

Percutaneous Axillary Artery Access for Endovascular Treatment of Complex Thoraco-abdominal Aortic Aneurysms

Daniela Branzan ^{a,*}, Sabine Steiner ^b, Martin Haensig ^a, Dierk Scheinert ^b, Andrej Schmidt ^b

^a Department of Vascular Surgery, University Hospital Leipzig, Germany

^b Department of Angiology, University Hospital Leipzig, Germany

WHAT THIS PAPER ADDS

This study shows that the direct puncture of the third segment of the axillary artery for delivery of bridging stent grafts during endovascular repair of complex thoraco-abdominal aortic aneurysms appears to be feasible and safe, with procedure success in all patients. Percutaneous closure of the axillary artery can be achieved with low complications using Perclose ProGlide percutaneous vascular closure devices alone, but only if the vessel diameter at the puncture site is >5 mm.

Objective: The aim of this study was to determine the feasibility and safety of percutaneous axillary artery (AxA) access using vascular closure devices (VCD) for endovascular repair (ER) of thoraco-abdominal aortic aneurysms (TAAA) using fenestrated, branched, and chimney stent grafts.

Methods: Between September 2013 and December 2017, 40 high risk patients (27 men; mean age: 72.7 ± 7.4 years) with TAAA underwent total percutaneous endovascular aortic repair by percutaneous puncture of the third segment of the left AxA, using a 12F sheath for delivery of the bridging visceral stent grafts. Percutaneous closure was performed using ultrasound guidance and two Perclose ProGlide VCDs per puncture site. Endpoints were device success defined as successful haemostasis of the axillary puncture site by VCD, procedure success defined as endovascularly assisted haemostasis of the AxA, major cerebrovascular and peripheral neurological complications, and 30 day mortality.

Results: The median diameter of the AxA in the third segment was 6.5 mm (range 4.4–10.4 mm). The procedure success was 100%. Device success was achieved in 33 patients (82.5%). Device success in patients with AxA diameter >5 mm was 97%. All patients with diameter of the AxA <5 mm developed stenosis or occlusions of the vessel ($n = 6$), which were treated by percutaneous stent implantation. One bleeding at the AxA puncture site was treated with trans-femoral implantation of a covered stent. No secondary open procedures were required. No neurological deficit of the left upper limb was seen at discharge. Overall mortality at 30 days was 10%.

Conclusions: Direct puncture of the AxA in the third segment and its use as an access vessel for large sheaths during total percutaneous treatment of complex endovascular aortic procedures appear to be feasible and safe in arteries with a diameter >5 mm. Complications can be managed using endovascular techniques.

Keywords: Percutaneous closure device, Stent graft, Upper extremity access

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INTRODUCTION

Total endovascular repair (ER) of thoraco-abdominal aortic aneurysm (TAAA) has achieved remarkable success over the past decade, offering low peri-operative morbidity and mortality.¹ Upper extremity access (UEA) is often required during complex endovascular aortic procedures to deliver bridging stents through branches and to deliver parallel visceral stents during chimney procedures. A variety of approaches and techniques have been described for arterial

UEA at the level of the brachial artery and of the axillary artery (AxA);^{2–4} however, there is no consensus on the best site and approach. A distinct benefit of axillary access over brachial access is the ability to accommodate sheath sizes > 7F, even up to 18F as has been demonstrated for transcatheter aortic valve repair (TAVR), without interruption of upper extremity perfusion.⁵ Another benefit is the shortening of the working distance to the visceral arteries. Direct punctures of the AxA after surgical cutdown, axillary cutdown with conduit construction,³ and percutaneous puncture of the AxA⁶ have been described. Potential lower risk of wound related complications, and reduction in operative time and blood loss have been demonstrated with percutaneous access of the femoral artery compared with open femoral access during complex endovascular aneurysm

* Corresponding author. Department of Vascular Surgery, University of Leipzig, Liebigstraße 20, 04103, Leipzig, Germany.

E-mail address: daniela.branzan@medizin.uni-leipzig.de (Daniela Branzan).

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repair.⁷ However, no data are currently available on the safety of percutaneous AxA access. Thus, the choice of the axillary access generally depends on the operator's preferences. Furthermore, no specific device has been developed for percutaneous closure of UEA.

The aim of this study was to assess the feasibility and safety of percutaneous AxA access in the third segment using the Perclose ProGlide percutaneous vascular closure device (PVCD) (Abbott Vascular, Santa Clara, CA, USA) for the ER of TAAA.

MATERIALS AND METHODS

Study design and patient selection

This was a retrospective analysis of 116 patients who underwent ER of TAAA with fenestrated, branched and chimney stent grafts between September 2013 and December 2017. Forty consecutive patients, 27 men, with a mean age of 72.5 ± 7.4 years, with a percutaneous axillary approach with a 12F sheath, either because of the need of a stabilizing femoro-axillary thorough and through wire, or because of the simultaneous presence of multiple guide-wires,⁴ were identified. Thirteen patients with axillary sheaths <12F were excluded from the study. Patients' demographics are presented in Table 1. Indications for endovascular aortic repair are summarised in Table 2. The Institutional Review Board of University of Leipzig approved the analysis of the retrospective data set.

Endovascular repair of the aneurysm and percutaneous closure technique

The aortic interventions were performed in a hybrid operating room (Philips, Allura Xper FD 20; Philips Healthcare, Netherlands). The branched and fenestrated stent graft implantation technique has been described elsewhere.⁴ The

Variables	No.	%
Sex		
Male	27	67.5
Female	13	32.5
Age, years		
Mean \pm SD	72.7 ± 7.4	
Median (range)	75 (56–84)	
History of hypertension	40	100
Chronic obstructive pulmonary disease (COPD)	13	32.5
Smoker	26	65.0
Coronary heart disease (CHD)	16	40.0
Diabetes mellitus	15	37.5
Renal insufficiency	24	60
Hyperlipidaemia	26	65
Body mass index (BMI), (kg/m²)		
Mean \pm SD	26.7 ± 4.4	
Median (range)	25.8 (18.7–35.3)	

Continuous data are presented as means \pm SD; categorical data are given as counts (percentage). BMI = body mass index; CHD = coronary heart disease; COPD = chronic obstructive pulmonary disease. SD = standard deviation.

Table 2. Indication for the endovascular treatment of thoraco-abdominal aortic aneurysms

Aneurysm characteristics	No.	%
Acute		
Rupture	4	10
Penetrating aortic ulcer	3	7.5
Pain	2	5
Chronic		
	31	77.5
Crawford Classification		
Type II	15	37.5
Type III	20	50
Type IV	5	12.5
Maximum aortic diameter, mm		
Mean \pm SD	67.2 ± 12.1	
Median (range)	65 (50–102)	
Previous repair of the aorta		
Thoracic	11	27.5
Abdominal	5	12.5
Thoraco-abdominal aortic aneurysms (TAAA)		
Atherosclerotic	36	90
Dissection	4	10
Previous coil of segmental arteries	17	42.5

Continuous data are presented as means \pm SD; categorical data are given as counts (percentage). TAAA = thoraco-abdominal aortic aneurysm. SD = standard deviation.

AxA was examined for patency, size, and presence of disease on duplex ultrasound and on computer tomography angiography (CTA) prior to the procedure. The puncture was planned to be performed on the third segment of the AxA, between the lateral border of the pectoralis minor muscle and the inferior border of the teres major muscle to limit the risk of pneumothorax and to permit manual compression of the vessel against the humeral head. The decision regarding which side to use was made with preference for the left side to minimise manipulations in the aortic arch.

An AxA with an anterior wall free of calcification and with a minimum diameter of 4.5 mm was felt to be appropriate for passage of the 12F sheath. Ultrasound guided puncture of the anterior wall of the AxA was performed using an 18G needle and a standard J wire. Care was taken to avoid injury to the brachial plexus and passage through the axillary vein. A 5F 11 cm long sheath was placed over a regular J wire into the AxA. A control angiogram confirmed the correct position of the sheath (Fig. 1A). Five thousand international units of heparin were administered intravenously and regularly thereafter, achieving an activated clotting time of 250 s.

A 5 mm long skin incision at the axillary puncture site and circumferential dilation of the subcutaneous tissue was performed to facilitate introduction of the PVCDs. Two Perclose ProGlide PVCDs (Abbott Vascular, Santa Clara, CA, USA) were deployed in the typical manner at a 90° angle before introduction of a 9F 11 cm long sheath over a regular J wire. After establishing a femoro-axillary thorough and through wire using a 300 cm long Lunderquist Guidewire (Cook Medical Inc, Bloomington, IN, USA), the 9F axillary sheath was replaced with a 12F Flexor Sheath (Cook Medical Incnd). Bilateral femoral artery access using \geq 18F diameter sheaths for delivery of the aortic component of

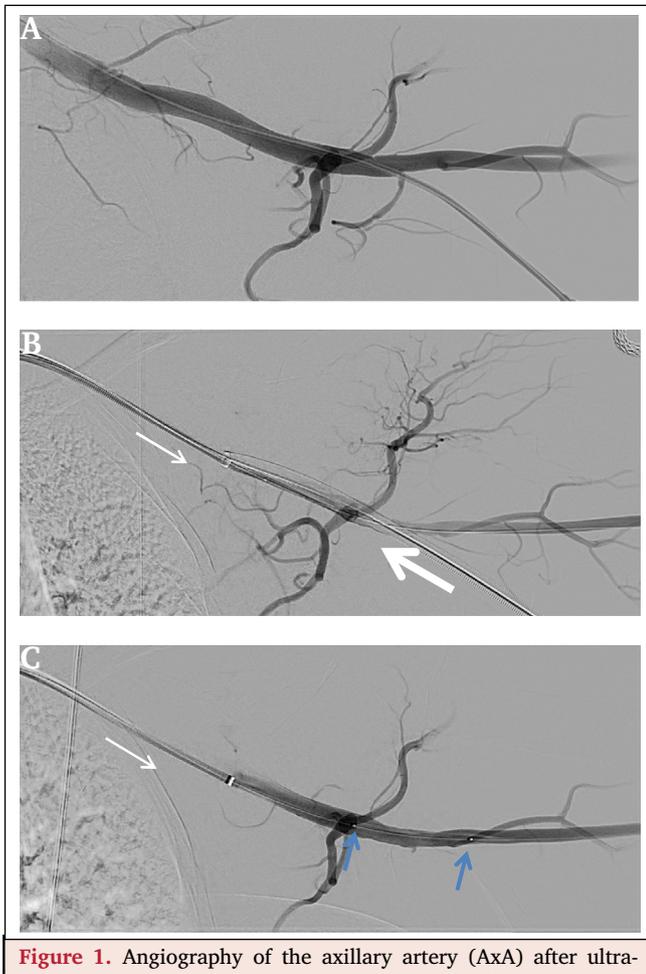


Figure 1. Angiography of the axillary artery (AxA) after ultrasound guided puncture: note the puncture in the third segment of the AxA (A). Sheaths in the AxA: the small arrow indicates the 90 cm long 7F Sheath coming from the left common femoral artery and the large arrow shows the 12F axillary sheath (B). Final angiogram of the AxA after closure with two percutaneous vascular closure devices (PVCD): Note the semi-compliant 2 cm long balloon (blue arrows) placed over a 0.018" guidewire in the AxA as a safety tool in case of failure of the PVCD (C).

the thoraco-abdominal stent graft was obtained percutaneously using the preloading technique with two PVCDs in all patients.⁷

After moulding the overlapping segments and the sealing zones of the stent graft with a compliant balloon, the right femoral access was closed and the left femoral access was downsized by exchanging the stent graft sheath with a 9F 11 cm long introducer. Haemostasis was achieved by pulling the long suture of the PVCDs. Thus, early restoration of blood flow was guaranteed to the pelvis and to the lower limbs. As a next step, stenting of the target visceral vessels was performed via the axillary access. At the end of the aortic procedure, a 7F 90 cm long Flexor sheath (Cook Medical Inc) was inserted into the 9F left femoral access and advanced over the stiff wire in an antegrade manner into a 12F sheath positioned in the descending thoracic aorta. The tip of the 7F 90 cm long sheath was positioned proximal to the axillary access site to immediately intervene in case of bleeding or stenosis (Fig. 1B). The through and

through guidewire was removed and a standard J wire was placed into the 12F axillary sheath. Then the 12F sheath was taken out and the sutures of the PVCDs were tied down over the safety J wire, while applying manual compression on the AxA over the humeral head.

Clinical and angiographic control confirmed the haemostasis (Fig. 1C). In patients with inadequate haemostasis, an additional PVCD was used. In patients with unsuccessful percutaneous closure, after proximal bleeding control with semi-compliant balloon occlusion, a covered self expanding stent (Viabahn, W.L. Gore&Associates, Flagstaff, AZ, USA) was placed in the AxA via the femoral 7F sheath. For flow limiting dissection or occlusion, antegrade treatment of the injured vessel was performed by implantation of a self expanding stent (S.M.A.R.T. Control, Cordis Corp, Fremont, CA, USA). The choice of stent was left at the discretion of the operator.

Peri-operative management and post-operative evaluation

All patients underwent standardized post-operative management with at least 24 h monitoring in the intermediate care unit. Before discharge, CTA was performed routinely for quality control. In the case of renal impairment, a contrast free CT scan was performed, followed by a contrast enhanced ultrasound of the aorta and a colour coded ultrasound of the puncture sites.

Clinical outcomes

Device success was defined as successful AxA closure with the PVCD and no evidence of persistent haemorrhage or arterial ischaemia requiring immediate endovascular or open surgical repair, and procedure success was defined as AxA haemostasis established using any endovascular method and freedom from major vascular complications. The 30 day mortality was recorded.

Data collection and statistical analysis

Data were extracted from a prospectively maintained aortic database. Complications were defined using the Society for Vascular Surgery's reporting standards for endovascular aortic aneurysm repair.⁸ Imaging studies were analysed using three dimensional image analysis techniques (3 Mensio Medical Imaging BV, Netherlands). Data were analysed using SPSS version 20.0 (IBM, Armonk, NY, USA). Categorical variables are presented as percentages, and continuous variables as mean \pm SD or median values.

RESULTS

Percutaneous closure of the axillary artery

All punctures were performed in the third segment of the left AxA. The median diameter of the vessel in this segment was 6.5 mm (range 4.5–10.4). None of the patients had significant calcification of the anterior wall of the vessel. All AxA puncture sites were closed percutaneously, achieving a procedure success of 100%. There were no major vascular complications after endovascular closure of the axillary puncture site. No conversion to open repair of the AxA was necessary. Device success was achieved in 33 of the 40

patients (82.5%). Seven patients (17.5%) were in need of adjunctive endovascular procedures to successfully close the AxA puncture. In three patients, AxA occlusion was noted immediately after deployment of two PVCDs and was treated by transfemoral implantation of 6 mm diameter self expanding uncovered stents in two cases, and of a 6 mm self expanding covered stent in another patient.

Another three patients developed a high grade stenosis at the puncture site, which was treated with 6 mm diameter self expanding uncovered stents. All six patients (15%) who developed stenosis or occlusion of the AxA at the puncture site, and only these patients, had a vessel diameter < 5 mm (Table 3). Device success in patients with AxA diameter >5 mm was 97%. In another patient the attempted closure of the AxA with PVCD failed because of wire entrapment in the suture material of the PVCD with the consecutive rupture of the sutures, and unsuccessful deployment of three further PVCD. This patient had an AxA diameter in the third segment of 7 mm. The bleeding was immediately stopped by rapidly inflating a 7 mm semi-compliant balloon in the proximal part of the AxA. Consecutively, a self expanding covered stent graft 8 mm in diameter was placed to close the puncture defect in the AxA. Acute arm ischaemia did not occur in any patient. Four minor vessel complications (10%) occurred at the AxA access site: one pseudo-aneurysm 1 cm in diameter, and three haematomas < 15 mm in thickness. All complications were treated conservatively. No other neurological complications or other damage to the brachial plexus were found at the site of puncture.

Endovascular repair of TAAA

One patient was treated with a custom made fenestrated stent graft, 27 patients received a branched stent graft,

three patients were treated with a combination of fenestration and branches, and nine patients were treated using commercially available stent grafts with the Chimney technique. The average total endovascular operating time was 219.6 ± 49.7 min. Technical success for visceral artery stenting was 99.3% (151/152), including stenting of 39 coeliac axes, 40 superior mesenteric arteries, and 73 renal arteries, with a mean of 3.7 ± 0.8 vessels per patient.

Thirty day mortality

Thirty day survival rate was 90%. In all four patients who died the cause of death was aneurysm related. Three patients died 24 h after endovascular treatment of ruptured TAAA, and one because of a retrograde type A aortic dissection.

Follow up

All the patients with stenting of the AxA were followed up with Duplex ultrasound. Two patients died within 30 days of the procedure. Five patients had a mean follow up of 21 months (range 6.5–40). No stenosis, no occlusion, and no stent fracture occurred in the AxA.

DISCUSSION

New endovascular TAAA treatment methods often necessitate UEA with large sized sheaths up to 12F.⁴ AxA, either by surgical exposure with or without temporary conduit or by percutaneous puncture and closure with PVCD, can be used as UEA accommodating large sheath sizes.^{2–4} So far, surgical AxA exposure has been used as the standard of care. A randomised controlled trial⁷ showed the potential benefits of percutaneous access of the femoral artery compared with open femoral access during complex

Table 3. Characteristics of patients with stenosis or occlusion of the axillary artery after deployment of the percutaneous vascular closure devices

	Pt. Nr. 5	Pt. Nr. 8	Pt. Nr. 19	Pt. Nr.22	Pt. Nr. 29	Pt. Nr. 34
Variables						
Age, years	64	71	75	78	71	71
Male	1	1	0	1	0	0
Body mass index (BMI), kg/m ²	33	27	24	28	33.4	35.3
Acute presentation	0	1	0	0	0	0
Aortic dissection	0	1	0	0	0	0
Aneurysm diameter, mm	80	77	50	55	65	70
Type of aneurysm						
Type II	1	1	0	0	1	1
Type III	0	0	0	1	0	0
Type IV	0	0	1	0	0	0
Axillary artery diameter, mm	4.7	4.8	4.5	4.8	4.8	4.7
Endovascular treatment with						
6 mm uncovered stent	1	1	0	1	1	1
6 mm covered stent	0	0	1	0	0	0
Surgical repair	0	0	0	0	0	0
Haematoma	0	0	0	0	0	0
Pseudo-aneurysm	0	0	0	0	0	0
Arm ischaemia	0	0	0	0	0	0
Stroke	0	0	0	0	0	0
30 day death	0	1	0	0	1	0

Categorical data are given as the counts. BMI = body mass index.

endovascular aneurysm repair, so the goal of the present study was to characterise the feasibility and safety of percutaneous AxA access for large bore sheaths.

At present, there are no dedicated PVCDs for percutaneous closure of the AxA. Schaefer et al. described percutaneous closure of AxA puncture after transaxillary TAVR in 100 patients. The authors punctured the first segment of the AxA under fluoroscopic guidance and showed that the ProGlide system was more effective than the ProStar XL system to occlude 18 F AxA puncture holes, and reported 11% AxA covered stent implantation.⁵ Using a similar technique, an Italian group presented 100% technical success for percutaneous closure of the first segment of the AxA in 14 patients treated for TAAA. A maximum sheath size of 12F was used only in eight patients. All the patients were treated by two experienced operators.⁶ The authors updated their experience during the 2018 Veith Symposium and reported in 50 patients a primary technical success of 92%, with a need for four stents (8%) for treating bleeding or dissections in the AxA. Five haematomas (10%) and two (4%) peripheral neurological complications were also described.¹⁰

Anatomically, the AxA can be divided into three segments.⁵ Because of its deep submuscular location and its multiple branches, the second segment is considered to be inadequate for direct puncture. The close location to the ribcage, with the risk of pneumothorax after AxA puncture, and the lack of an adequate posterior bony structure for compression of the first segment of the AxA, led to the decision to choose the third segment for puncture in the present study. A disadvantage could be the smaller diameter of the AxA at this level. A recent study describing the *in vivo* the size of the first and third segments of the AxA in 208 consecutive patients undergoing routine CTA prior to TAVR, showed that on the left side the mean distal axillary diameter at the junction of the second and third portions of the AxA was 5.6 ± 0.9 mm and the diameter in the first segment of the AxA was 5.9 ± 1 mm, thus both locations qualify for introduction of a 12F sheath.⁹

To the present authors' knowledge, this study is the first to demonstrate the feasibility and safety of percutaneous closure of the third segment of the AxA after large bore sheath insertion during percutaneous ER of TAAA. No conversion to open repair of the AxA was encountered. The device failure of 17.5% with consecutive stenting of the AxA mainly resulted from occlusive complications after PVCD, which developed exclusively in patients with an AxA diameter <5 mm. They were treated with self expanding stents. After a mean follow up of 21 months, 100% patency of the stented AxA was reported. However, large studies and long-term outcomes after endovascular treatment of injured AxA are limited. In a small cohort of 27 patients, covered stents for treating injuries of axillary arteries have been shown to have one year patency rates similar to open repair.¹¹ Device success in patients with AxA diameters >5 mm was 97% in the present study. This finding has changed practice, and at present percutaneous puncture of the AxA is performed only when the vessel is ≥ 5 mm in diameter. Unlike the cohort describing puncture of the first

segment of AxA for TAVR,⁵ where persistent bleeding was the main complication, in the present study the only bleeding was caused by rupture of the suture material of the VCD because of entrapment of the guidewire within the sutures. This event led to a change in the technique to never place a guidewire across the axillary access site. Similar bailout stenting of 15% was recently reported in a cohort of 18 patients after percutaneous closure of the infraclavicular AxA after puncture with 9.4 ± 1.6 F sheath.² No thrombotic or embolic events were noted to the ipsilateral hands or fingers in the present patients. The rate of local complications (10%) can be compared with the local complication rate of 14% after puncture of first segment of AxA for ER of TAAA presented by the Italian group.⁶ The three minor haematomas caused no compression of the brachial plexus and were managed conservatively, as well as the 1 cm large pseudo-aneurysm.

Limitations

The study population is too small to allow for multivariable analysis. As is well known with retrospective and non-controlled studies, effect sizes tend to be overestimated. Ultimate proof of the percutaneous axillary access requires a randomised control trial including comparison with classical open access and other axillary access locations as well as more long-term data, especially after bailout stenting.

Conclusions

Direct puncture of the AxA in the third segment and its use as an access vessel for large sheaths during total percutaneous treatment of complex aortic endovascular procedures seems to be safe; however, only in arteries with a diameter >5 mm. Complications can be managed using endovascular techniques.

CONFLICTS OF INTEREST

None.

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None.

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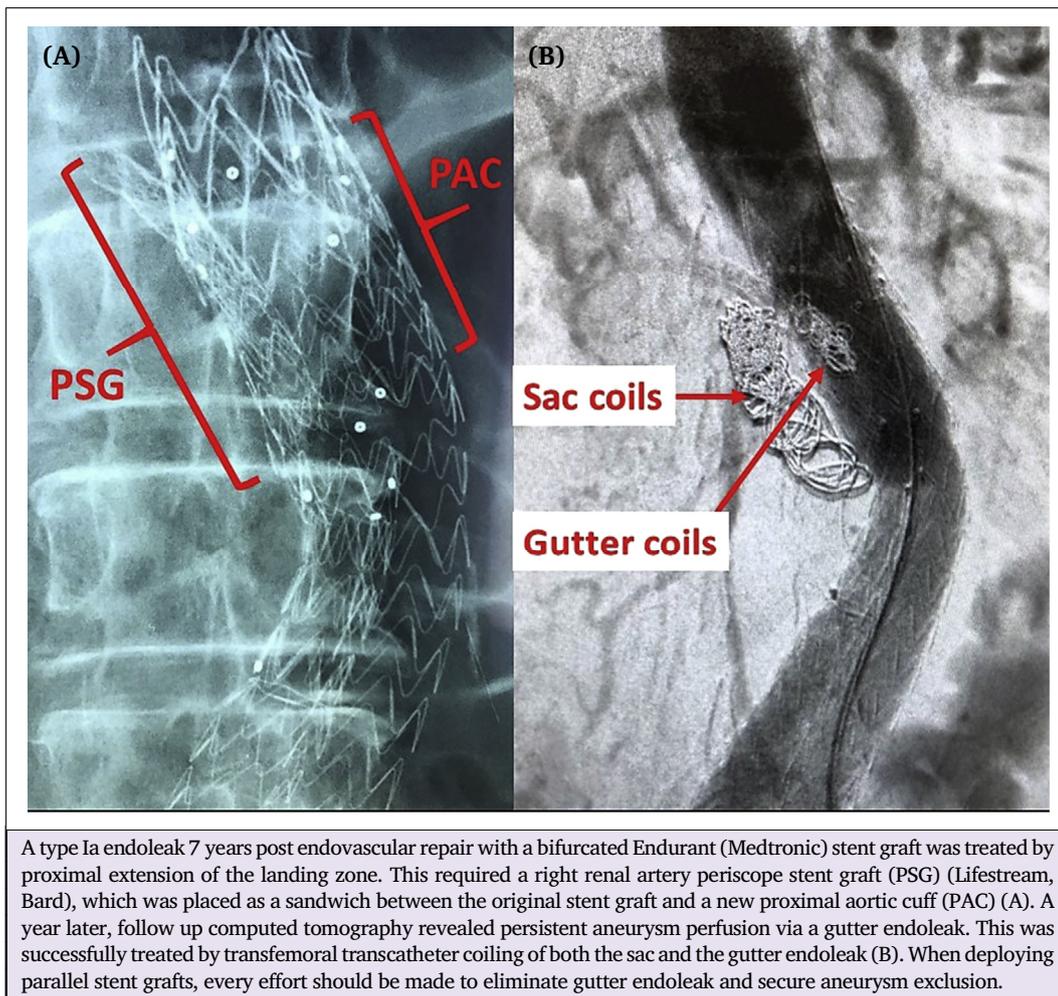
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COUP D'OEIL

How to Make the Perfect Sandwich

Christos D. Karkos*, Konstantinos O. Papazoglou

Vascular Unit, 5th Department of Surgery, Medical School, Aristotle University of Thessaloniki, Hippokratio Hospital, Thessaloniki, Greece



* Corresponding author. 5th Department of Surgery, Medical School, Aristotle University of Thessaloniki, Hippokratio Hospital, Konstantinoupoleos 49, Thessaloniki 54642, Greece.

E-mail address: ckarkos@hotmail.com (Christos D. Karkos).

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