Aneurysmal degeneration in the Omniflow II biosynthetic vascular graft

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Abstract
Despite advances in endovascular treatments, femoropopliteal bypass is still the best option for the treatment of lower-extremity occlusive artery disease. Omniflow II biosynthetic vascular grafts are often chosen as bypass grafts when autologous vein grafting is not possible. A negative feature of this graft is the tendency towards late biodegeneration with possible formation of graft aneurysms. In this case report, we present a thrombosed non-anastomotic biosynthetic graft aneurysm, which caused only a pulsatile mass in the inguinal region, in a 62-year-old male patient who had undergone a femoropopliteal bypass operation three years earlier. Aneurysm formation in vascular grafts is multifactorial and can cause life-threatening consequences. Therefore, all patients with biosynthetic vascular grafts should remain under lifetime surveillance with duplex ultrasound for aneurysmal graft degeneration and graft thrombosis.

Keywords: peripheral arterial disease, grafts, aneurysm

Case Report

Fig. 1. Aneurysmatic three-dimensional computed tomography view of the left femoral artery vascular biosynthetic graft (Omniflow II). A. View of organised thrombus (black arrows) removed from vascular graft. B. Aneurysm sac after aneurysmectomy.

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Despite advances in endovascular treatments, femoropopliteal bypass is still the best option for the treatment of lower-extremity occlusive artery disease. The great saphenous vein is the autogenous graft of choice for infra-inguinal reconstructions but is not always suitable for grafting. In these cases, arterial reconstruction using a prosthetic graft is an option.1,2

Synthetic and biological vascular grafts have been used since the 1950s.3 Over time, synthetic grafts tend to increase rather than decrease their thrombogenic potential with neo-intimal formation. Therefore, biological grafts have become an alternative to synthetic grafts for peripheral arterial disease.

For various reasons, most biological grafts have been withdrawn from the market and Omniflow® II (Bio Nova International, Victoria, Australia) is currently the only biological vascular prosthesis (OBVG) available for peripheral revascularisation.¹ A negative feature of the OBVG is the tendency toward late biodegeneration with possible formation of graft aneurysms.¹⁴

Surprisingly, data about late outcome and possible biodegeneration of the OBVG are scarce in the literature. In this
case, we report symptomatic spontaneous true aneurysm of an OBVG in a patient with generalised atherosclerosis.

Case report

The OBVG had been inserted in the left above-knee femoropopliteal location of a 62-year-old male patient due to peripheral artery disease three years earlier. The patient received dual antiplatelet treatment (clopidogrel 75 mg/day + acetylsalicylic acid 100 mg/day) for the first three months postoperatively, and then regularly used acetylsalicylic acid 300 mg/day.

Follow-up angiogram and sonograms were negative for graft-related complications such as anastomotic stenosis, involved thrombus or aneurysms. However, the patient presented with the complaint of a palpable pulsatile mass in the left lower extremity but no other complaints were described. There was no history of trauma or soft tissue infection. In addition to his peripheral vascular disease, his history was also significant for coronary artery disease, hypertension, dyslipidaemia and previous tobacco use.

Physical examination was unremarkable except for a palpable pulsatile mass on the graft trace in the left lower extremity. In addition to the patent left femoropopliteal bypass graft, a computed tomography angiogram of the lower extremities further illuminated the 48 × 15-mm fusiform aneurysm at the junction of the middle third of the femoropopliteal bypass graft (Fig. 1A). The aneurysm was close to the proximal anastomosis site, and the distal anastomosis site was intact (Fig. 2A).

The patient was informed about the aneurysm repair operation and written consent was obtained from the patient for the publication of this case report. Before the procedure, the patient underwent detailed venous mapping for the great saphenous vein. Nevertheless, it was decided that the diameter (< 3 mm) of the great saphenous vein was not suitable for the graft. Therefore, a synthetic graft was preferred.
During the operation, the abnormal segment was resected and the graft was repaired with a 10-mm polytetrafluoroethylene (PTFE) graft interposition under antibiotic cover (Figs 1B, 2B). Post-operatively the patient made a good recovery and was discharged five days after the operation. No organisms were cultured from the graft or thrombus.

Discussion

Due to the problems of patency, durability, infection, graft–host reactions and ease of use of biological and synthetic grafts used in vascular surgery today, the search for the ideal graft closest to human vascular tissue still continues. While synthetic components provide strength and durability to the grafts, biological components facilitate textural adaptation.

All biological materials may undergo biological degeneration over time, with the formation of aneurysms or stenotic lesions. Aneurysmal degeneration of biological grafts may impair graft patency by causing thrombosis as well as local symptoms. Three years later, aneurysmatic degeneration was observed in the biosynthetic graft used in this case, and a thrombus had also formed within the aneurysm. However, graft patency performance was not affected by this degeneration, causing only the local symptom of pulsatile swelling.

An aneurysm is a vascular condition that can be defined as localised abnormal dilation of a vessel due to weakness. Weak points in grafts that lead to aneurysms may be caused by infection, trauma, anastomosis lines, intra-operative damage, intrinsic graft failure due to manufacturing flaws, improper sterilisation or storage, and expansion of the polyester mesh providing strength to the graft wall. However, the position of the graft in the extremity and the patient’s systemic diseases, such as hypertension, dyslipidaemia and autoimmune diseases, may also contribute to aneurysm formation. Articles reporting that aneurysms develop in all different types of grafts implanted in the same patients support this thesis.

Aneurysms can be classified as true or false aneurysms. The definition of true aneurysms includes an increase in vessel diameter of 50% or more and involves all three layers of the vessel wall. True aneurysms are more regular in shape and different in appearance. They are more likely to have a wide neck compared to a pseudo-aneurysm. In this case, the aneurysm was compatible with a true aneurysm, 48 mm wide in the middle of the graft, and there was no history of trauma and no sign of local infection causing leakage at the incision line.

Aneurysm formation is multifactorial and it is not always possible to determine the exact cause, as in this case. Nevertheless, we considered the patient’s existing systemic diseases and graft degeneration, which may occur over time due to mechanical flexion forces loaded on the inguinal region, as predisposing factors for this patient’s non-anastomotic aneurysm formation.

The potential degeneration of biosynthetic grafts and the formation of a true aneurysm, as observed in autologous vein grafts, is a well-known problem. In a recent study, a synthetic PTFE graft and OBVG were compared for infra-inguinal bypass surgery, and graft performance was found to be similar. However, while no aneurysm was observed after two years with PTFE, 8% aneurysm was observed in the OBVG. Koch et al. reported only a small aneurysm rate of 1.1% in a series of 267 operations with an eight-year observation period. Another study reported a total of 12.6% aneurysmatic degeneration, 10.7% of which were non-anastomotic, in the OBVGs used for femoropopliteal bypass surgery.

The fact that such different rates were reported for aneurysm formation in OBVGs makes us think that the underlying predisposing factors are predominantly patient related. However, more comprehensive studies are needed to confirm this situation. OBVG is presently the closest to the ideal arterial prosthetic graft currently available on the market as a bypass graft for cases where autologous vein use is not possible. The three-year patency rate of the above-knee OBVG was reported to be 83.7 to 98%. However, it has a tendency to develop late biodegeneration with possible graft aneurysm formation due to the negative features of the biological material.

Aneurysm formation can result in thrombus formation over time. This, in turn, disrupts the patency of the graft, causing ischaemia, rupture, haematoma and infections, and is life-threatening. Therefore, peripheral graft patients should be followed regularly with physical examination and duplex ultrasound to reduce graft failure rates and detect rare complications such as degenerative aneurysm. In addition, patients should be instructed to seek immediate hospitalisation in cases of unexplained peripheral swelling along the leg graft tracing.

Open surgery (repair of aneurysmal degeneration or replacement of the entire graft) is the most commonly preferred treatment for aneurysmatic peripheral bypasses. However, percutaneous implantation of the stent graft may be an alternative treatment in patients at high risk. If there is no suitable area for distal anastomosis in open surgery, aneurysmal degeneration repair should be chosen. In our case, as there was no suitable area for distal anastomosis, we excised the aneurysmatic biological graft segment and performed synthetic PTFE graft interposition.

Conclusion

Despite technological advances in tissue engineering of vascular grafts, degenerations can be seen at different rates in biosynthetic vascular grafts. Therefore, as in our case, the fact that physical examinations of patients are normal (palpable pedal pulses) or the absence of claudication complaints in the control examinations performed after the femoropopliteal bypass do not mean that the synthetic graft is healthy. In particular, we believe that performing radiological imaging of the graft at more frequent periods (six months) will be beneficial for the early detection of graft-related complications.

References


