

# Endovascular Treatment of a Hepatic Artery Pseudoaneurysm Using a Novel Pericardium Covered Stent

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8

9 **Abstract**

10 Visceral and renal artery aneurysms (VRAAs) and pseudoaneurysms are rare. Their increasing  
11 incidence is largely thought to be due to advances in medical imaging. Twenty percent of VRAAs  
12 occur in hepatic arteries, with approximately fifty percent of these represented by pseudoaneurysms,  
13 which are prone to spontaneous rupture. Many treatments for VRAAs exist, with the endovascular  
14 approach being favoured. Treatment aims to preserve visceral perfusion and exclude the aneurysm;  
15 however complex aneurysms may require parent artery or end-organ sacrifice. Covered stents allow  
16 rapid aneurysm exclusion while preserving parent artery patency, a favourable outcome when parent  
17 artery or end-organ sacrifice is undesirable. The AneuGraft pericardium covered stent (PCS)  
18 combines the benefits of a low-profile covered stent with those of a low immunogenic material. We  
19 describe the endovascular treatment of a patient with a hepatic artery pseudoaneurysm, where parent  
20 artery sacrifice was considered unacceptable. The AneuGraft PCS was used to provide immediate  
21 and complete exclusion, with dual antiplatelet therapy for 1 week, followed by single antiplatelet use.  
22 The procedure was a technical success, with preservation of the hepatic arteries, and complete  
23 exclusion of the pseudoaneurysm. There were no complications immediately following the procedure,  
24 or on post-procedural follow up. The pseudoaneurysm remained excluded at 6-week CTA follow up.  
25 This case describes a safe and effective method for completely excluding a complex  
26 pseudoaneurysm, utilising the AneuGraft PCS, allowing for the potential management of a wider  
27 range of aneurysms with unfavourable morphology.

28

29 **Background**

30 Visceral and renal artery aneurysms (VRAAs) and pseudoaneurysms occur rarely, with a reported  
31 prevalence between 0.1-2% (1-3). Increases in the number of percutaneous biliary tract procedures  
32 and laparoscopic treatments, and advances in medical imaging are thought to contribute to the  
33 increasing incidence of VRAA and pseudoaneurysm diagnoses (2-4). Twenty percent of all VRAAs

1 occur in branches of the hepatic arteries, with approximately fifty percent of these represented by  
2 pseudoaneurysms (1, 5, 6). Pseudoaneurysms are prone to spontaneous rupture into both the biliary  
3 tree and peritoneum, resulting in significant morbidity and mortality (1, 3-5, 7). Therefore, visceral  
4 pseudoaneurysms of any size at any location require prompt treatment (3, 4, 7, 8).

5 There are a wide variety of endovascular approaches described for VRAA treatment but the common  
6 aim is to exclude the aneurysm and preserve parent vessel patency and visceral perfusion, where  
7 possible (3). Parent arteries with a tortuous path, wide-necked aneurysms, and aneurysms located at  
8 arterial bifurcations present challenges to aneurysm occlusion (9). Such aneurysms typically require  
9 parent artery sacrifice or adequate exclusion to prevent complications or recurrence of the aneurysm.  
10 However, the former requires intact collateral blood supply of the viscera to preserve end-organ  
11 perfusion (3, 9, 10). This is of particular importance for transplanted viscera in which collateral blood  
12 supply may be absent, resulting in visceral ischaemia or infarction (11).

13 Covered stent grafts permit complete exclusion of an aneurysm or pseudoaneurysm while maintaining  
14 parent artery patency, overcoming the ischaemic risk associated with parent artery sacrifice and  
15 embolisation of the aneurysm neck (12). Synthetic stent coverings such as PTFE have been shown to  
16 promote thrombosis and slow endothelialisation (10, 13). Pericardium is a well utilised graft material,  
17 suitable for use as a stent covering with low immunogenicity and high durability (13, 14). In our  
18 experience early institution of dual antiplatelet therapy using 100 mg aspirin and 75 mg clopidogrel is  
19 used for many cases, however the pericardium covering allows for single antiplatelet therapy when  
20 dual antiplatelet therapy is not indicated or is inappropriate.

21 The AneuGraft pericardium covered stent (PCS) (Amnis Therapeutics Ltd, Or Akiva, Israel) (Fig. 1) is  
22 a highly flexible, laser cut, 316 L stainless-steel balloon-expandable stent, which is covered with a  
23 single layer of equine pericardium delivered through a 6 French guiding catheter, trackable over a  
24 0.014" guidewire allowing for deployment in smaller and more distal vessels. It is designed for use in  
25 vessels from 2.5mm to 4.0mm in diameter and comes in a range of lengths from 13mm to 27mm. The  
26 AneuGraft PCS, with its low profile and high flexibility, has been shown to have increased  
27 deliverability when compared to the Graftmaster PTFE-covered stent (Abbott Vascular, Santa Rosa,  
28 CA) in both phantom and porcine coronary artery models (15).

29 The AneuGraft PCS has been used successfully in the management of coronary stenosis and  
30 coronary aneurysms (16, 17). There are few studies that have examined the AneuGraft PCS in the  
31 management of non-cardiac aneurysms. Case studies outlining its use in the management of hepatic  
32 artery pseudoaneurysms and internal carotid and vertebral artery aneurysms have reported complete  
33 aneurysm exclusion and maintenance of parent artery patency for all patients (8, 13, 18). Currently,  
34 the AneuGraft PCS is TGA approved for use in the coronary circulation. Here we describe the off-  
35 label use of the AneuGraft PCS to treat a pseudoaneurysm of the right hepatic artery in a post-liver  
36 transplant patient.

37

# 1 Case Report

## 2 Presentation

3 A 58 year-old-male presented 7 months after an orthoptic liver transplant for alcoholic cirrhosis with  
4 nausea, vomiting, and generalised abdominal pain. A CT abdomen showed a periportal collection,  
5 small bowel obstruction, and a proximal right hepatic artery pseudoaneurysm (Fig. 2A), which  
6 required prompt treatment. The patient had a percutaneous pigtail catheter inserted to drain the  
7 periportal collection, and a biliary stent for a post-transplant ischaemic stricture. The presence of an  
8 occlusive portal vein thrombus at the anastomosis made open surgical and endovascular approaches  
9 of parent artery sacrifice less favourable in view of the compromised portal supply, where  
10 preservation of hepatic artery patency was preferred to prevent visceral ischaemia. As such, an  
11 endovascular strategy utilising a covered stent graft was chosen to exclude the pseudoaneurysm over  
12 other available flow modulating devices (such as flow diverting stents). Given the patient was acutely  
13 unwell and there was a possibility of needing to return to theatre for either a washout or repeat liver  
14 transplant, single antiplatelet therapy was determined to be more appropriate.

15

## 16 Procedure

17 Following written informed consent, under sterile technique and general anaesthesia, the right  
18 common femoral artery (CFA) was visualised under ultrasound guidance and punctured, before  
19 insertion of an 8-French introducer sheath (Terumo, Tokyo, Japan). After 5000 units of intra-arterial  
20 heparin and 500 mg IV Aspirin, the coeliac trunk, transplanted common hepatic artery, and right  
21 hepatic artery were selectively catheterised with a SIM 2 catheter (Cook Medical, Bloomington, USA).  
22 Digital subtraction angiography (DSA) confirmed a 2.7cm pseudoaneurysm in the proximal right  
23 hepatic artery (Fig. 2B). The SIM 2 catheter was subsequently exchanged for a guide catheter  
24 (Neuron MAX 088, MicroVention, California, USA) over an exchange length wire. 5-French and 6-  
25 French intermediate catheters (Sofia, MicroVention, California, USA) together with a microcatheter  
26 (SL10, Stryker, Fremont CA, USA) were used to define the in and out-flow anatomy of the  
27 pseudoaneurysm and achieve a stable distal position for device delivery (Fig. 2C). The 6-French  
28 intermediate catheter was used in the event that more microcatheters were required to navigate the  
29 pseudoaneurysm, with the 5-French intermediate catheter being used due to its longer length.  
30 Following definition of the pseudoaneurysm, a 2.5 x 18 mm AneuGraft PCS (Amnis Therapeutics Ltd,  
31 OR, Akiva, Israel) was deployed across the neck of the pseudoaneurysm over a synchro soft  
32 guidewire (Stryker, MI, USA), preserving the left hepatic artery branch (Fig. 2D). The stent was  
33 balloon dilated to 3mm and 2.5 mg intra-arterial tirofiban was used to treat a small focus of developing  
34 platelet aggregation (Fig. 2E). After stent deployment, final DSA showed complete exclusion of the  
35 pseudoaneurysm with maintained distal perfusion (Fig. 2F). Haemostasis was achieved with an 8-  
36 French vascular closure device (AngioSeal, Terumo, Tokyo, Japan). The patient was continued on a  
37 short course of dual antiplatelet therapy for 1 week and subsequently continued on 100mg aspirin  
38 daily indefinitely.

1

## 2 **Results**

3 The procedure was a technical success, with preservation of right and left hepatic artery perfusion,  
4 and full exclusion of the aneurysm. There were no immediate complications following the procedure,  
5 nor during the post-procedural follow up. Multiphase CT angiography performed 6-week post-  
6 procedure showed complete exclusion of the pseudoaneurysm (Fig. 2G). Both right and left hepatic  
7 arteries were preserved. No ischaemic complications were encountered.

8

## 9 **Discussion**

10 The frequency of asymptomatic VRAA and pseudoaneurysm diagnoses has increased with  
11 advancements in the use of cross-sectional imaging (3). Although treatment guidelines vary for true  
12 aneurysms, intervention is suggested for pseudoaneurysms at any location and of any size, due to  
13 high morbidity and mortality of 70% associated with rupture (4, 7, 8). Traditionally VRAA and  
14 pseudoaneurysm treatment has involved open surgical approaches, including aneurysm ligation,  
15 aneurysm resection and subsequent parent artery reunion, and resection of the end-organ, but is  
16 associated with a significant morbidity in up to 18% of patients (2, 6). In comparison, endovascular  
17 approaches to treatment are now considered first line, associated with 3.7% morbidity, 1.5% mortality  
18 at 30 days, and 4.4% reintervention rates with a 93.6% technical success rate and preserved visceral  
19 perfusion in 99.1% (10). Endovascular treatment algorithms involve exclusion of the aneurysm with  
20 flow modulation (flow diverting or covered stents), or embolisation of the aneurysm via coils or liquid  
21 embolic agents (3). Treatment of complex aneurysms and pseudoaneurysms may require alternative  
22 methods such as parent artery sacrifice or parent artery remodelling (9).

23 Covered stents are one of many approaches available to manage aneurysms. Such stent treatments  
24 have shown to provide complete exclusion of an aneurysm while maintaining parent artery patency,  
25 allowing for the successful treatment of complicated aneurysms and avoiding the need for end-organ  
26 resection, particularly useful when treating high risk pseudoaneurysms, although ongoing surveillance  
27 of stent position and patency may be warranted (8, 18). The AneuGraft PCS has been used  
28 extensively in Cardiology practice and is currently indicated for the management of both coronary  
29 bypass-vein graft stenosis and coronary bypass-vein graft aneurysms (14). There is limited data  
30 directly comparing the AneuGraft PCS to other covered stents, with one study reporting the rates of  
31 thrombosis in PTFE-covered stents and pericardium covered stents as high as 8.6% and 5.7%,  
32 respectively. They also showed no significant difference in rates of in-stent restenosis (ISR) (19).  
33 However, other studies have independently shown ISR rates as high as 54.6% for PTFE-covered  
34 stents (20), and 26.3% for PCS (21). Little evidence exists for its use for other indications, however it  
35 has been reported as safe in the management of coronary vessel rupture and exclusion of coronary  
36 aneurysms (16, 17, 21). There are few case reports that explore the use of the AneuGraft PCS

1 beyond the coronary circulation. Corti et al. reported complete exclusion of a hepatic artery  
2 pseudoaneurysm and preservation of a ruptured renal artery, in parent arteries that were not  
3 considered to be expendable. They showed that at six months, vessel patency was at 65%, and there  
4 were no signs or symptoms related to vessel occlusion or end-organ dysfunction (18). Treatment of  
5 internal carotid artery and vertebral artery aneurysms was achieved by Vulev et al (13). The  
6 AneuGraft PCS was used in these cases to reduce the risk of complications such as aneurysm re-  
7 rupture, and in-stent stenosis and thrombosis associated with endovascular coiling and flow diverting  
8 stents. Deployment of the stent over the neck allowed for complete exclusion, with one aneurysm  
9 requiring two stents to bridge the whole neck. Three month follow-up CTA identified complete  
10 exclusion and shrinkage of the aneurysm (13). Ferlini et al. illustrated the safe use of the AneuGraft  
11 PCS in the management of a large iatrogenic pseudoaneurysm of the hepatic artery. Complete  
12 exclusion of the pseudoaneurysm with no procedure related complications was noted at one week  
13 follow up (8). Beyond this, the stent has the potential for occlusion of vessel side branches, which  
14 must be taken into account by the operator (13). Here we used the pericardium covered stent to allow  
15 for effective exclusion of the pseudoaneurysm while reducing the risk of complications such as in-  
16 stent restenosis and thrombus formation, associated with the use of bare metal stents and PTFE-  
17 covered stents (19, 21). Given the lack of a true aneurysm wall, coil embolisation was avoided to  
18 reduce the risk of pseudoaneurysm expansion or rupture and haemorrhage (13). Because of  
19 increased graft porosity and metal coverage ranging from 20-50%, the use of flow diverting stents is  
20 not generally accepted as an efficacious method to treat pseudoaneurysms (7), and as such was  
21 avoided here. Furthermore, the AneuGraft PCS provided a suitable alternative to bare metal and  
22 PTFE-covered stents given the preference for single antiplatelet use in this patient.

23 This case describes the difficulties of treating an aneurysm in which parent artery patency and end-  
24 organ perfusion are to be maintained. The pseudoaneurysm described above was at a high risk of  
25 rupture given its size, and was further complicated by its wide-necked morphology and a concomitant  
26 occlusive portal vein thrombus. As the patient had received a liver transplant 7 months earlier and the  
27 occlusive portal vein thrombus was present, preservation of hepatic artery flow was of utmost  
28 importance to obviate ischaemic complications within the graft. It was unknown whether collateral  
29 vessels capable of adequately supplying the liver had formed in this patient. As such, there was  
30 significant risk of liver ischaemia in the event of pseudoaneurysm rupture or occlusion of the parent  
31 artery via endovascular procedures or thromboembolism. The tendency of visceral pseudoaneurysms  
32 to rupture and the significant morbidity and mortality associated with such an event, coupled with the  
33 inherent complexities of many aneurysms, drives the need for the development and utilisation of safer  
34 and more effective devices.

35

## 36 **Conclusion**

37 The AneuGraft PCS has demonstrated early safety and efficacy for complete exclusion of a wide-  
38 necked hepatic artery pseudoaneurysm. This case describes another safe and effective method for

1 completely excluding complex aneurysms from the circulation, allowing for the potential management  
2 of a wider range of complex aneurysms with unfavourable morphology.

3

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6

#### 7 **References**

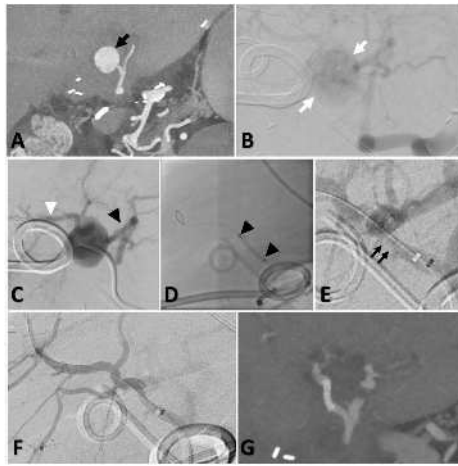
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