Use of the Percutaneous Vascular Surgery Device for Closure of Femoral Access Sites during Endovascular Aneurysm Repair: Lessons from our Experience

L. G. Teh, K. Sieunarine*, G. van Schie, M. A. Goodman, M. Lawrence-Brown, F. J. Prendergast and D. Hartley

Departments of Vascular Surgery and Radiology, Royal Perth Hospital, Wellington Street, Perth 6000 WA, Australia

Objectives: to evaluate the results of our early experience with a percutaneous closure device for aortic aneurysm repair and to identify device related and patient related factors leading to procedure failure.

Methods: eighty-two percutaneous closures in forty-four patients was performed using the 10F Prostar XL Percutaneous Vascular Surgery device during the repair of 1 iliac, 1 thoracic and 42 abdominal aortic aneurysms.

Results: successful closure was achieved in 70 access sites (85%) with 12 sites requiring conversion to an open groin incision. The reasons for failure include difficult device introduction due to a tortuous iliac, deflection of needles due to previous scar, femoral artery occlusion and failure of the device to close the arteriotomy. There was one intraoperative death from retroperitoneal haemorrhage and another patient developed a pseudoaneurysm at the cannulation site.

Conclusions: use of the percutaneous closure device requires very careful patient selection. Preoperative radiological assessment of the ilio-femoral vessels is vital to assess for calcification and tortuosity. High device failure rates can be expected from obese patients and those with scarred groins. When difficulty is encountered during the procedure, there should be a low threshold for conversion to an open groin incision. The device and the method of introduction can be further improved to address some of these issues.

Key Words: Vascular closure devices; Endovascular grafting; Abdominal aortic aneurysm; Technique; Complications.

Introduction

Endoluminal repair for aortic aneurysms was first undertaken at our institution in 1993 with an aortic to right iliac tube graft in combination with a right to left ilio-femoral bypass graft and occlusion of the left common iliac artery with wire coils. In 1994, bifurcate grafts were introduced and, as a result, the open component of the procedure was significantly reduced. The early studies showed that despite the higher risk profile of the patients undergoing endoluminal repair, they shared the same perioperative risk as those undergoing open repair, suffered less blood loss and had shorter lengths of stay in the intensive care unit and in hospital. The increasing confidence in this procedure has seen an expansion in the indications for endovascular repair. Although the long-term results remain to be seen, mid-term follow-up data have been encouraging.

The common practice for access to the femoral artery in endoluminal repairs has been an open femoral incision. However, the trend to minimise the extent of the open incision with the expected benefit of further reductions in morbidity, in particular local complications such as seromas and lymphoceles, has led to the trial use of percutaneous closure devices, allowing the entire procedure to be performed without an open component. This study outlines our early results with one such device and our recommendations based on this experience.

Methods

Between February 2000 and January 2001, 44 patients underwent percutaneous repair of aortic aneurysms for standard accepted indications. One had a descending thoracic aneurysm, one had an iliac aneurysm and the remainder had infrarenal abdominal aortic aneurysms. The aneurysms were excluded using the...
Zenith AAA endovascular graft (Cook Australia, Brisbane) and 10F Prostar XL Percutaneous Vascular Surgery devices (Perclose Inc, Redwood City, California) were used for closure.

At a very early stage, a product specialist from the device manufacturer mentored and familiarised the surgeons and interventional radiologists with the device and technique of deployment. The 10F Percutaneous Vascular Surgery (PVS) device is indicated for closure of arteriotomy sites no larger than 10F and is designed to be inserted and deployed at the end of a procedure. Because of the larger sheath sizes used during endoluminal grafting, the “preclose” technique for closure with this device was developed. This refers to the deployment of the sutures around a 10F arteriotomy site at the beginning of the procedure before dilatation by the larger sheath sizes used during endoluminal grafting. The device has a soft shaft with a wire port located 27 cm from the J-loop tip (Fig. 1). Two pairs of straight needles are housed in the shaft proximal to the wire port (Fig. 1, inset). When the plunger is pulled, the needles track proximally into the barrel pulling their sutures along.

As part of the workup for endoluminal repair, all patients had a preoperative abdominal/pelvic spiral CT scan and aortogram. All procedures were performed under general anaesthesia in a suite with complete angiographic facilities by a team of vascular surgeons and interventional radiologists. A cut equal to the size of the sheath was made below the inguinal ligament. Arterial access at the level of the inguinal ligament was achieved with an 18-gauge Cook needle, followed by a 0.035 inch standard J guide wire and 10F sheath. Following removal of the wire and introducer, a haemostat was used to dilate the tract along and around the sheath until the arterial wall was felt. A guide wire was then passed into the aorta under fluoroscopy and, once position was satisfactory, the 10F sheath was exchanged. The PVS device was prepared with heparin saline in the sheath for lubrication and clot prevention, and then inserted under angiographic guidance. The wire was removed before the wire entry port passed under the skin. At this point, the device tip is usually located in the aneurysm sac. When the proximal neck was angulated, advancing the device past this point without the aid of a guide wire can be difficult. Some of us (KS and GvS) routinely leave the wire in situ until the device tip had negotiated past the proximal neck of the aneurysm. The device was then slowly advanced in a rotary fashion until pulsatile blood flow emerged from the marker lumen (Fig. 1). This “mark” indicated that the arterial wall was now in position between the needles intraluminally and the receiving barrel on the extra-luminal side. At this point, the device was handled very carefully to maintain this position as the needles were deployed. The sutures were then tested to ensure that they ran freely, grouped according to colour and left untied (Fig. 2a).

The wire was reinserted and the device exchanged. When sheaths over 18F were used, a second device was inserted in a similar manner except that the needles were deployed at 45 degrees relative to the first device. For sheaths less than 18F, only one device was used in most cases. The 10F sheath was then reinserted for haemostasis and the endograft deployed in the usual fashion. We generally used 18–20F sheaths for the main body stent graft introduction (a 22F sheath was used in the case of the thoracic aneurysm) and 16–18F sheaths for the contralateral limb.
Following angiographic confirmation of satisfactory endograft placement, the sutures were repeatedly cleaned with saline and tested to ensure that they ran freely. Beginning with the paired white sutures, a slip-knot was fashioned and slid down onto the arteriotomy with the supplied knot pusher. The arteriotomy was closed with the two pairs of sutures crossing each other (Fig. 2b). At the end of the operation, a careful survey for bleeding was undertaken and all threads were inspected again. A transverse open incision to expose the femoral artery was performed at any stage if local complications were encountered. Device failures were categorised into three phases – introduction, deployment of needles and closure of artery. Perioperative complications such as bleeding, dissections, distal emboli, limb ischaemia, wound seromas and infections were recorded. The groin sites were examined clinically every 15 min for 4 h and a duplex ultrasound performed only when there were concerns about the puncture site.

**Results**

Out of 44 patients, 82 groins were closed percutaneously during our study period. Abdominal aortic aneurysm repair was undertaken in 42 patients, 1 involved repair of a descending thoracic aortic aneurysm and 1 for a common iliac aneurysm. Six femoral cannulations were electively performed through an open incision due to previous scarring (3 patients), hard calcified plaque on computed tomography (2 patients) and femoral aneurysmal disease (1 patient).

We experienced 12 closure failures (14.6%) which occurred in 11 patients necessitating conversion to an open groin incision (Table 1). Before we changed our practice to removing the guide wire only when the device was in the aneurysmal neck, we had two failures (Sites 1 and 2) related to tortuous iliac arteries where the device could not be advanced easily without risk of injury to the artery. In Site 3, subcutaneous scarring from a previous operation caused deflection of the needles could not be retrieved. Bleeding was encountered in Site 4 because the sutures became caught and were unable to be advanced down to the arteriotomy.

The most common cause of bleeding was attributed to patient obesity (Sites 5–9). In one obese patient, both femoral wounds (Sites 8 and 9) bled after closure, one of which occurred in the retroperitoneum and was not diagnosed until the patient became profoundly hypotensive. The haematoma on the contralateral side was evident and the arteriotomy was repaired via an open incision before the patient suffered a fatal cardiac arrest. Inadvertent cannulation of a high bifurcating common femoral artery caused vessel occlusion in one patient (Site 10) necessitating a thrombectomy with patch repair and bleeding in another (Site 11).
Table 1. Causes of failed percutaneous femoral closures.

<table>
<thead>
<tr>
<th>Site</th>
<th>Stage of procedure and problem encountered</th>
<th>Reason for failure</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device introduction</td>
<td>1 Unable to advance device</td>
<td>Tortuosity of iliac vessels</td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>2 Unable to advance device</td>
<td>Tortuosity of iliac vessels</td>
<td>Open conversion</td>
</tr>
<tr>
<td>Needle deployment</td>
<td>3 Unable to retrieve needles</td>
<td>Groin scarring causing needle deflection</td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>Closure of arteriotomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>4 Unable to slip knot due to sutures catching</td>
<td></td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>5 Difficult knot slippage due to obesity</td>
<td></td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>6 Difficult knot slippage due to obesity</td>
<td></td>
<td>Open conversion</td>
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<tr>
<td></td>
<td>7 Difficult knot slippage due to obesity</td>
<td></td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>8 Difficult knot slippage due to obesity</td>
<td></td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td>9 High puncture and difficult knot slippage due to obesity</td>
<td></td>
<td>Death from cardiac arrest</td>
</tr>
<tr>
<td>Occlusion</td>
<td>10 High common femoral artery bifurcation</td>
<td></td>
<td>Open conversion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Device entry into SFA</td>
</tr>
<tr>
<td>Late complication</td>
<td>Pseudoaneurysm</td>
<td>Incomplete seal of the arteriotomy site</td>
<td>Open repair</td>
</tr>
</tbody>
</table>

Discussion

Endovascular stenting has revolutionised the treatment of aortic aneurysms. Patients previously deemed unfit for open surgery were able to be considered for the endoluminal approach. Data from the Zenith Endoluminal Stent Graft Program indicate that significant mid-term complications or aneurysm rupture are low. The move to a totally percutaneous approach to this technique was a natural step in the evolution of the endoluminal procedure. In coronary diagnostic and interventional procedures, percutaneous closure devices have been shown to be safe and achieve faster haemostasis and ambulation times with a potential reduction in access site complications when compared with manual compression. In 1999, Haas et al. described the use of the PVS device to close large percutaneous arteriotomies following endovascular aortic aneurysmal repair. Thirteen closures were performed in 12 patients with no perioperative complications. The majority (75%) of the sheaths used were 16F but there was a successful closure of a 22F access site using two PVS devices.

To achieve closure, the 10F PVS device delivers 2 pairs of needles around the arteriotomy site through a barrel to be recovered above the incision. Haemostasis is attained when these sutures are tied together the sides of arteriotomy and also the perivascular tissue over the top. It is not a true over-the-wire system as the wire emerges from a side port. As a result, the wire has to be removed prior to deploying the needles because of the risk of needle deflection. Secondly, the sutures may not pass through the arterial wall or may have a lesser purchase on the wall as the presence of a wire across the arteriotomy causes the arteriotomy to be enlarged. The fear is that these sutures may cut through the artery when the 10F arteriotomy is later dilated during graft deployment by the introduction of 16–20F size sheaths.

A high bifurcation of the common femoral artery led to two complications in our series. This was not appreciated until an open incision was undertaken. Apart from the risk of embolisation, femoral artery calcification has been known to cause the needles to deflect and not enter the barrel of the device, although pushing the needle plunger back into the device can sometimes retrieve this situation. We found that scarring in the subcutaneous tissues, apart from making advancement of the device hub difficult, can also cause the needles to deflect. One of the authors (MAG) routinely dissects down to the artery with his finger at the start of the procedure prior to puncturing the femoral artery. If significant calcification or scar tissue is felt, a standard open incision is carried out.

Advancing the PVS device is difficult in the presence of tortuous and calcified iliac arteries as the device is both long and soft, and thus prone to bending. Excessive manipulation in this setting predisposes to distal embolisation and vessel dissection. To overcome this problem, some of us remove the wire only after the device tip had entered into the proximal neck of the aneurysm. In our preoperative assessment, we have modified our CT protocol to extend to the common femoral artery to assess for a high common femoral bifurcation, calcification and aneurysmal disease. Preoperative ultrasound of the groin is also sometimes used.
It is important that surgical instruments for cut-down are always available on the operating tray. In our series, bleeding was the most common reason for open conversion. Difficulties encountered during knot slippage down to the arteriotomy were the underlying reason for the majority of these failures. Obesity was the main risk factor. Knots not infrequently became caught with fat whilst traversing the long subcutaneous tract in these patients. Due to the importance of this step in attaining haemostasis, we adopt a regimental approach in the tying and slipping of these sutures. We routinely test and wet the sutures to ensure they run freely and that the thread is taut in the subcutaneous tract. Because of the one mortality in our series, we are now wary of punctures above the inguinal ligament and have a low threshold for open conversion when difficulty is encountered especially in obese patients.

Reports from other studies encountered similar problems in varying frequencies. In a series of 17 patients, Traul et al. experienced a 61.5% success rate in percutaneous deployment of the main body stent graft via a 22–24F sheath and a 64.7% success rate on the 16F contralateral limb access site. The main reasons for open conversion were found to be bleeding and iliofemoral dissection. The major risk factors identified in their study were use of 24F sheaths, small calibre external iliac vessels and sutures catching on other sutures during closure. A more recent study of 144 patients undergoing endoluminal grafting with the AneuRx stent-graft (Medtronic AVE, California) by Howell et al. reported a successful closure rate with the PVS device of 94.4% with no immediate or mid-term complications noted in this group of patients. Only 16F sheaths were used for the access sites and patients with heavy femoral calcification on CT and those requiring 22F sheaths were excluded. The eight failures experienced were due to obesity (2 cases) and calcified femoral arteries (6 cases).

In our opinion, the current device can be improved upon. A true over-the-wire system would greatly improve the safety profile and the ease of handling for the multiple exchanges required, particularly when two devices are used. In the setting of aneurysm disease, manipulation of the device with its tip free in the aneurysm sac could in theory lead to embolisation or perforation of the sac. Ideally the wire should pass through the aneurysm sac only once and remain above the aneurysm for the entire procedure. The current device presumably is not over-the-wire in an effort to keep the profile to 10F, but this is not an issue during endovascular grafting where the arteriotomy is enlarged to 14F or greater. Furthermore larger calibre devices that more closely resemble the sheath sizes used during endograft deployment will be more effective in achieving haemostasis and may obliterate the need to use two devices for large arteriotomies. An alternative to an over-the-wire system would be to have the wire port closer to the barrel end of the device. These device-related problems will decrease when second generation closure devices designed specifically for endoluminal grafting are developed.

Based on these results, we feel that the percutaneous technique is suitable for selected patients in institutions experienced with endoluminal grafting and where there has been adequate training in the use of the closure device by a product specialist. Complications can be largely avoided with pre-operative imaging to include the femoral arteries and the exclusion of patients with unfavourable iliofemoral anatomy, groin scars and morbid obesity. Given the ease of open groin exposures for endoluminal grafting, a trial to compare open and percutaneous closure is required to evaluate the relative safety and cost benefits of this new technique.

Acknowledgements

We thank the following surgeons for their role in contributing cases toward this study: Mr B. Stanley, Vascular Surgeon, Sir Charles Gairdner Hospital; Dr W. Yusuf, Vascular Registrar, Royal Perth Hospital; Dr R. Evans, Vascular Registrar, Royal Perth Hospital; Medical Illustrations, Royal Perth Hospital. We thank Miss L. Allison, Clinical Specialist at Perclose Australia for familiarising the use of the closure device by a product specialist. The authors with the use of the PVS device. Illustrations were reproduced with written permission from Perclose Australia obtained 28 June 2001.

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Accepted 18 August 2001