. Control angiography of the endograft and outflow vessels was routinely performed. All patients received statin treatment and dual antiplatelet inhibitors for at least 6 months, unless oral anticoagulation was indicated for other reasons.

Table I. Baseline characteristics including cardiovascular risk factors, Rutherford classification, and ankle-brachial index (*ABI*)

Tobacco use	39 (56)
Hyperlipidemia	54 (77)
Diabetes mellitus	30 (43)
Hypertension	59 (84)
Renal failure	15 (21)
Pulmonary disease	16 (23)
Coronary artery disease	26 (37)
Cerebrovascular disease	8 (11)
Rutherford classification	
3	51 (73)
4	7 (10)
5	11 (16)
6	1 (1)
ABI	0.59 ± 0.17
ABI exercise (n = 15)	0.39 ± 0.23
ASA class	
1	1 (1)
2	32 (46)
3	34 (49)
4	3 (4)

ASA, American Society of Anesthesiologists.
Continuous variables are presented as mean ± standard deviation, and categorical variables are presented as number (%).

Definitions. Primary patency was defined as the absence of restenosis or occlusion in the treated segment as measured on duplex ultrasound. Primary assisted patency was defined as patency achieved by secondary endovascular interventions to treat restenosis of the target vessel. Secondary patency was defined as patency achieved by all procedures aimed at recanalizing an occluded endograft, preserving the endograft. Restenosis was defined as a peak systolic velocity ratio >2.5, as measured on duplex ultrasound.[15] An occlusion was defined as absence of flow in the treated segment. A failure of the endoluminal graft was defined as occlusion of the endograft, with or without clinical symptoms, not responding to therapy. Limb salvage was defined as the absence of an above-ankle amputation.

End points. The primary end points of this study were the 3-year primary, primary assisted, and secondary patency rates of the endograft. Secondary end points included adverse outcomes, defined as secondary interventions and amputation rate.

Statistical analysis. Normality was tested with the Shapiro-Wilk test. Categorical variables are presented as numbers followed by percentages; continuous variables are presented as mean ± standard deviation or as median with

Table II. Lesion characteristics including lesion length, popliteal level, and outflow vessels

Left leg/right leg	34 (47)/39 (53)
Lesion length, cm	17.4 ± 7.0
Flush occlusion	21 (28)
Occlusions	40/73 (55)
TASC II	
A	1 (1)
B	9 (15)
C	24 (33)
D	37 (51)
Popliteal level	
P1	50 (69)
P2	20 (27)
P3	3 (4)
Outflow vessels	
0	1 (1)
1	6 (8)
2	14 (19)
3	52 (71)

TASC II, TransAtlantic Inter-Society Consensus II.
Continuous variables are presented as mean ± standard deviation, and categorical variables are presented as number (%).

range when appropriate. Patency rates were determined by the Kaplan-Meier life-table method. Cox regression analyses were performed to analyze potential risk factors for loss of primary patency. *P* values < .05 were considered statistically significant. All analyses were performed with SPSS 22.0 (SPSS Inc, Chicago, Ill).

RESULTS

A total of 73 SFAs in 70 patients were treated with a heparin-bonded Viabahn during the study period and were included in the study group. Fifty-four patients were male (77%), and the mean age was 70.0 ± 9.1 years. Patient characteristics are shown in Table I. Fourteen patients (20%) had previously undergone treatment of the ipsilateral leg, which consisted of angioplasty of the SFA (n = 7), angioplasty of the iliac artery (n = 1), angioplasty of the iliac artery and stent placement of the iliac artery (n = 2), aortoiliac bypass surgery (n = 1), and endarterectomy of the common femoral artery (n = 1). Two patients had already undergone an ipsilateral toe amputation. Lesion characteristics are shown in Table II.

Procedural aspects. Twenty-two subjects (30%) were treated under local, 26 (36%) under spinal, and 25 (34%) under general anesthesia. During all procedures, heparin was administered intravenously. Twenty-four lesions (34%) were treated with one endograft, 23 (31%) with two endografts, 25 (34%) with three endografts, and 1 (1%) with four endografts. In total, 149 endografts were used, of which 9 (6%) had a diameter of 5 mm, 116 (78%) had a diameter of 6 mm, 22 (15%) had a diameter of 7 mm, and 2 (1%) had a diameter of 8 mm. Concomitant treatment was performed in 29 procedures (39%), consisting of endarterectomy of the common femoral artery (n = 13), angioplasty of the iliac arteries (n = 7), angioplasty of the popliteal artery (n = 3), endovascular abdominal aneurysm repairs (n = 2), surgical débridement of an ulcer (n = 2), and toe amputation (n = 1); one subject was treated with thrombolytic therapy because of preprocedural crural thrombosis.

There were two procedural complications: one due to a perioperative thrombosis, which was treated with thrombolysis; and one due to a dissection of the popliteal artery, which was treated with an additional endograft.

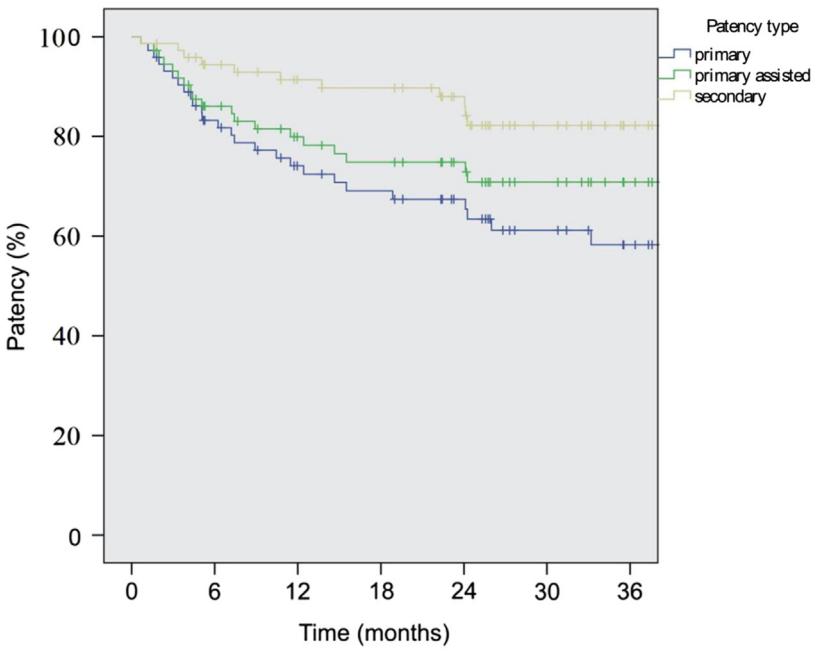
Postoperative period. Postoperative complications occurred in 10 cases (14%). In two cases, a rebleed in the groin required surgery; one patient had atrial fibrillation, which was treated with medication; another patient had a hematoma of the groin, and one patient had a wound infection, both treated conservatively. One patient underwent a nonscheduled forefoot amputation because of progression of necrosis with a patent endograft. One patient had hypopotassemia, which was treated with oral medication; another had a dislocation of the hip, after falling out of bed, which was treated with a closed reduction; a patient had urine retention, which was treated with a urinary catheter; and a last patient developed pneumonia, which was treated with antibiotics. With the two previously mentioned procedural complications, the total 30-day morbidity rate was 16%.

The median hospital stay was 2 days (range, 1-12 days). The majority of patients were postoperatively treated with acetylsalicylic acid 80 mg in combination with clopidogrel 75 mg daily (n = 57). The remaining patients were treated with a daily dose of acetylsalicylic acid 80 mg and dipyridamole 400 mg (n = 9) and coumarin derivates alone (n = 1) or in combination with clopidogrel 75 mg (n = 3) or acetylsalicylic acid 80 mg (n = 3).

Follow-up. The median follow-up was 25 months (range, 2-55 months). Seventeen patients (24%) died during the study period unrelated to the treatment. During follow-up, 14 patients (20%) were lost to follow-up because of moving from the hospital area, patient preference, and terminal illness. In another 11 patients (15%), not all data could be retrieved from the case files.

The majority of patients (92%) had an improved Rutherford category after endograft placement. The mean postprocedural ankle-brachial index was 0.95 ± 0.19. In five cases, early occlusion occurred, of which four were successfully treated with thrombolytic therapy, and one received a surgical bypass. These early occlusions were considered primary failures. The 1-, 2-, and 3-year primary patency rates were 73%, 64%, and 58%, respectively (Fig). The primary assisted patency rates were 78%, 71%, and 71%, and the secondary patency rates were 91%, 82%, 82% at 1, 2, and 3 years, respectively.

The Cox regression analysis of factors that could affect patency did not show any significant differences. The use of multiple stents showed a nonsignificant difference



Limbs at risk							
Primary patency	73	56	45	41	34	24	18
Primary assisted patency	73	58	48	44	38	28	20
Secondary patency	73	64	56	54	46	30	21
Patency (%)							
Primary patency	100	83	74	69	67	61	58
Primary assisted patency	100	86	80	75	71	71	71
Secondary patency	100	94	91	90	88	82	82
SE (%)							
Primary patency	0	04	05	06	06	06	07
Primary assisted patency	0	04	05	05	06	06	06
Secondary patency	0	03	03	04	04	05	05

Fig. Primary, primary assisted, and secondary patency rates up to 36 months of follow-up. *SE,* Standard error.

in the 3-year primary patency of 73%, 56%, and 45% with one stent, two stents, and three stents, respectively ($P = .77$).

Occlusions. Of the 73 SFAs treated with a heparin-bonded endograft, 14 (19%) presented with an occlusion, including the 5 early occlusions mentioned before, during follow-up, and all were treated with thrombolytic therapy, 9 successfully. During follow-up, four of these reoccluded and failed, leading to a total of nine endografts with a permanent failure. Six patients with a permanent failure were eventually treated with a surgical bypass, one above the knee and five below the knee. The remaining three permanent failures were treated conservatively because of lack of clinical symptoms. During follow-up, no major amputations were performed.

DISCUSSION

In this study, we have shown that the heparin-bonded Viabahn inserted for SFA occlusive disease is related to a good midterm outcome. This is the first study describing a 3-year follow-up with the newest generation Viabahn. In a recent meta-analysis, Rychlik et al[16] have shown that the 3-year primary patency rate for prosthetic above-knee bypasses is 46% to 70%, which is in line with the results of our study. Obviously, patient groups might not be comparable as they have not been matched. Nevertheless, 84% our patients were treated for TASC II type C and D lesions with a mean lesion length of 17.8 ± 7.2 cm. In a randomized trial, McQuade et al[17] have already shown that the regular Viabahn was related to similar patency rates as the above-knee prosthetic bypass up to 4 years. The 3-year primary patency of McQuade et al was 63% for both the endograft and the surgical bypass groups, which is close to the 59% described in our study. Whether the heparin-bonding technology indeed improves patency rates of the Viabahn remains therefore to be shown. The heparin-bonding technology lowers platelet deposition and reduces thrombogenicity.[18] Moreover, the laser-cut contoured proximal edge may improve apposition of the device to the vessel wall, possibly improving endograft performance.

The role of endografts in the treatment of SFA occlusive disease will remain under debate. Several studies have shown

a satisfying outcome after treatment of extensive SFA occlusive disease using paclitaxel-based stents or balloons.[19-21] The advantage of the use of drug-coated balloons could be that no foreign materials are implanted and that collaterals are preserved. Direct comparative studies are clearly needed to assess the position of both techniques in the treatment algorithm. Previously, we have shown that overstenting of collaterals does not deteriorate clinical outcome in case of failure, suggesting that the clinical relevance of overstenting collaterals in the SFA is low.[10] In our study, only nine treated SFAs had a permanent failure, of which six were eventually treated with a surgical bypass, whereas the amputation rate was 0%, confirming the safety of the technique. To date, surgery is still considered the "gold standard" for extensive SFA occlusive disease in various guidelines that could be considered outdated. Minimally invasive techniques may yield fewer complications in this group of often frail patients. Nevertheless, studies like the SuperB trial, comparing the heparin-bonded Viabahn with the venous bypass, are essential to provide further support for an endovascular-first strategy also in extensive SFA occlusive disease.[8]

The minimally invasive character of the endovascular treatment may be reflected in the low morbidity rate. Surgical bypass of the femoropopliteal region is known for a relatively high morbidity, including wound healing problems, graft infection, and edema. The incidence of these complications varies between 5% and 60%.[22-25] Our study showed an overall complication rate of 16%. Because of its minimally invasive character and a low complication and amputation rate, treatment with a heparin-bonded endograft could also be considered a supplementary treatment option, thus postponing surgical reconstructions.

Limitations of our study were the retrospective design of the study and small sample size, rendering any subanalysis unreliable. The small sample size is related to the fact that the use of self-expanding covered stents for SFA occlusive disease is not a widely accepted treatment modality in our country. In addition, the entire cohort did not complete the 36 months of follow-up. We could not exclude a selection bias as patients were treated according to the institutional standards and at the discretion of the surgeon and interventional radiologist. Unfortunately, a reliable comparison with other treatment modalities is not feasible owing to the retrospective design of the study. Moreover, an identification of performed alternative treatments for the same indication is not possible with the current hospital registration databases.

CONCLUSIONS

Use of heparin-bonded endografts for SFA occlusive disease is a safe and good treatment option with low morbidity and amputation rates. The 3-year patency rates are promising but need to be established in comparative studies with both other endovascular options and surgery.

AUTHOR CONTRIBUTIONS

Conception and design: BG, ML, CZ, MR
Analysis and interpretation: BG, CZ, MR
Data collection: BG, RK, LvW, ML
Writing the article: BG, MR
Critical revision of the article: RK, LvW, CZ, MR
Final approval of the article: BG, RK, LvW, CZ, MR
Statistical analysis: BG
Obtained funding: MR
Overall responsibility: MR

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