Canadian experience with percutaneous endovascular aneurysm repair: short-term outcomes

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Background: To decrease the morbidity associated with cut-downs during endovascular aneurysm repair, some authors have suggested the totally percutaneous endovascular repair (PEVAR). The goal of this report is to evaluate and describe our centre's experience with the total percutaneous endovascular aneurysm repair (PEVAR) for aortic abdominal aneurysm (AAA).

Methods: We performed a retrospective analysis of 15 consecutive patients with AAA, including 1 with right common iliac artery aneurysm.

Results: There were 12 men and 3 women with a mean age of 74 (standard deviation [SD] 2) years who underwent PEVAR with a Perclose ProGlide suture-mediated closure system between July 2007 and July 2008. All surgeries were elective. Forty percent of patients had a history of smoking, 73% were hypertensive, 33% were diabetic, 20% had chronic obstructive pulmonary disease and 40% had coronary artery disease. Fourteen patients had bilateral deployment for bifurcated devices (7 bifurcated Gore Excluder, 7 bifurcated Cook Zenith grafts), and 1 patient had unilateral deployment for a Cook Zenith device. The outer diameter of the sheaths used for puncture sites was on average 18.1-Fr (SD 0.6), with main bodies being 21.1-Fr (SD 0.3) and contralateral sides 15-Fr (SD 0.3). Procedural success was 93%, with 1 patient requiring a femoral artery cut-down because of failure of the Perclose device to deploy in the groin. Another patient had persistent venous bleeding in 1 puncture site that stopped with skin suturing. Endovascular aneurysm repair was 100% with no conversion to open surgery and no type-I endoleaks. The mean length of stay in hospital was 2.2 (SD 0.4) days. There were no long-term groin complications at 6 (SD 1) months' follow-up.

Conclusion: To our knowledge, this is the first Canadian report of experience with PEVAR using the Perclose device. The technique is safe, reliable and allows discharge of patients soon after surgery.

Contexte : Afin de réduire la morbidité associée aux dénudations au cours de la réparation d'un anévrisme par voie endovasculaire, des auteurs ont suggéré d'utiliser la réparation endovasculaire entièrement percutanée (PEVAR). Ce rapport vise à évaluer et à décrire l'expérience, à notre centre, de la réparation d'un anévrisme de l'aorte abdominale (AAA) par voie endovasculaire entièrement percutanée (PEVAR).

Méthodes : Nous avons procédé à une analyse rétrospective de 15 patients consécutifs qui ont subi un AAA, dont un anévrisme de l'artère iliaque commune droite.

Résultats : Les 12 hommes et 3 femmes avaient en moyenne 74 (écart-type [ET] 2) ans et ont subi une réparation PEVAR pratiquée au moyen du système d'obturation vasculaire par suture Perclose ProGlide entre juillet 2007 et juillet 2008. Toutes les interventions chirurgicales ont été électives. Quarante pour cent des patients avaient des antécédents de tabagisme, 73 %, de l'hypertension, 33 %, le diabète, 20 %, une maladie pulmonaire obstructive chronique et 40 %, une coronaropathie. Quatorze patients avaient des dispositifs bifurqués bilatéraux (7 Gore Excluder bifurqués, 7 greffons Cook Zenith bifurqués) et 1 patient avait un dispositif Cook Zenith à déploiement unilatéral. Le diamètre extérieur des gaines utilisées au point de perforation s'établissait en moyenne à 18,1-Fr (ET 0,6), les corps principaux ayant 21,1-Fr (ET 0,3) et les côtés contralatéraux, 15-Fr (ET 0,3). Les interventions ont réussi à 93 %; il a fallu pratiquer une incision dans l'artère fémorale d'un patient parce que le dispositif Perclose ne s'était pas déployé dans l'aine. Un autre patient avait un saignement veineux persistant à un point de perforation, qui s'est arrêté après la suture de la peau. La réparation de l'anévrisme s'est faite entièrement par voie endovasculaire et il n'y a eu aucune conversion en chirurgie sanglante ni aucune endofuite de type I. La

durée moyenne du séjour à l'hôpital a été de 2,2 (ET 0,4) jours. Il n'y a eu aucune complication à long terme à l'aine à 6 (ET 1) mois.

Conclusion : Sauf erreur, il s'agit du premier rapport canadien portant sur une expérience d'intervention PEVAR pratiquée avec le système Perclose. La technique, sécuritaire et fiable, permet de donner son congé au patient peu après l'intervention chirurgicale.

Abdominal aortic aneurysms (AAAs) were traditionally treated with open surgical repair until the development of endovascular aneurysm repair (EVAR), as described by Parodi in 1991.[1] Since then, many studies have demonstrated the safety and efficacy of EVAR, even in patients with ruptured aortic aneurysms.[2–4] The original EVAR procedure is performed through bilateral femoral artery cut-downs. Although these cutdowns are usually well tolerated, wound complications such as infection, lymphatic leakage and femoral nerve pain and parasthesia are not infrequent.

To decrease the morbidity associated with cut-downs during EVAR, some authors have suggested the totally percutaneous endovascular repair (PEVAR).[5–7] The "Perclose" technique has been described for the Perclose Prostar XL device[8] (Abbott Vascular) and Perclose ProGlide device[5] (Abbott Vascular) and consists of deploying the closure devices before insertion of a large sheath, leaving the suture ends to be tied at the end of the procedure. The technical success with such percutaneous suture-mediated closure systems has been in the range of 62%–100% in published series.[5,8–14] The Perclose ProGlide device is a 6-Fr suture-mediated closure device that is inserted at the beginning of the case over a 0.035-inch guidewire, deploying a single 3–0 polypropylene suture with a full-thickness vertically oriented bite of the artery using a pair of nitinol needles. The system deploys a slip knot that is colour-coded for the tying and locking strand. Closure of the arteriotomy is performed after EVAR by tying down the preformed slipknot with a knot pusher. These sutures are tightened with the guidewire in place. Once hemostasis is assured, the guidewire is removed. As described by Lee and colleages,[5] 2 ProGlide devices are used on each femoral artery before insertion of the large sheath.

The goal of the present report was to analyze our centre's initial experience with the feasibility, safety and efficacy of PEVAR for the treatment of AAAs.

Methods

We performed a retrospective analysis on 15 consecutive patients who underwent PEVAR for treatment of their AAAs between July 2007 and July 2008. All procedures took place at Vancouver General Hospital (VGH) in Vancouver, BC, a tertiary-care university-affiliated teaching hospital. All patients had computed tomography angiograms (CTAs) preoperatively and within 6 months of aneurysm repair. The criteria for repair were rapid growth, size greater than 5 cm at the largest diameter for AAA and diameter greater than 3 cm for isolated iliac artery aneurysms. Exclusion criteria were implantation of an aorto-uni-iliac endograft with femoral–femoral bypass, previous groin surgery, presence of inguinal arterial prosthesis, severely tortuous iliac artery and calcified or narrowed femoral arteries. The endograft device used needed to be a sheath-based system, such that the largest sheath could be left in situ until the end of the procedure for hemostasis. The primary outcome was procedural success, which we defined as completion of PEVAR without need for femoral artery cut-down or open repair. The choice of grafts in each case was based on the preferences of the attending vascular surgeons, patient anatomy and device availability. We performed the procedures in an operating room equipped with standard fluoroscopy (GE 9800, General Electric).

We recorded access-related complications including bleeding, arterial stenosis, occlusion, infection and pseudoaneurysm. Follow-up CTAs and clinic visits with the vascular surgeon took place at 6 weeks and 6 months after surgery and annually thereafter unless closer follow-up was necessary. Patients received specific instructions to contact their vascular surgeons at the onset of new or worsening symptoms, including abdominal or groin pain, swelling or drainage.

The steps for PEVAR were as follows. We accessed the common femoral artery (CFA) percutaneously using ultrasound guidance, taking care to ensure the puncture was in the centre of the common femoral artery. We introduced a 0.035-inch guidewire into the aorta and then dilated the puncture site with 7-Fr sheath. Next, we introduced the ProGlide device over the wire with medial rotation at 30° and then deployed the device with the strands of prolene sutures left loose extracorporeally and taped down and out of the way with wide steri-strips. We deployed a second ProGlide device, this one rotated laterally at 30°, and reintroduced a 7-Fr sheath. The same procedure was then repeated on the contralateral groin. We completed the endovascular repair, followed by removal of the introducer sheath with manual compression at the groin and maintenance of the 0.035-inch guidewire access. We tightened the preformed knots and pushed them down firmly with the knot pusher sequentially. After verification that proper hemostasis was obtained, we removed the guidewire access; sutures were cut below the skin level and manual pressure applied. Heparin was reversed with protamine after feet

examination confirmed good distal perfusion. If hemostasis was not adequate after tightening of both stitches, we deployed a third device in the usual fashion using the retained guidewire.

We performed statistical analysis with STATA software (StataCorp). We considered values of $p < 0.05$ to be significant.

Results

We performed EVAR in 84 patients during the study period. OF these, 23 patients had aorto-uni stent-graft with femoral–femoral bypass, which made them ineligible for PEVAR. The PEVAR procedure accounted for 18% of all EVAR procedures or 30% of the bifurcated cases.

We assessed 15 consecutive patients (12 men and 3 women) with a mean age of 74 (SD 2) years who underwent PEVAR for asymptomatic aneurysms (Table 1). Of the 15 patients, 14 had abdominal aortic aneurysms and 1 had a right common iliac aneurysm. Forty percent of patients had a history of smoking, 73% were hypertensive, 33% were diabetic, 20% had chronic obstructive pulmonary disease and 40% had coronary artery disease. One patient had chronic renal failure not requiring dialysis. Thirty-three percent had a history of cancer. One patient presented with blue-toe syndrome.

All repairs were elective and were performed under general anesthesia. We used 7 bifurcated Gore Excluders, 7 bifurcated Cook Zenith grafts and 1 unilateral Cook device. Overall, the outer diameters of devices used for all puncture sites were 18.1-Fr (SD 0.6), with main bodies being 21.1-Fr (SD 0.3) and contralateral side 15-Fr (SD 0.3).

Table 1. Clinical outcomes of patients treated with percutaneous endovascular aneurysm repair

Pt. no.	Age, yr	Sex	Diagnosis	Graft type	LOS	Complications	Treatment
1	82	M	AAA	Bifurcated	1	No	N/A
2	85	M	AAA	Bifurcated	4	No	N/A
3	79	M	AAA	Bifurcated	2	No	N/A
4	70	M	AAA	Bifurcated	3	Mild bleeding from groins	Pressure, skin suture
5	75	M	AAA	Bifurcated	1	No	N/A
6	74	M	AAA	Bifurcated	1	No	N/A
7	65	M	AAA	Bifurcated	1	No	N/A
8	82	M	AAA	Bifurcated	2	No	N/A
9	70	F	AAA	Bifurcated	4	Failure of right Perclose device to deploy	Cut-down and repair with direct suture
10	89	M	AAA	Bifurcated	7	No	N/A
11	67	M	AAA	Bifurcated	1	No	N/A
12	77	M	AAA	Bifurcated	2	No	N/A
13	71	M	AAA	Bifurcated	1	No	N/A
14	77	F	Right iliac aneurysm	Bifurcated	1	No	N/A
15	49	F	AAA and blue-toe syndrome	Tubular	2	No	N/A

AAA = abdominal aortic aneurysm; F = female; M = male; LOS = length of stay; N/A = not applicable; Pt. = patient.

The PEVAR procedure was successful in 14 (93%) patients; a Perclose device failed to deploy in 1 patient, requiring cut-down and direct repair of the common femoral artery with suture. This failure occurred early on (patient number 3) in our experience. This patient was an 85-year-old slim female with good anatomy. We applied the Perclose closure after the EVAR procedure (Gore Excluder with main-body from left femoral artery) in both sides of her groin. Initially there was ongoing oozing from the left groin, which stopped with 20 minutes of pressure. Heparin was not reversed with protamine. She was initially stable, but she became more hypotensive 8 hours postoperatively despite fluid infusion. We found an expanding hematoma in the left groin, and she was taken to the operating room immediately for exploration of the left groin. Intraoperatively, we found a modest hematoma, and the puncture was 1 cm below the inguinal ligament at 12 o'clock in the common femoral artery. The suture loops were very loose and nonocclusive. We found active bleeding with minimal tissue manipulation. We performed 5-0 prolene stitch repair, and the patient had an uncomplicated postoperative course. Another patient experienced mild bleeding from both sides of the groin; however, no treatment other than pressure and a single prolene skin suture was required. We counted this patient as having a successful PEVAR procedure. We used a third perclose ProGlide device in 1 patient who did not have adequate hemostasis after both sutures were tightened. Hemostasis was achieved with this third device.

Endovascular aneurysm was successful in 100% of patients, with no type-I or type-III leaks and no conversions to open repair. One patient had inadvertent covering of the left internal iliac artery. The average length of stay in hospital was 2.2 (SD 0.4) days.

Retrospective analysis of our open versus percutaneous EVAR during the same period revealed a significant difference in the length of stay in hospital (2.2 [SD 0.4] v. 4.2 [SD 0.4], unpaired t test, $p = 0.047$).

We followed patients for a mean of 6 (SD 1) months with clinical examinations and serial CTAs. At follow-up, 3 patients had small type-II endoleaks, which we followed clinically. There were no groin site complications. One patient was lost to follow-up.

Discussion

To our knowledge, this is the first report of a Canadian experience with PEVAR. Our procedural success of 93% and EVAR success of 100% may encourage other centres to pursue this technique.

The technique failed in only 1 patient, occurring early in our experience. We believe the failure was caused by the

suture loop and knots not being tightened sufficiently during the initial deployment. Suture knots may sometimes be caught in the sheath tract. Since the knots for both devices are preformed, they have the potential to entangle within the tract. We advocate careful attention when tightening the sutures. The knots should be pushed using the knot pusher sequentially and firmly on both suture loops to make sure they seat properly on to the artery. Another factor that may have contributed to bleeding in this patient was the fact that anticoagulation was not reversed after the procedure.

The Perclose ProGlide system is the only device approved in Canada that allows the PEVAR technique to be performed. According to the instruction manual, the Perclose device is intended for closure of defects made by sheaths 8-Fr or smaller. The technique of using 2 devices at off-centred and opposite angles has been described for closure of larger defects. Lee and colleagues[15] reported a technical success rate of 94% in 292 patients, which is comparable with our reported procedural success. Failures in their study were related to coagulopathy, high puncture sites, dissection, pseudoaneurysm or sutures pulling through the artery. They also reported a shorter mean procedural time, which has also been seen by other authors.[12] At a medium-term follow-up of 12 months, Lee and colleagues reported 3 long-term complications in 292 patients: 1 femoral dissection and 2 pseudoaneurysms.[15] The same group proposed the following contra-indications for PEVAR: obesity, severely scarred groin, high femoral bifurcation, the need for frequent introducer sheath removals and insertion, proximal iliac occlusive disease, small iliofemoral arteries and anterior or near circumferential calcific disease.[5] We believe that obesity may actually become an indication to perform PEVAR as one becomes familiar with this technique since these patients are usually at higher risk for groin complications with a cut-down approach.

Failure of the Perclose device to achieve hemostasis may occur if the sutures did not provide for adequate seal or if they cut out from the arterial wall. It is crucial for the surgeon to be prepared in the event of device failure and bleeding. It is of paramount importance that the guidewire be kept in the artery until one is confident that hemostasis is achieved. The puncture site should be completely hemostatic when the sutures are tightened. If ongoing bleeding is present after both sutures were tightened, a third device can be deployed over the guidewire. If bleeding persists, hemostasis can be assured be replacing the large sheath back into the femoral artery to plug the entry site. Open arterial repair can be done leisurely by cutting down on the femoral artery following the guidewire and dilator. On the other hand, if bleeding is to occur after the guidewire is removed, the situation will be more difficult. Standard vascular principles should apply with firm digital pressure on the bleeding site and rapid control of proximal and distal artery followed by open arterial repair.

This report documents our initial experience with PEVAR. The technique was brought to our institution by a surgeon (J.C.C.) who went on sabbatical to a centre that used this technique. The surgeon proctored 4 others (including J.G. and Y.N.H.) in our institution. The 4 learners rated the difficulty of this technique and its learning curve as 3 out of 5, with 5 corresponding to the most difficult rating. On average, the learners felt they needed 4 proctored cases before they were totally comfortable with the procedure.

Nonsheath–based endograft devices such as the Anaconda (Vascutek, a Terumo Company) and Talent (World Medical/Medtronic) are less amenable to PEVAR, as introduction and removal of these devices without sheaths can result in increased risk of bleeding and groin hematoma. We believe it is still possible to perform PEVAR with these devices if a large sheath (from a different manufacturer) is used for the femoral artery and facilitate hemostasis after the endograft device is deployed and removed.

The cost of EVAR is a major issue in most hospitals owing to resource constraints. Perclose ProGlide is a commonly used closure device that is priced competitively. The cost of 4 devices (4 are needed for each PEVAR case) is about one-quarter the cost of one piece of leg extension stent-graft or about two-thirds of the cost of a 1-day stay in our hospital. We have demonstrated that length of stay is shortened for patients who undergo PEVAR compared with those who undergo open cut-down EVAR. We believe PEVAR is a potentially a cost-saving measure. Further detailed randomized studies are needed to verify this impression. In terms of time in the operating room, we did not find PEVAR to be much faster than open cut-down EVAR.

Regarding length of stay in hospital (2.2 d), we feel that there is room for improvement. Our study documents our initial experience with PEVAR, and we were quite conservative in keeping patients in hospital at first. We kept some patients for extra days owing to postimplant fever, confusion and urinary retention. We believe with more experience, most of these patients' stays can be reduced to 1 day, which will translate into further savings.

Conclusion

To our knowledge, this is a first Canadian report on the use of the PEVAR technique. Based on our experience with this procedure, we recommend the use of this technique in patients undergoing endovascular repair of AAAs, provided there is no previous history of groin dissection, and in whom iliac or femoral occlusive disease is not present.

Competing interests: None declared.

Contributors: Drs. Grenon and Chen designed the study. All authors acquired and analyzed the data. Drs. Grenon, Hsiang and Chen wrote the article, which Drs. Gagnon and Chen reviewed. All authors approved publication.

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