

# Implementation of a successful endovascular surgical program in a non-teaching tertiary-care centre in Ontario

Rod P.N. Willoughby, MD;\* John A. Fenton, MD;\* Santosh R. Pudupakkam, MD;\* Robert A. Greco, MD;† Evan W.D. Roberts, MD;† Guy DeRose, MD;‡ Stewart Kribs, MD§

Endovascular surgical techniques have become an accepted standard of care for high-risk patients with abdominal aortic aneurysms and for certain patients with thoracic aortic pathology and peripheral arterial aneurysms. In Canada, endovascular surgery has been concentrated in tertiary-care academic teaching institutions. As the technology evolves and as expertise advances, the applicability of endovascular techniques will expand. With time, and as the demand for endovascular techniques rises, this expertise will increasingly need to be delivered by dedicated vascular surgical services in nonteaching institutions. The dissemination of endovascular surgical capabilities represent a unique challenge. We report the successful implementation of an endovascular surgical program in a tertiary-care nonteaching institution using a carefully planned preceptorship model. We review our initial 49 cases and discuss 6 factors important to the successful establishment of an endovascular surgical service: education, teamwork, strict selection of patients, use of a single stent-graft manufacturer, industry support and endovascular preceptorship. Our experience may be used as a model by other institutions in Canada.

Les techniques de chirurgie endovasculaire sont devenues une norme acceptée de soin chez les patients présentant un risque élevé d'anévrisme de l'aorte abdominale et chez certains patients atteints d'une pathologie de l'aorte thoracique et d'anévrismes des artères périphériques. Au Canada, la chirurgie endovasculaire a été concentrée dans les établissements universitaires de soins tertiaires. À mesure que la technologie évoluera et que l'expertise progressera, il sera possible d'étendre l'applicabilité des techniques endovasculaires. Avec le temps, et à mesure de l'augmentation de la demande de techniques endovasculaires, cette expertise devra de plus en plus être assurée par des services consacrés exclusivement à la chirurgie vasculaire, dans des établissements non universitaires. La diffusion des capacités en chirurgie endovasculaire pose un défi sans pareil. Nous présentons un compte rendu de la mise en œuvre réussie d'un programme de chirurgie endovasculaire dans un établissement de soins tertiaires non universitaire, en suivant un modèle de préceptorat planifié avec soin. Nous passons en revue nos 49 premiers cas et discutons de 6 facteurs importants pour la réussite de l'implantation d'un service de chirurgie endovasculaire : éducation, travail d'équipe, sélection rigoureuse des patients, utilisation d'un seul fabricant de stents-greffons, appui de l'industrie et préceptorat en chirurgie endovasculaire. D'autres établissements du Canada pourront s'inspirer de notre expérience.

**A** bdominal aortic aneurysm (AAA) is a relatively common and preventable cause of death in the elderly.<sup>1</sup> Thoracic aortic and peripheral arterial aneurysms, although less

common, are also important and treatable vascular conditions.<sup>2,3</sup> Since 1951, open AAA repair involving replacement of the diseased artery with a prosthetic graft has been estab-

lished as a durable therapy, and continues to be considered the gold standard of treatment.<sup>4,5</sup> Open AAA repair is an invasive procedure with marked associated morbidity and risk

From the \*Division of Vascular Surgery and †Department of Radiology, Sudbury Regional Hospital, Sudbury, Ont., and the ‡Division of Vascular Surgery and §Department of Radiology, London Health Sciences Centre, London, Ont.

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**Correspondence to:** Dr. Rod P.N. Willoughby, Sudbury Regional Hospital, Memorial Site, 865 Regent St., Sudbury ON P3E 3Y9; fax 705 522-4158; rwilloughby@hrsrh.on.ca

of mortality.<sup>1,6,7</sup> The presence of comorbidities such as cardiac, respiratory and renal diseases will influence surgical decision-making, and in some cases preclude patients from surgery because of excessive risk of perioperative morbidity and mortality.<sup>8,9</sup> Although perioperative mortality after open AAA repair in low-risk patients is a relatively acceptable 1.2% to 5.8%,<sup>1,10-15</sup> in high-risk patients mortality and morbidity increase to as much as 4-fold.<sup>6,7,9-11,16-20</sup>

Successful endovascular (EV) surgical repair of AAA was first performed in 1991.<sup>21</sup> This revolutionary technique involves inserting a stent-graft into the aneurysm, usually via the common femoral artery, effectively excluding the aneurysm sac from the systemic circulation. The procedure may be performed without general anesthesia, eliminates laparotomy and aortic cross-clamping, and greatly reduces attendant surgical stresses on cardiac, pulmonary and renal function.<sup>22-24</sup> In high-risk patients, the EV technique has reduced perioperative morbidity and mortality to 1.5%–4.2%, a notable improvement over open AAA repair.<sup>24-27</sup> EV AAA repair has therefore become the treatment of choice for high-risk patients. EV techniques also play a role in the treatment of thoracic aortic pathology and certain peripheral arterial aneurysms.<sup>28</sup>

In Canada, EV surgery is essentially concentrated in tertiary-care institutions engaged in academic teaching. As the technology evolves and expertise advances, so will the use of EV techniques expand. As demand rises, EV techniques will increasingly be expected from dedicated vascular surgical services in non-teaching institutions.

The dissemination of EV surgical capabilities is a unique challenge. With careful planning and expert guidance, the first successful EV surgical program in a Canadian tertiary-care non-teaching institution was established. We review our initial 49 cases and discuss factors important in

the successful establishment of an EV service, which may be employed as a model by other centres in Canada.

## Method

We recognized 6 key factors as essential to initiating an EV surgical program. Each is addressed below and summarized in Box 1.

### Education

Considerable planning and preparation took place before our first EV case could be attempted. Two of the vascular surgeons in our centre had received EV exposure during vascular surgery fellowship training at the University of Western Ontario (London, Ont.). All members of our EV team attended meetings and symposia for EV surgery to attain further education. Through education and presentations to our hospital administrators, we were granted permission to initiate an EV surgical program. Funds were provided to acquire a carbon-fibre table (Skytron, Grand Rapids, Mich.) and high-resolution portable C-arm (OEC Medical Systems, Inc., Salt Lake City, Utah). An annual operating budget has been established for purchase of stent-graft devices.

### Teamwork

Our EV team comprises 3 dedicated vascular surgeons and 2 interventional radiologists. All team members are

involved in the work-up, treatment and follow-up of our patients. A group of interested anesthetists participate. Operating-room (OR) nursing personnel received special training in catheter-based techniques and EV aneurysm repair, and are integral to our success. During EV procedures, 2 surgeons and 1 interventional radiologist are always present. All patients are treated in the OR.

### Strict patient selection

Patient selection was paramount and strictly adhered to. Most patients (92%,  $n = 45$ ) receiving EV AAA repair were considered to be in the high-risk category for standard open AAA repair. Patients were considered to be high-risk if they exhibited 1 or more of the medical comorbidities listed in Box 2. Other patients were considered for EV repair if they manifested such technical factors as hostile abdomen, pelvic irradiation, colostomy, ileal conduit, renal transplant or previous aortic reconstruction.

Work-up involved helical contrast-enhanced computed tomography (CT) imaging, angiography using calibrated catheters, stent-graft selection based on measurements from imaging studies, and preoperative anesthetic consultation. During our initial experience we accepted patients felt to have uncomplicated cases and straightforward anatomy; as we gained experience, we gradually attempted more challenging cases. Anatomical criteria for inclusion as EV candidates are summarized in Box 3, and anatomical features that required attention for stent-graft selection in Box 4.

### Single stent-graft manufacturer

We chose to restrict ourselves to a single manufacturer for aortic and iliac devices: all received Talent<sup>®</sup> stent-grafts by Medtronic (Santa Rosa, Calif.). Stent-graft options included aorto-bi-iliac and aorto-uni-iliac con-

### Box 1. Factors key to successful implementation of an endovascular program

- Education
- Teamwork
- Strict patient selection
- Single stent-graft manufacturer
- Industry support
- Endovascular preceptorship

figurations, as well as stent-grafts that were custom-constructed for unique or difficult anatomy. All AAA cases received devices that provided supra-renal fixation. Selection of stent-graft configuration was based primarily upon patient anatomy (Box 3). Subclavian artery aneurysms received the Wallgraft® device (Boston Scientific, Minneapolis, Mass.).

Use of a single stent-graft product afforded earlier expertise with the device and eliminated a potential source of variability while we were learning the technique.

#### **Support from industry**

Support from Medtronic was and continues to be important in maintaining our EV program. Ongoing support for education, training and equipment remains an important component of our program. Regular communication among ourselves and with our administration about stent-graft costs and incentives permits us to continue to make use of this expensive technology. At present,

Medtronic supplies on-site intraoperative support from a field clinical specialist as long as required, which provides on-site technical expertise.

#### **Structured endovascular preceptorship**

The most important success factor, structured preceptorship, was provided by the EV team at the London Health Sciences Centre. The London (Ont.) EV team possesses the greatest Canadian EV experience.

The preceptorship was structured in 3 stages. Initially, members of the Sudbury EV team travelled to London to observe cases on-site. Next, the initial 5 cases performed in Sudbury were planned and approved in association with the London EV team. These 5 cases were completed with the London preceptors (including a surgeon, radiologist and OR nurse) scrubbed and on-site in Sudbury. Finally, case planning for the next 20 cases performed in Sudbury was reviewed and approved by the London preceptors prior to stent-

graft insertion. Several times, our plans were modified for the better by the preceptors.

#### **Results**

Our EV surgery program began June 16, 2000. By Oct. 1, 2002, we had completed 49 cases. Our annual caseload is 25–30, an average of 30% of the centre's elective infrarenal AAA cases. Most patients were male (92%,  $n = 45$ ). Most cases (Table 1) involved infrarenal AAA, followed by iliac and subclavian artery aneurysm.

Both of the patients with subcla-

#### **Box 2. Medical comorbidities that render patients at high risk for standard open-abdominal aortic aneurysm repair**

- American Society of Anesthesia (ASA) classification 3 or 4
- Age  $\geq 80$  yr

##### **Cardiac comorbidities**

- Unstable angina
- History of recent congestive heart failure ( $\leq 6$  mo)
- Recent myocardial infarction ( $\leq 6$  mo)
- Grade 3 or 4 left ventricle on echocardiography

##### **Respiratory comorbidities**

- Moderate or severe chronic obstructive pulmonary disease or restrictive disease confirmed with pulmonary function tests
- Reduced forced expiratory volume:  $FEV_1 \leq 30\%$  predicted
- Home oxygen dependence

##### **Renal comorbidities**

- Dialysis-dependence
- Renal insufficiency (creatinine  $\geq 180$   $\mu\text{mol/L}$ )

#### **Box 3. Anatomical criteria for endovascular repair**

##### **Aortic neck**

- Length  $\geq 10$  mm
- Diameter  $\leq 28$  mm
- Angulation  $\leq 60^\circ$
- Calcification absent or minimal
- No ulcerated atheroma
- No mural thrombus

##### **Iliac arteries**

- Diameter  $\geq 7$  mm
- Tortuosity no greater than mild or moderate
- Calcification absent or minimal

#### **Box 4. Anatomical features important to case planning**

##### **Renal arteries**

- Accessory arteries
- Presence of stenosis
- Horseshoe kidney
- Renal transplant

##### **Iliac arteries**

- Aneurysm in common iliac artery
- Aneurysm in internal iliac artery
- Stenosis

##### **Mesenteric arteries**

- Occlusive disease in superior mesenteric artery

vian aneurysms were 38 years old. EV techniques permitted repair without median sternotomy, markedly reducing morbidity.

Patients needing aortic or iliac repair were 57 to 88 years of age. Cardiac comorbidity was the most frequent primary indication (49%) for the EV technique in cases of AAA and iliac aneurysm. Two patients had undergone previous open vascular reconstruction. Twenty (41%) required preoperative coil embolization of an internal iliac artery (1 bilateral) to facilitate repair.<sup>29</sup> Primary indications for EV repair of aortic or iliac aneurysms are summarized in Table 2; the procedures performed, in Table 3.

As our EV team gained experience, we modified our approach; the differences in treatment between the first 25 and latter 24 of our patients so far is summarized in Table 4. Our use of spinal rather than general anesthetic increased from under 40% of patients to over 80%, and our dependence on postoperative intensive care has decreased even more radically: transfer of patients from the operating room directly to the ward has risen from under 10% to two-thirds of our

team's cases.

Stent-graft selection is dictated primarily by patient anatomy. Our overall use of aorto-uni-iliac and aorto-bi-iliac stent-grafts has been nearly equal (Table 3). But as we began accepting patients with more challenging anatomy, the devices used have become predominantly aorto-uni-iliac, rising from less than one-quarter to more than four-fifths of stent-grafts placed (Table 4). A sizable proportion of our cases (over 40%) have required customized devices (Table 3).

In terms of intention to treat, 100% of our cases attempted were completed. There were no deployment failures, conversions to open repair, intraoperative mortality nor type I endoleaks.<sup>30</sup> A type I endoleak describes an inadequate seal between the stent-graft and the native arterial wall such that the aneurysm is not excluded from the systemic circulation, compelling further treatment.<sup>31</sup>

An endoleak is categorized as type II when the aneurysm sac is perfused via lumbar arteries or the inferior mesenteric artery. These endoleaks are considered relatively unimportant because the great majority throm-

bose spontaneously.<sup>31,32</sup> Immediately after stent-graft insertion, type II endoleaks occurred in 59% of our cases ( $n = 29$ ). One patient continues to harbour a persistent type II endoleak (a rate of 2%), confirmed by means of angiography 9 months after stent-graft placement. The aneurysm sac has remained stable in size, and further intervention has not been required. All other type II endoleaks have resolved spontaneously.

To date, our patients have had 4 stent-graft-related complications, for a rate of 8.2%: 1 intraoperative stent-graft migration that resulted in occlusion of the renal artery and 3 postoperative stent-graft thromboses (1 subclavian, 1 in a single aorto-bi-iliac limb, and 1 aorto-uni-iliac).

One intraoperative complication occurred, for an intraoperative technical success rate of 98%. The case involved cephalad migration of the stent-graft, occluding both renal arteries. One renal artery was successfully stented by the interventional radiologist during the operation, salvaging renal function. At discharge the patient felt well and tested normal for serum creatinine.

Our overall 30-day technical success was 94%. One patient required emergency vascular reconstruction on postoperative day (POD) 3 for stent-graft thrombosis. A single perioperative death occurred on POD 14 from exacerbation of chronic obstructive pulmonary disease. Overall 30-day mortality for all patients was 2%. No patient has died for device-related reasons.

Duration of follow-up stands at 1–29 months (mean 11.5 mo). All patients had contrast-enhanced CT imaging within 4 weeks and again 12 weeks after stent-graft insertion. Serial contrast-enhanced CT and abdominal duplex ultrasound imaging is performed thereafter every 6 months for life. Patients are assessed clinically within 12 weeks after surgery, and every 6 months thereafter. Except for the single perioperative death, all patients are doing well.

**Table 1**

**Summary of insertion sites**

Location of aneurysm	<i>n</i>	% of 49
Abdominal aortic	42	86
Iliac	5	10
Subclavian	2	4

**Table 2**

**Primary indications for aortic or iliac endovascular repair**

Indication	<i>n</i>
Cardiac problems	24
Respiratory problems	13
Advanced age	7
Prior aortic reconstruction	2
Renal transplant	1

**Table 3**

**Summary of stent-grafts used**

Configuration	<i>n</i>
Aorto-bi-iliac	21
Aorto-uni-iliac	22
Tube (includes Wallgraft®)	6
Custom	20

**Table 4**

**Changes in treatment factors for endovascular correction of aortic and iliac aneurysms, in % of cases**

Utilization of	Cases 1–25,* <i>n</i> = 23	Cases 26–49, <i>n</i> = 24
Spinal anesthetic	39	83
Intensive Care admission	91	33
Aorto-uniliac stent-graft	24	82

\*includes repair of 2 subclavian aneurysms

Stent-graft-related complications have occurred in 3 patients (6%) during follow-up, all involving stent-graft thrombosis. The first patient developed thrombosis of a Wallgraft device within 3 months of stent-graft repair of an aneurysm in the subclavian artery. Thrombolysis with tissue plasminogen activator (tPA) was successful, and no etiology for thrombosis could be identified. But despite subsequent anticoagulation, the stent-graft rethrombosed. The patient has minimal claudication in his nondominant arm and has not required surgical revascularization.

The second patient developed thrombosis of 1 iliac limb of an aorto-bi-iliac stent-graft for AAA within 3 months of insertion. This patient has 200-metre claudication and has not required surgical revascularization.

The third patient had received an aorto-uni-iliac stent-graft and femoral-femoral crossover graft for AAA. On POD 3, the stent-graft thrombosed, producing acute bilateral limb-threatening ischemia and lower-extremity paresis. Emergency axillo-bifemoral revascularization was conducted, and the patient recovered completely.

Including angiography for the persistent type II endoleak, 3 secondary procedures (6%) have been performed to date.

## Discussion

We have demonstrated that endovascular surgical capabilities may be successfully delivered by a dedicated vascular surgical group in a tertiary-care non-teaching institution. Our results are consistent with those published by others.<sup>33-36</sup> As we have gained experience, we have successfully treated patients with more challenging anatomy. We currently enjoy a capable and successful EV program that offers all vascular surgical options to our patient population. We have not yet had the opportunity to treat a thoracic aortic aneurysm with EV techniques, but we look forward to

that opportunity.

We believe the 6 key factors outlined in Box 1 should be respected, to maximize the likelihood for successful establishment of an EV surgical program. Education is clearly the initial step. Current and future vascular fellows will be exposed to EV techniques during fellowship training; established vascular surgeons will need to educate themselves at meetings and symposia, and would benefit from an EV course or mini-fellowship. Greater preparation increases the odds of early success.

EV surgery truly requires a multidisciplinary approach. Vascular surgeons and interventional radiologists bring a different set of skills to the table. Both sets of skills are important for work-up, successful deployment and proper follow-up protocol. Although some centres have not included interventional radiologists as part of their EV team, in our centre we considered their participation would permit us to implement our program earlier and with greater likelihood for success. Perhaps their greatest contribution is the ability to salvage the EV technique and avoid conversion to open repair. Our case where the radiologist was able to access and stent a renal artery when both renal arteries became occluded by stent-graft migration is an example of the value interventional radiologists bring to the team.

Genuine teamwork promotes interest and generates excitement in all individuals involved. A great deal of satisfaction can be realized in successfully delivering this new and challenging technology to patients.

When initiating an EV program, team members will be eager to perform procedures as quickly as possible, to gain experience. While this is understandable, this enthusiasm has to be tempered by patience, good judgement and strict patient selection. All eyes will likely be upon the team beginning a program of this cutting-edge procedure, and in any institution there may be persons who might pre-

fer to see an expensive program fail. Therefore, only patients with ideal anatomy should be selected initially. Once the team gains experience and confidence with straightforward cases, progressively more challenging cases may then be approached.

A learning curve has been shown to exist with any new technology.<sup>22</sup> Because of this, we suggest when learning the technique that you select a single stent-graft device only. Although several stent-graft devices are available for aortic and iliac aneurysms, the last thing a new team needs to do is complicate matters by "shopping around" early in their experience. There are enough variables that may confound EV procedures; restricting the number of stent-graft devices while learning will restrict those that exist between different devices. We are not advocating one device over another; simply select one and become expert with it. Device familiarity will enhance intraoperative problem-solving when it is needed.

Support from the industry is paramount for success. Regardless of the stent-graft manufacturer chosen, support is provided to EV teams initiating new programs because it is in the manufacturer's interest for new programs to be successful. Support for education, equipment, stent-graft supply and technical support are all important components. On-site intraoperative technical support was provided by the Medtronic field clinical specialist for our initial 15 cases, and he remains immediately available at all times.

The most important factor, we suggest, is the structured preceptorship. It brings all factors together and provides the expert guidance required to maximize your opportunity for early success. Given that all vascular surgeons at our institution trained in London (Ont.), we naturally have a special relationship with the vascular surgeons there. Without the support of the London EV team, we would not have realized the early success that we have enjoyed. We re-

main indebted to the London EV preceptors. The ultimate benefit afforded by the preceptorship is that it altered our learning curve for the better, benefiting our EV program and patients alike.

EV techniques are now established as the standard of care for high-risk patients with AAA. Clearly, EV surgery is an expensive technology, one that requires considerable expertise to deliver safely. Given the degree of expertise necessary, it is reasonable that only centres possessing certain prerequisites should seriously consider establishing an EV program. Potential candidate health centres must have dedicated vascular surgeons, 1 or more dedicated interventional radiologists, interested anesthesia and nursing personnel, full intensive-care support and a supportive hospital administration.

It is likely that provincial governments will be, and should be, involved in regionalization of delivery of this specialized care. That said, as we move forward, EV capabilities will need to be increasingly delivered by vascular surgeons in non-teaching institutions that meet the necessary requirements for a successful program. A structured preceptorship modelled after our experience will permit dissemination of this technology in a safe and efficient manner, and will increase the likelihood of early success.

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