Ontario Health Technology Assessment Series 2009; Vol. 9, No. 4

Fenestrated Endovascular Grafts for the Repair of Juxtarenal Aortic Aneurysms

An Evidence-Based Analysis

Presented to the Ontario Health Technology Advisory Committee March 2009

July 2009

Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

Suggested Citation

This report should be cited as follows: Medical Advisory Secretariat. Fenestrated endovascular grafts for the repair of juxtarenal aortic aneurysms: an evidence-based analysis. *Ontario Health Technology Assessment Series* 2008;9(4).

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ISSN 1915-7398 (Online)
ISBN 978-1-4249-9999-6 (PDF)

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Executive Summary

Endovascular repair of abdominal aortic aneurysm (AAA) allows the exclusion of the dilated aneurismal segment of the aorta from the systematic circulation. The procedure requires, however, that the endograft extends to the healthy parts of the aorta above and below the aneurysm, yet the neck of a juxtarenal aortic aneurysm (JRA) is too short for a standard endovascular repair. Fenestrated endovascular aortic repair (f–EVAR) provides a solution to overcome this problem by enabling the continuation of blood flow to the renal and visceral arteries through holes or 'fenestrations' in the graft. These fenestrations are designed to match the ostial diameter of the renal and visceral arteries.

There are three varieties fenestration, small, large, and scallop, and their location needs to be customized to fit the anatomy of the patient. If the device is not properly designed, if the alignment is inaccurate, or if the catheterization of the visceral arteries is not possible, the procedure may fail. In such cases, conversion to open surgery may become the only option as fenestrated endografts are not retrievable.

It is recommended that a stent be placed within each small fenestration to the target artery to prevent shuttering of the artery or occlusion. Many authors have noted an increased risk of vessel occlusion in unstented fenestrations and scallops.

Once placed in a patient, life-long follow-up at regular intervals is necessary to ensure the graft remains in its intended location, and that the components have adequate overlap. Should the need arise, routine follow-up allows the performance of timely and appropriate intervention through detection of events that could impact the long-term outcomes.

Alternative Technology

The technique of fenestrated endovascular grafting is still in evolution and few studies have been with published mid-term outcome data. As the technique become more common in vascular surgery practices, it will be important to determine if it can provide better outcomes than open surgical repair (OSR).

In an OSR approach, aortic clamping above one or both renal arteries, or above the visceral arteries, is required. The higher the level of aortic clamping, the greater the risk of cardiac stress and renal or visceral ischemia. During suprarenal or supraceliac aortic clamping, strain-induced myocardial ischemia may also occur due to concomitant rise in cardiac afterload and a decrease in cardiac output. Reports indicate that 6% of patients undergoing surgical repair develop myocardial infarction. The ideal level of clamp location remains controversial with conflicting views having been reported.

Method

A search of electronic databases (OVID MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, The Cochrane Library, and the International Agency for Health Technology Assessment [INAHTA] database was undertaken to identify evidence published from January 1, 2004 to December 19, 2008. The search was limited to English-language articles and human studies. The automatic search alerts were received and reviewed up to March 23, 2009.

The literature search and automatic search update identified 320 citations, of which 13 met inclusion/exclusion criteria. One comparative study presented at an international seminar, five single-arm studies on f–EVAR, and 7 studies on OSR (one prospective and six retrospective) were considered for this analysis.

To grade the strength of the body of evidence, the grading system formulated by the GRADE working group and adopted by MAS, was applied. The GRADE system classifies evidence quality as high (Grade A), moderate (Grade B), or low (Grade C) according to four key elements: study design, study quality, consistency across studies, and directness.

A summary of the characteristics of the f–EVAR and OSR studies found through the literature search is shown in Table ES-1.

ES-1. Patient Characteristics: f–EVAR Studies versus OSR Studies

Technique	Number of Patients	Mean Age (Range), Years	Aneurysm Diameter (Range),mm	Mean Duration of Follow-up, Years
f–EVAR (5 studies)	274	74 (72-75)	63 (59-68)	9.4-25.8
OSR (7 studies)	856: JRA: 675 SRA: 136 TAA: 45	72 (67-78)	62 (50-70)	1-48

JRA, Juxtarenal aortic aneurysm; SRA, Suprarenal aortic aneurysm; TAA, Thoracic aortic aneurysm

Mortality Outcomes

The pooled estimate for 30-day mortality was 1.8% among the f–EVAR studies and 3.1% among the OSR studies that reported data for the repair of JRA separately. The pooled estimate for late mortality was 12.8% among the f–EVAR studies and 23.7% among the OSR studies that reported data for JRA separately.

Visceral Artery Events Reported in f–EVAR Studies

Renal Events during f-EVAR

A total of three main renal arteries and two accessory renal arteries became occluded during the procedure. These were all due to technical issues, except one accessory renal artery in which the artery was intentionally covered. One patient required open surgery following the procedure.

Renal Events During the follow-up

A total of 12 renal arteries (12 patients) were found to be occluded during follow-up. In two patients, the same side accessory renal artery was also occluded. Four (1.5%) patients lost one kidney and five (2.3%) patients underwent dialysis, three (1.4%) of which became permanent.

A total of 16 cases of renal artery stenosis (16 patients) occurred during follow-up. Eight of these were treated and eight were observed. Segmental renal infarcts were found in six patients but renal function was not impaired.

Mesenteric Events during f-EVAR

Three mesenteric events occurred during the f-EVAR procedures resulting in two deaths. One patient developed bowel ischemia due to embolization of the superior mesenteric artery (SMA); this patient died 13 days after the procedure from multiorgan failure. One patient died eights days after the procedure from mesenteric ischemia and bowel perforation. The third SMA event occurred during surgery with subsequent occlusion in early follow-up.

Mesenteric Events during Follow-up

During follow-up, five (1.8%) SMA occlusions/partial occlusions and one SMA stenosis were noted. Three of the five patients with SMA occlusion/partial occlusion remained asymptomatic and no further intervention was necessary. One patient underwent SMA bypass surgery and in two patients, the problem solved by SMA stenting. A summary of the outcomes reported in the f–EVAR and OSR studies is shown in Table ES-2.

ES-2. Summary of Outcomes: Fenestrated Endovascular Graft Versus Open Surgical Repair for Treatment of Juxtarenal Aortic Aneurysm

Outcome	f–EVAR	OSR
Pooled Estimate (Rate)		
30-day mortality	1.8	3.1
Late mortality	12.8	23.7
Permanent dialysis	0-2.5	0-3.5
Loss of kidney	1.5	No report of kidney loss Incidence of post-op renal insufficiency: 14.4%
Mesentric ischemia	3.3	2.9
Aortic rupture	0	0
Post-op cardiac complications	1.5	10.7
Post-op pulmonary complications	0.7	13.4
Post-op GI complications	0.7	5.9
Aneurysm expansion	1.4	0
Secondary intervention (Non-endoleak)	8.8	7.8
Endoleak	Type I: 4 Type 2: 16.8 Type III: 1.8	N/A
Endoleak required treatment	Type I: 2.9 Type 2: 3.3 Type III: 1.1	
Graft migration	1.5	N/A
Graft separation	0.7	
Duration (Mean)		
Operation time (min)	240	287
Hospital stay (days)	6	13

Summary

Short- and medium-term results (up to 2 years) of f–EVAR for the repair of JRA showed that outcomes in f–EVAR series compare favourably with the figures for the OSR series; however, uncertainty remains regarding the long-term results. The following observations are based on low quality evidence.

- F–EVAR has lower 30-day mortality than OSR (1.8% vs. 3.1%) and a lower late-mortality over the period of time that patients have been followed (12.8% vs. 23.7%).
- There is a potential for the loss of target vessels during or after f–EVAR procedures. Loss of a target vessel may lead to loss of its respective end organ. The risk associated with this technique is mainly due to branch vessel ischemia or occlusion (primarily among the renal arteries and SMA). Ischemia or occlusion of these arteries can occur during surgery due to technical failure and/or embolization or it may occur during follow-up due to graft complications such as graft migration, component separation, or arterial thrombosis. The risk of kidney loss in this series of f–EVAR studies was 1.5% and the risk of mesenteric ischemia was 3.3%. In the OSR studies, the risk of developing renal insufficiency was 14.4% and the risk of mesenteric ischemia was 2.9%.
- F–EVAR has a lower rate of postoperative cardiac and pulmonary complications.
- Endoleak occurs in 22.5% of patients undergoing f–EVAR (all types) and about 8% of these require treatment. Most of the interventions performed to treat such endoleaks conducted using a minimally invasive approach.
- Due to the complexity of the technique, patients must be appropriately selected for f–EVAR, the procedure performed by highly experienced operators, and in centers with advanced, high-resolution imaging systems to minimize the risk of complications.
- Graft fenestrations have to be custom designed for each patient to fit and match the anatomy of their visceral arteries. Planning and sizing thus requires scrutiny of the target vessels with a high degree precision. This is important not only to prevent end organ ischemia and infarction, but to avoid prolonging procedures and subsequent adverse outcomes.
- Assuming the average cost range of FEVAR procedure is $24,395-$30,070 as per hospital data and assuming the maximum number of annual cases in Ontario is 116, the average estimated cost impact range to the province for FEVAR procedures is $2.83M-$3.49M annually.

Background

Clinical Need

Endovascular Aneurysm Repair (EVAR) has gained widespread acceptance for the treatment of abdominal aortic aneurysms (AAA). The results of a large randomized controlled trial (EVAR1 trial) (1) in which patients were suitable for both EVAR and open surgical repair (OSR) have shown a significantly lower 30-day mortality among patients who underwent EVAR compared to those who underwent OSR. (EVAR 1.7%, OSR 4.7%; odds ratio 0.35, 95% CI: 0.16-0.77; *P*=.009). However, the application of the EVAR technique is limited to patients in whom there is adequate healthy aorta below the renal arteries to provide an adequate proximal sealing zone. The presence of a short neck (<15 mm) at the proximal site is a contraindication for standard EVAR. Customized fenestrated grafts have thus been developed to allow the proximal sealing zone of the grafts to be placed in a healthier part of the aorta above the renal arteries. Known as fenestrated EVAR, or f–EVAR, this technology is enabling an expansion of the patient population, increasing the number that may be eligible for endovascular repair.

A fenestrated endograft has holes or 'fenestrations' in its fabric that can be aligned and positioned in front of the renal and visceral arteries to preserve their blood flow and the flow of blood to their respective end organ. The f–EVAR procedure still, however, requires an acceptable sealing zone of 4 mm below the renal arteries. Shorter necks will require the use of a different graft called the "Branched Endograft," which has pre-attached limbs or cuffs targeted for visceral vessels.

The implantation of standard EVAR is a relatively simpler procedure, requiring accurate longitudinal placement of the graft. The f–EVAR procedure is more challenging as graft positioning requires both longitudinal and rotational alignment of the fenestrations with the target vessels. Any misalignment can lead to partial or total covering of the ostia of the target vessel (shuttering), resulting in reduced blood flow or occlusion.

Target Population

The target patient population for f–EVAR is primarily made up of those patients with infrarenal AAA at risk of rupture who are unsuitable for OSR due to the presence of significant comorbid conditions, and who are unsuitable for treatment with a standard EVA because of the presence of a short proximal neck.

F-EVAR requires appropriate patient selection to identify those patients who will most likely benefit from the repair. Since deployment of a fenestrated endograft involves repeated manipulation of guidewires and catheters within the lumen of the aorta, there is the potential for disrupting friable plaques attached to the aortic wall. Therefore, significant atheroma or mural thrombus within abdominal segment of the aorta (working area) may be considered as a relative contraindication for f–EVAR. The turtuosity of the aorta and the anatomy of the iliac arteries are also important considerations for patient selection. The presence of narrow, calcified and tortuous iliac arteries has been considered as another relative contraindication for f–EVAR because the procedure requires an unobstructed access through these arteries. (2)

Juxtarenal Aortic Aneurysm

By definition, a juxtarenal aortic aneurysm (JRA) is an infrarenal AAA that extends up to the renal arteries but does not involve these arteries (see figure 1).

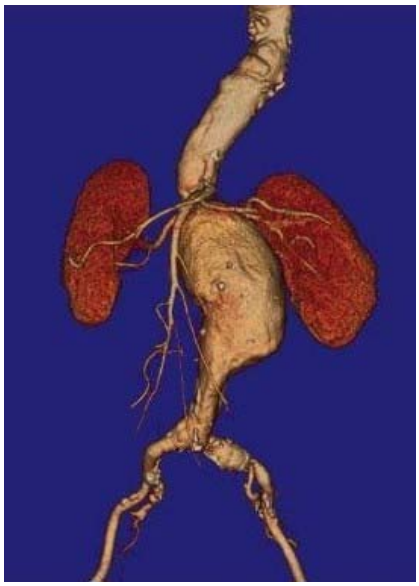

Figure 1. Juxtarenal Aortic Aneurysm

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Risk of Rupture of Abdominal Aortic Aneurysm

If an aneurysm is left untreated, it may rupture resulting in the death. Several factors contribute to the risk of rupture, the diameter of the aneurysm being the most important. The risk of rupture is significant if the diameter of aneurysm exceeds 5 cm. The correlation between the risk of rupture and diameter is, however, non-linear. A 4-5 cm aneurysm has an annual risk of rupture of 0.5% to 5%, whereas a 6-7 cm aneurysm has an annual risk of rupture of 10% to 20%. (3) These factors become important as the decision to perform a prophylactic intervention on asymptomatic patients must take into account the risk of mortality due the intervention compared to the risk of rupture. Generally, patients will have a survival benefit if the size of their aneurysm exceeds 5-5.5 cm. (3)

A systematic review and meta-analysis of rupture rates of AAA with diameter of 5 cm or more in patients not considered for OSR was conducted by Powel et al. (4) The pooled rupture rate was 18.2 (95% CI: 13.7-24.1) per 100 person years. There was a 2.5-fold increase (95% CI: 1.69–3.85) in rupture rate for patients with AAA 6 cm or larger versus those less than 6 cm.

There are indications that patients with short infrarenal necks who are not anatomically suitable for standard EVAR carry a higher risk of rupture than those who are because of the extensive nature of the disease. This was also considered by Powel et al. who noted that patients with shorter aneurysm neck length appeared to have a higher rupture rate than those with longer aneurysm neck length. (4)

Prevalence of Juxtarenal Aortic Aneurysm

The incidence of JRA reported by an institution minimally biased by tertiary referral was 15.5%. In this study (5), a 5-year retrospective review of all aortic surgeries was performed. Of 174 infrarenal aortic aneurysectomies performed, 27 (15.5%, 95% CI: 10.5% to 21.8%) involved the juxtarenal aorta. (5)

In another study (6), 859 open surgical procedures were performed for repair of infrarenal AAA between June 1994 and December 2000. JRA accounted for 16% of all these procedures.

The New Technology

Fenestrated Endovascular Stent Grafts

Body of the Graft

Fenestrated endovascular grafts have three principal components, a proximal main body, a distal bifurcated main body, and a leg extension (see Figure 2). The proximal main body is implanted first and independently from the other two parts. This allows the physician to focus on accurate positioning of the graft and to align the fenestrations to the orifice of the branch target vessels. This feature also helps to minimize the likelihood of graft migration and helps the fenestrations to remain in their intended location.

The body of the graft is fully stented with self-expanding stainless steel z-stents to provide stability with the radial forces of the stent helping the graft to stay in place. Barbs at the most proximal site of the graft then provide anchorage of the graft into the aortic wall.

The standard EVAR has one joint overlap between the main body and the iliac extension leg, whereas fenestrated endografts have two overlaps, one between the proximal and distal main body, and one between the proximal main body and iliac extension leg. The two-piece main body has been incorporated into the design of the graft to enable independent alignment and orientation of the proximal and distal bodies. The manufacturer recommends two-stent overlap to provide more stability between the proximal and distal components.

Fenestrations

There are three basic types of fenestrations and all are designed to match the ostial diameter of the renal and visceral arteries. Small fenestrations, approximately 4–6 mm (width) by 4–8 mm (height) are used mostly for renal arteries and have no crossing stent struts (they are not large enough) and occupy only the space between stent struts. Large fenestrations with diameters between 9 and 12 mm are used mostly for the superior mesenteric artery (SMA) and are supported by a crossing stent strut to prevent them from collapsing. Thus this type of fenestration does not routinely require stenting. The third type of fenestration is a scallop, which is carved out of the proximal end of the fabric with a width of 10 mm and a height of 6 to 12 mm. (7)

The location of the fenestrations in each graft needs to be customized to fit the anatomy of each patient. (7) If the device is not properly designed, if alignment is inaccurate, or if the catheterization of the visceral arteries is not possible, the procedure may fail. In such cases, conversion to open surgery may become the only option as fenestrated endografts are not retrievable. (8)

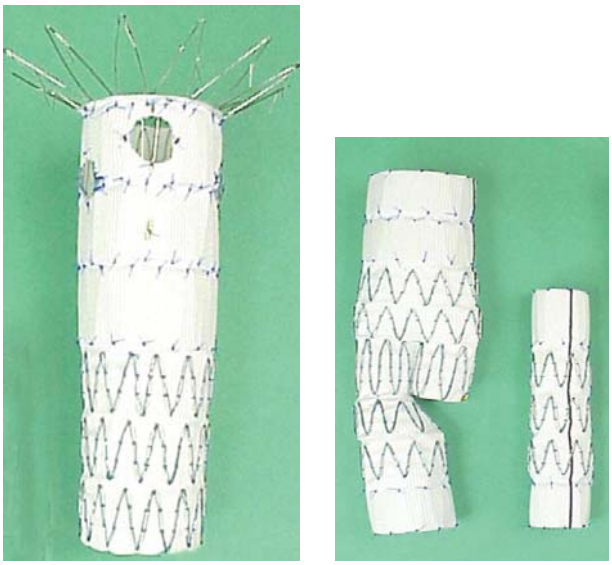

Figure 2. Components of Fenestrated Endograft

Reproduced from: Moore R, Hinojosa CA, O'Neill S, Mastracci TM, Cina CS. Fenestrated endovascular grafts for juxtarenal aortic aneurysms: a step by step technical approach. Catheterization & Cardiovascular Interventions 2007; 69(4):554-571.

Graft Materials

The fabric of the graft is composed of woven polyester and the stents are stainless steel. The barbs or hooks at the most proximal edge of the graft are uncovered. Radiopaque gold markers at the margins of the fenestrations are for positioning and orientation of the fenestrations during graft implantation. The margins of the fenestrations are also reinforced with a nitinol ring to prevent them from collapsing, to facilitate cannulation, and to reduce the time required for stenting the target vessels.

Stenting the Target Arteries

It is recommended that a stent be placed within each small fenestration to prevent shuttering or occlusion of the target arteries. Many authors have noted an increased risk of vessel occlusion in unstented fenestrations and scallops. (9) When implanted, the stent is positioned such that one-third of the device remains in the aorta and two-thirds into the target artery. The selection of a covered versus open stent has been a matter of controversy, however, the current trend is toward covered stents. There are some reports that open cell stents permit the fabric to pass between stent struts resulting in shuttering of the lumen, (2) though there are still advantages and disadvantages for both types. (10) Of note, stents that are currently being used to secure fenestrations have not been designed specifically for this purpose (2) and a stent specifically designed for this has yet to be developed. According to the manufacturer, target artery occlusion may result as a response to stent placement. Therefore, specific criteria have been established by the manufacturer with respect to pre-existing stenosis of the target vessel and have been listed for consideration during patient selection.

Risks Associated with Fenestrated Endograft

Many of the risks associated with fenestrated endografts are similar to those for standard EVAR including risk of death, embolization, endoleak, graft migration, and component separation. There are, however, additional risks posed by the presence of fenestrations or design of the graft. These include:

1. Risk of vessel occlusion/stenosis that may result in end organ ischemia or infarction (i.e. renal arteries and SMA). Occlusion of the renal artery may lead to kidney loss and renal artery events during the procedure or during the follow-up may affect renal function and pose a risk of hemodialysis. Occlusion of the mesenteric artery may lead to mesenteric ischemia resulting in end organs infarction
2. Risk associated with catheterization and the stenting target arteries (e.g. arterial perforation)
3. Risks associated with inappropriate planning and sizing of the graft which expose the patient to a prolonged procedure and its related consequences. The use of appropriate software for planning and sizing can minimize this risk.
4. Risk associated with the experience of the physician performing the procedure
5. Risk associated with prolonged exposure to x-ray radiation during the intraoperative imaging
6. Risk associated with the use of contrast agents during intraoperative imaging, which may increase the risk of renal failure

If the above risks are at an acceptable level, they can be offset by the benefit of providing an effective treatment for patients who would otherwise have limited (if any) choices for treatment.

Life-Long follow-up

Life-long follow-up at regular intervals is necessary to ensure the graft remains in its intended location and that the components have adequate overlap. Routine follow-up allows the performance of timely and appropriate interventions through detection of possible events that could impact the long-term outcomes.

Alternative Technology

Open Surgical Repair

The technique of f-EVAR is still evolving and few studies have published mid-term outcome data. As the techniques become more common in vascular surgery practices, it will be important to determine if it can provide better outcomes than OSR.

In an OSR approach, aortic clamping above one or both renal arteries or above the visceral arteries is required. The higher the level of aortic clamping, the greater the risk of cardiac stress and renal or visceral ischemia. (11) The level of clamping will dictate mesenteric and renal ischemia duration and the type of repair. Because of the need for suprarenal or supraceliac aortic clamping, as well as the concomitant increase in cardiac afterload and decrease in cardiac output, strain-induced myocardial ischemia may occur. Reports indicate that 6% of patients undergoing surgical repair develop myocardial infarction. (6;11) The ideal clamp level remains controversial and conflicting views have been reported. (11)

In addition to the abdominal incision, some patients may also require a small thoracic incision depending on a number of factors such as body size and complexity. In patients with severe COPD or other respiratory conditions, this can add to the risk of surgical repair of JRA. Surgical repair of JRA is more challenging than surgical repair of infrarenal aneurysm (7) and is associated with greater morbidity and

mortality. (12) First, the higher clamp location places added strain on the heart. Second, the higher extent of the aneurysm requires more operative dissection with a greater likelihood of blood loss and fluid shift. (12) Third, renal artery revascularization is more often required. Fourth, it requires aortic clamping and a period of renal or mesentric ischemia that may result in end-organ ischemia and infarction. (12)

Literature Review of Effectiveness

Research Question

How do outcomes of treatment with f–EVAR compare with those obtained with the gold standard of OSR in the treatment of patients with JRA?

Outcome Measures

Primary Outcomes

- 30-day mortality
- Late mortality
- Permanent dialysis

Secondary Outcomes

- Technical success rate
- Conversion to surgical repair
- Renal events due to the procedure
- Temporary dialysis
- Mesentric events due to the procedure
- Aneurysm expansion and rupture
- Target vessels patency
- Graft migration and component separation
- Endoleak
- Post-procedural complication
- Secondary procedures
- Operating room data
  - Operation time
  - Blood loss
  - Contrast used
- Hospitalization data
  - ICU stay
  - Hospital stay
  - Fluoroscopy time

Methods

Published studies on f–EVAR meeting the inclusion criteria were selected from the search results. Data on the study characteristics, patient characteristics, perioperative data, primary and secondary treatment outcomes, and postoperative complications were abstracted.

Since published studies of f–EVAR were single arm, the literature was searched to identify studies on OSR of JRA published during the same time period as f–EVAR studies. In this review, the results of OSR studies were considered as a historical comparison group by which the effectiveness and safety of f–EVAR could be evaluated. The same inclusion/exclusion criteria were applied for OSR studies.

Inclusion Criteria

- Prospective studies that reported on f–EVAR procedure in patients with JRA
- Studies reporting primary outcomes and most of the secondary outcomes selected for this review
- Studies published since 2004
- Sample size ≥15 patients

Exclusion Criteria

- Retrospective studies on f–EVAR
- Studies reporting technical aspects of the graft implantation
- Reports that did not contain patient data
- Sample size <15
- Other anatomical location of aneurysm

Results of Literature Search

A search of electronic databases (OVID MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, The Cochrane Library, and the International Agency for Health Technology Assessment [INAHTA] database was undertaken to identify evidence published from January 1, 2004 to December 19, 2008. The search was limited to English-language articles and human studies. The automatic search alerts were received and reviewed up to March 23, 2009. The search strategy is detailed in Appendix 1.

Results of Literature Review

The literature search and automatic search update identified 320 citations, of which 13 met inclusion/exclusion criteria. One comparative study presented at an international seminar, five single-arm studies on f–EVAR, and seven studies on OSR (one prospective and six retrospective) were considered for this analysis (see Table 1).

Table 1. Quality of Evidence of Included Studies*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic reviews of RCT	1	0
Large RCT unpublished but reported to an international scientific meeting	1(g)	0
Small RCT	2	0
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	1
Non-RCT with historical controls	3b	
Non-RCT presented at international conference	3(g)	1
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	5 f–EVAR 7 OSR (1 prospective, 6 retrospective)
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*RCT refers to randomized controlled trial; g indicates grey literature.

Grading the Body of Evidence

To grade the strength of the body of evidence, the grading system formulated by the GRADE working group and adopted by MAS was applied. The GRADE system classifies quality of evidence as high (Grade A), moderate (Grade B), or low (Grade C) according to four key elements: study design, study quality, consistency across studies, and directness (details in Appendix 2).

Results of Comparative Study: f-EVAR versus OSR

One study (13) was published in the form of abstract but was identified through the systematic search. Since this was the only published study that compared the results of f–EVAR with those of OSR, it was included in this assessment. The study was a prospective, concurrent, non-randomized study conducted in Alberta, Canada between September 2001 and August 2005 (Table 2). In it, 45 patients with JRA underwent surgical or endovascular repair of the aneurysm. Twenty nine patients underwent OSR and 16 underwent f–EVAR. Five patients in the f-EVAR group and one in the OSR group were female. Patients in the f-EVAR group were generally older than patients in OSR group (Mean age 77.6±6 vs. 69.6±8) and had a significantly greater incidence of severe cardiac and pulmonary comorbidities and diabetes ($P<.5$). Forty three vessels were treated by f–EVAR.

There were no significant differences in 30-day mortality between the two groups. One patient in f–EVAR group and two patients in OSR group died within 30-days of treatment. One renal artery was lost in each group. There were three patients with ischemic colons in the f–EVAR group and one in the OSR group. One patient in the OSR group required dialysis. There was no type I endoleak but five types II and one type III endoleak was observed in the f–EVAR group. There were no significant differences in cardiac or pulmonary complications between the two groups (Table 3). There were also no significant differences in duration of surgery, ICU stay, or hospital stay (Table 4).

The authors concluded that f–EVAR is feasible and associated with good technical success rates. They suggested that patients with severe comorbidities can be treated with f–EVAR for treatment of JRA as the postoperative outcomes are similar to OSR.

Prospective Cohort Studies of f-EVAR for JRA Repair

Five single-centre, single-arm prospective cohort studies on f–EVAR were published between 2004 and 2009. (2;9;14-16) Sample sizes ranged from 18 to 119 patients. Male patients predominated and comprised 84.7% of the study population. The mean age of the patients across the studies ranged from 72 to 75 years. All of the studies included patients with JRA, however, in the study by Kristmundsson et al. (9), three patients had aortic ulceration, while in the study by Muhs et al. (15), 8 patients had thoracoabdominal aortic aneurysm.

All patients included in these studies were considered to be at high risk for OSR and were unfit for infrarenal standard EVAR due to short neck. Endovascular repair for JRA was performed with a customized fenestrated Zenith® stent graft. A branched graft was used for one patient in the study by Muhs et al. (15)

A total of 686 vessels were targeted through fenestrations. The mean number of targeted vessels per patient ranged from 2.3 to 2.6. The majority of target vessels were renal arteries. Table 5 shows study and patient characteristics.

Studies reported good technical success rates ranging from 90% to 100%. In the study by Kristmundsson et al. (9), a percutaneous approach to common femoral arteries was possible in 44 patients and in nine patients the surgical approach to access the artery became necessary to secure hemostasis or adequate lower extremity circulation. Conversion to open surgery was required in only one case for an improper graft positioning that resulted in narrowing of both renal arteries. Serum creatinine started to rise postoperatively and the patient underwent open surgery on day 1.

Rates of technical success and conversion to open repair are shown in Table 6.

Table 2. Comparative Study: Patient Characteristics (13)

Technique	Anatomical Location of Aneurysm	Patients, No.	Male/Female No.	Mean Age ± SD, Years	Mean Aneurysm Diameter (Range), cm	Target Vessels, No.	Renal artery reconstruction, No. procedures
F–EVAR	JRA	16	15/1	77.6±6	5.7 (4.9-12)	43	N/A
OSR	JRA	29	24/5	69.6±8	6.3 (5-7.6)	N/A	40

F–EVAR, Fenestrated endovascular grafting; OSR, Open surgical repair; NA, Not applicable; JRA, Juxtarenal aortic aneurysm

Table 3. Comparative Study: Post-Operative Outcomes (13)

Technique	30-day mortality, No. (%)	Dialysis, No. (%)	Vessel lost, No. (%)	Colonic Ischemia	Endoleak, No. (%)	Cardiac Complication, No. (%)	Pulmonary Complications, No. (%)
F–EVAR	1 (6)	0 (0)	1 (6)	3 (18.8)	Type I: 0 Type II: 5 (31) Type III: 1 (6)	5 (31)	4 (25)
OSR	2 (7)	1 (3.5%)	1 (3.5)	1 (3.5)	N/A	10 (34)	3 (10)

F–EVAR, Fenestrated endovascular grafting; OSR, Open surgical repair; N/A, Not applicable

Table 4. Comparative Study: Duration of Surgery and Hospital Stay (13)

Technique	Mean Duration of Surgery ±SD, Min	Hospital Stay Mean ±SD Days	ICU Stay Mean (SD), Days	Fluoroscopy time Mean (SD), Min	Contrast used Mean (SD), mL
F–EVAR	268±113	14.8±17.3	4 (8.5)	82.8 (37.9)	230.8 (45.7)
OSR	205±196	13±8	1.7 (2.7)	N/A	N/A

F–EVAR, Fenestrated endovascular grafting; OSR, Open surgical repair; N/A, Not applicable

Table 5. Fenestrated Endovascular Grafting: Patient Characteristics and Number of Target Vessels

Study Year, Country	Patients, No.	Male/Female	Mean Age ±SD (Range)	Mean Aneurysm Diameter ±SD (Range), mm	Mean Infrarenal Aortic Neck Length ±SD (Range), mm	Target Vessels, No.	Target Vessel per Patient
Kristmundsson et al. 2009 (9) Sweden	54†	46/8	72* (68-76)	60* (53-66)	NR	134	2.5
Scurr et al. 2008 (2) UK	45	41/4	73* (53–85)	68* (55–100)	6* (0–13)	117	2.6
O'Neill et al. 2006 (14) USA	119	98/21	75±7	65±11 (46-102)	8±4 (3–18)	302	2.5
Muhs et al. 2006 (15) The Netherlands	38Ŧ	31/7	NR	NR	NR	87	2.3
Verhoeven et al. 2004 (16) The Netherlands	18	16/2	74 (60-85)	59 (55-70)	7.8 (4-10)	46	2.6

*Reported median; †includes 3 aortic ulcer; Ŧ includes 8 thoracoabdominal aortic aneurysms and one branched graft

Table 6. Fenestrated Endovascular Grafting: Procedural Outcomes

Study, Year	Technical Success Rate % of Target Vessels	Conversion to Open Surgical Repair, No.
Kristmundsson et al., 2009 (9)	90.1	0
Scurr et al., 2008 (2)	98.3	0
O'Neill et al., 2006 (14)	99.7	0
Muhs et al., 2006 (15)	94	1 performed on day 1 (due to malpositioning of the graft)
Verhoeven et al., 2004 (15)	100	0

The mean duration of surgery varied across the studies, ranging from 166 to 350 minutes. In f–EVAR studies only four patients required ICU stay. Two patients in the study by Scurr et al. (2) required ICU stay; one was the patient who died from multiorgan failure and the other was a patient with severe chronic obstructive pulmonary disease (COPD) who was discharged from hospital on day 4 and readmitted the following day due to respiratory failure. The patient stayed in ICU for 14 days and a tracheostomy was performed. In the study by Verhoeven et al. (16), two patients required ICU stay; one was for a one day precaution and the other had cardiac complications.

The mean duration of hospital stay was about 6 days and consistent across the studies. While the comparative study (13) showed much longer hospital and ICU stays, this may have been the result of the inclusion more patients with comorbidities from serious cardiac and pulmonary conditions and diabetes.

The mean fluoroscopy time during intraoperative imaging ranged from 30 to 78 minutes. One study (16) used pulse fluoroscopy and reported a fluoroscopy time of 16 minutes, a considerably lower time than those reported by other studies. The mean volume of contrast agent used for intraoperative imaging ranged from 170 to 270 mL and mean blood loss during the procedure ranged from 450 to 600 ml (see Table 7).

Mortality Outcomes

Pooled estimate for 30-day mortality was 1.8% in f–EVAR studies and 3.1% in OSR studies in which data were reported for repair of juxtarenal aneurysm separately. (11;17-20) Late mortality rates in both f–EVAR and OSR studies were much higher than 30-day mortality. Pooled estimate for late mortality was 12.8% in f–EVAR studies and 23.7% in OSR studies in which data were reported for repair of juxtarenal aneurysm separately. (17;18)

In f–EVAR studies, the causes of late death were mostly unrelated to the aneurysm repair. Only 2 late deaths was related to the endovascular aneurysm repair; one was due to a redo surgery for infection and the other was due to atheroembolism. However, this could not be determined for OSR because the causes of late death were not reported in most of the studies.

Mean duration of follow-up, number of patients lost to follow-up, 30-day and late mortality rates are shown in Table 8.

Table 7. Fenestrated Endovascular Grafting: Perioperative Data

Study, Year	Mean Duration of Surgery ± SD (Range+), min	Mean Hospital Stay ± SD (Range), Days	Mean Fluoroscopic Time ± SD (Range), Min	Mean Contrast volume Used ± SD (Range), mL	Mean Blood Loss (SD, Range), mL
Kristmundsson et al. 2009(9)	250* (210-333)	NR	78* (59-108)	270*	600* (400-1,000)
Scurr et al. 2008 (2)	350* (240-600)	6* (3-90)	NR	NR	NR
O'Neill et al. 2006 (14)	227±76	NR	56±22	179±53	739
Muhs et al. 2006 (15)	192±65 (110–360)	5.9±2.8 (3–12)	30±23 (5-85)	182±62 (80-400)	557±581 (100-2500)
Verhoeven et al. 2004 (16)	166 (110-270)	6.4 (3-12)	16 (9-28) (used pulse fluoroscopy)	170 (80-240)	450 (100-1700)

*Reported median; NR, Not reported

Table 8. Fenestrated Endovascular Grafting: Duration of Follow-up and Mortality Rate

Study, Year	Mean Duration of Follow-up ± SD (Range), Months	Lost to Follow-up, No.	30-day Mortality, No. (%)	Late Mortality, No. (%)
Kristmundsson et al. 2009 (9)	25* (12-32)	NR	2 (3.7) ▪ 1 due to trash embolization and MOF ▪ 1 due to retroperitoneal bleeding caused by a RA perforation	10 (18.5) ▪ 1 Due to massive bleeding during redo surgery for infection ▪ 9 unrelated to aneurysm repair
Scurr et al. 2008 (2)	24* (1–48)	1	1 (2) ▪ Due to MI on the fifth day	5 (11) ▪ 1 due to atheroembolism leading to MOF (patient had previous open repair and there was considerable atheroma in the wall of aorta) ▪ 4 unrelated to the aneurysm repair)
O'Neill et al. 2006 (14)	19 (0–48)	NR	1 (0.8) ▪ Morbidly obese patient with COPD developed an ileus and suffered complications, died of sepsis and MOF at 7th day	15 (12.6) ▪ All unrelated to the aneurysm repair
Muhs et al. 2006 (15)	25.8±12.7 (9–46)	0	1 (2.6) ▪ At 8th day due to mesenteric ischemia and bowel infarction as a result of embolism due to guidewire manipulation (patient was classified as ASA class IV)	4 (10.5) ▪ Unrelated to the aneurysm repair
Verhoeven et al. 2004 (16)	9.4 (1-18)	NR	0	1 (5.5) ▪ After 8 month patient who lost kidney died due to metastatic adenocarcinoma

*Reported median; ASA, American Society of Anesthesiologists; COPD, Chronic Obstructive Pulmonary Disease; MOF, Multi-organ failure; RA, Renal artery; MI, Myocardial infarction; NR, Not reported

Visceral Arteries Events

Renal Events during the Procedure

A total of three main renal arteries and two accessory renal arteries became occluded during the procedure. These were all due to technical issues except, one accessory renal artery in which the artery was intentionally covered. One patient required open surgery following the procedure. This patient, in whom a graft with one small renal artery fenestration was used, developed a severe stenosis of the left renal artery and narrowing of the right renal artery from improper endograft positioning causing bilateral renal artery narrowing. Serum creatinine started to rise postoperatively and on day 1the patient underwent open surgery to open the aorta and reposition the graft. The left renal artery problem was solved but the right renal artery was covered after repositioning, therefore, a right renal artery bypass was also performed to restore the blood supply. The serum creatinine in this patient rose from a baseline of 70 mmol/L to 176 mmol/L on day 3 but stabilized later on. At 1-year follow-up, it was 123 mmol/l.

Renal Events During the follow-up

A total of 12 renal arteries (12 patients) were found to be occluded during follow-up. In two patients, the same side accessory renal artery was also occluded. Four (1.5%) patients lost a kidney and five (2.3%) patients underwent dialysis; in three (1.4%) this became permanent.

A total of 16 renal arteries stenosis (16 patients) occurred during follow-up. Eight of these were treated and eight were observed. Segmental renal infarcts were found in six patients but renal function was not impaired. Table 9 shows renal events during the procedure and follow-up.

Table 9. Fenestrated Endovascular Grafting: Renal Events

Study, Year	During Surgery	Post Surgery/Follow-up	Clinical Consequence
Kristmundsson et al. 2009 (9)		Case 1: RA was occluded due to placement of a Giant Palmaz stent during the primary procedure to control type I endoleak while the RA already had a reduced blood flow due to a guidewire-induced dissection	Case 1: NR
		Case 2: Dissection in RA which was left untreated because completion angiography showed unaffected blood flow to the kidney. This resulted in RA occlusion	Case 2: NR
		Cases 3-4: Two stenosis was seen on 1 year CT scan	Cases 3-4: Performed successful percutaneous transluminal angioplasty on both. Renal function did not decrease
		Cases 5-6: Two stented RAs showed significant stenosis on 1 year CT scan	Cases 5-6: No treatment because one had disseminated malignancy and in the other case the kidney had shrunken and was non-functional
		Cases 7-8: Two unstented RAs became partially covered by the stent graft fabric	Cases 7-8: Caused no significant occlusion or stenosis during the follow-up period
Scurr et al. 2008 (2)	Case 1: One accessory RA that was erroneously stented occluded during surgery. The main RA was preserved. (Patient had 3 RAs at one side)	Case 2: One RA stented with covered stent occluded unexpectedly 4 months after surgery	Case 1: There was no clinical sequelae Case 2: Patient lost kidney. However, serum creatinine remained stable at 94 umol/L
		Cases 3-8: Six patients developed segmental renal infarcts	Cases 3-8: None showed evidence of renal impairment
Verhoeven et al. 2004 (16)	No renal event reported	Case 1; 1 accessory RA and the same side main RA was occluded one month after the procedure due to inability to stent the RA at that side	Case 1: Patient lost kidney. This patient died after 8 months due to metastatic adenocarcinoma

Study, Year	During Surgery	Post Surgery/Follow-up	Clinical Consequence
O'Neill et al. 2006 (14)	Case 1: RA occluded due to inability to gain wire access to RA for stenting Case 2: 1 RA occluded due to dissection that occurred during placement of the stent within a severely diseased RA Case 3: One RA occlusion on post-operative angiography	Case 4: One RA was shown to be occluded when patient presented with a ruptured TAA Cases 5-10: Six more RAs were occluded (no explanation was given by the authors) Cases 11-22: 12 RA stenosis	Cases 1-10: All demonstrated an increase in serum creatinine. Five ultimately underwent dialysis (3 permanent) Cases 11-22: 6 were treated and six were observed
Muhs et al. 2006 (15)	Case 1: 1 malpositioning of the graft resulted in narrowing of both RAs. Case 2: 1 accessory RA was intentionally covered to avoid open surgery	Case 3: One accessory RA was lost during surgery and the same side main RA were occluded 1 month later	Case 1: Patient underwent open surgery and opening of the aorta to pull the endograft distally. A renal artery bypass was also performed to restore perfusion Case 2: There was no clinical sequelae Case 3: patient lost kidney
Total			**4 lost kidney** **5 underwent dialysis (3 became permanent)** **1 malpositioning of the graft underwent open surgery** **2 RA stenosis were successfully treated by percutaneous transluminal angioplasty, 6 by other methods** **8 RA stenosis were observed**

RA, Renal artery; NR, Not reported

Mesenteric Events during the Procedure

Three mesenteric events occurred during the f-EVAR procedures resulting in two deaths. One patient developed bowel ischemia due to embolization of the superior mesenteric artery (SMA); this patient died 13 days after the procedure from multiorgan failure. One patient died eights days after the procedure from mesenteric ischemia and bowel perforation. The procedure was successfully completed in this patient with the implantation of a graft with two fenestrations for renal arteries and one scallop for SMA. There was no technical difficulty and SMA was patent on completion angiogram. Autopsy also showed a patent SMA; the authors concluded that mesenteric ischemia may have been secondary to embolic event due to guidewire manipulation, or a severe low flow state. This patient had a pre-operative ejection fraction of 23% and pre-op morbidities included two significant retroperitoneal bleeding events, myocardial infarction and arrhythmia, two surgical site infections, two nosocomial infections at bladder and lung sites, and one case of urinary retention. This patient was classified as American Society of Anesthesiologists (ASA) IV.

The third SMA event occurred during surgery with subsequent occlusion in early follow-up. This patient had relatively narrow calcified iliac arteries causing the device to twist its way to the aorta; there was also an issue of a previous graft. The combination of the two problems contributed to a less than ideal positioning at the completion of angiography with the orifice of SMA with scallop was shown to be partially shuttered. Further attempts to solve the problem by deploying a stent were unsuccessful and the vessel occluded shortly after. Fortunately, the patient did not develop bowel ischemia and remained asymptomatic due to good celiac artery collaterals.

Mesenteric Events during Follow-up

During follow-up, five (1.8%) SMA occlusions/partial occlusions and one SMA stenosis were noted. Three of the five patients with SMA occlusion/partial occlusion remained asymptomatic and no further intervention was necessary. In one patient, the completion of angiography was satisfactory but a web like stenosis within stented SMA was noted during follow-up. The upper margin of the graft fabric was passing between the stent cells due to a slight distal migration of the graft, causing partial occlusion of the lumen of the SMA. This patient underwent SMA bypass surgery. In another patient a kinked stent graft was causing SMA ischemia. The patient was treated by retrieval of one stent and replacement with a longer stent. The patient remained asymptomatic after the intervention.

In one patient, stenosis due to the graft fabric material caused a mesenteric ischemia. The problem was solved by stenting the SMA and there was no evidence of restenosis after the intervention.

The mesentric events during the procedure and at follow-up are summarized in Table 10.

Aneurysm Related Outcomes

No aneurysm rupture or dissection occurred following f–EVAR. Most of the authors reported that the aneurysms decreased in size or remained stable during follow-up. Aneurysm expansion occurred in four (1.5%) patients and all were due to type II endoleak (see Table 11)

Table 10. Fenestrated Endovascular Grafting: Superior Mesenteric Artery Events

Study	During Surgery	At follow-up	Clinical Consequence
Kristmundsson et al. 2009(9)	Case 1: One SMA embolization	Cases 2-4: Three SMAs occluded during the follow-up; all had scallop and were unstented	Case 1: Patient developed bowel ischemia and died from MOF on 13th day Cases 2-4 remained asymptomatic and no further intervention was necessary
Scurr et al. 2008 (2)	Case 1: One SMA occluded due to malrotation of the endograft. Patient had a previous EVAR and had calcified iliac arteries which both caused the device to twist its way into the aorta	Case 2: One SMA was partially occluded most probably due to distal migration of the endograft. A web-like stenosis was noted within the stent	Case 1: Patient remained asymptomatic due to good collateral arteries Case 2: Patient underwent SMA bypass surgery. There was no clinical sequelae
O'Neill et al. 2006 (14)	No SMA event reported	Case 1: One SMA stenosis within 30 day following the procedure causing persistent post-prandial abdominal pain. Fabric material was obstructing the SMA origin	Case 1: Patient was treated by stenting SMA and there was no evidence of re-stenosis after intervention
Muhs et al. 2006 (15)	Case 1: One mesentric ischemia	Case 2: One patient had kinked stent graft at SMA causing partial occlusion and mesenteric ischemia	Case 1: Patient died at 8th day due to mesenteric ischemia and bowel infarction probably as a result of embolism due to guidewire manipulation (patient was classified as ASA class IV) Case 2: This case was successfully treated and patient remained asymptomatic after intervention
Verhoeven et al. 2004 (16)	No SMA event reported	No SMA event reported	N/A
Total	3	**6**	**2 died** **3 were successfully treated** **4 remained asymptomatic**

RA, Renal artery; SMA, Superior mesenteric artery; N/A, Not applicable; ASA, American Society of Anesthesiologists; MOF, Multi-system organ failure

Table 11. Fenestrated Endovascular Grafting: Aneurysm Outcomes

Study, Year	Changes in Aneurysm Size	Aneurysm Expansion, No.	Aortic Rupture/Dissection, No.
Kristmundsson et al., 2009 (9)	Decreased ≥5 mm in 47% at year 1 Increased ≥5 mm in 3% Remained stable in 50%	1 (due to type II endoleak)	0
Scurr et al., 2008 (2)	All were stable or shrinking	0	0
O'Neill et al., 2006 (14)	Mean aneurysm size decreased 15 mm in 3 years	1 (due to type II endoleak; patient refused intervention)	0
Muhs et al., 2006 (15)	Decreased significantly during the first year and then remained stable	2 (due to type II endoleak)	0
Verhoeven et al., 2004 (16)	NR	0	0

NR, Not reported

Graft Related Complications

Type I endoleaks occurred in 11 (4%) of patients; two were resolved, one was observed, and eight (2.9%) were treated. Type II endoleaks occurred in 46 (16.8%) patients; 14 resolved, 22 were observed, and 10 (3.7%) were treated including one laparatomy. Type III endoleaks occurred in five (1.8%) patients; one resolved, one observed, and three (1.1%) were treated. Table 12 summarizes the rate and fate of endoleaks in the reviewed studies and Table 13 summarizes the overall occurrence of endoleaks.

Table 12. Fenestrated Endovascular Grafting: Rate and Fate of Endoleaks

Study, Year	Endoleak, No.	Treatment of Endoleak	Clinical Outcome
Kristmundsson et al. 2009 (9)	Type I: 3	▪ 1 resolved ▪ 2 were treated	▪ Resolved
	Type II: 13	▪ 9 resolved ▪ 2 were treated ▪ 2 NR	▪ 9 resolved and 2 were treated
	Type III: 1	▪ Not treated	▪ Patient died from complications due to bowel ischemia prior to any control angiography
Scurr et al. 2008 (2)	Type I: 0	▪ N/A	▪ N/A
	Type II: 4 (8.9)	▪ No treatment	▪ Resolved or continued to be observed
	Type III: 0	▪ N/A	▪ N/A
O'Neill et al. 2006 (14)	Type I: 7 (5.9)	▪ 1 resolved by 1 month ▪ 4 underwent secondary procedures prior to discharge ▪ 1 underwent secondary procedure after 12 months ▪ 1 treated by coil embolization	▪ Did not recur ▪ All 4 resolved and did not recur ▪ Resolved and did not recur ▪ NR
	Type II: 19 (16)	▪ 4 were treated	▪ No sequelae resulted from type II endoleaks
	Type III: 4 (3.4)	▪ 3 were treated ▪ 1 was not treated	▪ Resolved and did not recur ▪ Resolved within 1 months and did not recur
Muhs et al. 2006 (15)	Type I:1 (2.6)	▪ Observation	▪ Further investigation was considered for this patient
	Type II: 7 (18.4)	▪ 2 were treated	▪ NR
	Type III: 0	▪ N/A	▪ N/A
Verhoeven et al. 2004 (16)	Type I: 0	▪ N/A	▪ N/A
	Type II: 3 (16.7)	▪ 1 was treated ▪ 1 was not treated ▪ 1 underwent laparatomy	▪ Resolved ▪ Resolved ▪ Patient recovered well from laparatomy
	Type III: 0	▪ N/A	▪ N/A

Table 13. Summary of Endoleak Data

Endoleak, No. (%)	Resolved, N (%)	Treated, N (%)	Observed, N (%)	Underwent Laparatomy, N (%)
Type I=11 (4%)	2 (0.7)	8 (2.9)	1 (0.36)	0 (0.0)
Type II=46 (16.8%)	14 (5.0)	9 (3.3)	22 (8.0)	1 (0.4)
Type III=5 (1.8%)	1 (0.36)	3 (1.1)	1 (0.36)	0 (0.0)
Total=62	**17 (27.4)**	**20 (32.3)**	**24 (38.7)**	**1 (1.6)**

Primary vessel patency ranged from 92% to 97.8% across the reviewed studies. There were four cases of graft migration and two cases in which graft components were separated (see Table 14).

Table 14. Fenestrated Endovascular Grafting: Graft-Related Outcomes

Study, Year	Primary Vessel Patency, %	Graft Migration/Component Separation, No.
Kristmundsson et al., 2009 (9)	96	0
Scurr et al., 2008 (2)	96.6	Migration: 3 Component separation: 1
O'Neill et al., 2006 (14)	96.7	Migration: 1 Component separation: 1
Muhs et al., 2006 (15)	92	0
Verhoeven et al. 2004 (16)	97.8	0

Secondary Intervention

A total of 24 (8.8%) secondary procedures were performed across the studies. In addition, 20 (7.3%) procedures were performed after f–EVAR for the treatment of endoleaks (see Table 15).

Table 15. Fenestrated Endovascular Grafting: Secondary Interventions

Study, Year	Secondary Intervention, No.	
	For Treatment of Endoleak, No.	For Other Reasons, No.
Kristmundsson et al., 2009 (9)	Type I: 2 Type II: 2	3
Scurr et al., 2008 (2)	0	6
O'Neill et al., 2006 (14)	Type I: 6 Type II: 4 Type III: 3	12
Muhs et al., 2006 (15)	Type II: 2	2 (one was open surgery)
Verhoeven et al., 2004 (16)	Type II: 1 (Laparatomy)	1
Total	**20 (7.3%)**	**24 (8.8%)**

Post f–EVAR cardiac complications included two myocardial infarctions (MI), one of which resulted in death, as well as one cardiac arrest and one case of atrial fibrillation. The patient who had a cardiac arrest suffered from kidney damage afterward. The patient who developed atrial fibrillation was treated with medication.

Only one case of stroke during hospital stay was reported and just two cases of pulmonary complications. One patient who had pre-existing severe form of chronic pulmonary obstructive disease (COPD) was re-admitted to the hospital due to respiratory failure. The patient required 14 days of intensive care and a tracheostomy. The second patient had a minor MI and developed pneumonia.

Intestinal complications other than those related to SMA occlusion or stenosis were similarly infrequent. One case of bowel perforation due to an incidental benign tumour was reported. The patient required a left hemicolectomy and colostomy on day 5. Other complications included two cases of ischemia in the leg, one of which was due to stenosis in the common femoral artery (caused by a suture). This patient was treated on day 115. In the other ischemia case, the endograft occluded the internal iliac artery causing symptoms in the buttock that resolved in one week.

The postoperative complications encountered in the reviewed studies are summarized in Table 16.

Table 16. Fenestrated Endovascular Grafting: Postoperative Complications in Other Organs

Study, Year	Cardiac, No.	Pulmonary, No.	Stroke, No.	Intestinal, No.	Other, No.
Kristmundsson et al., 2009(9)	NR	NR	NR	0	1 ischemia in the leg
Scurr et al., 2008 (2)	1 (died due to MI on day 5)	1 (patient had severe COPD)	1 (in hospital)	1 bowel perforation due to incidental benign tumour. (This required a left hemi-colectomy. There was no evidence of bowel ischemia)	1 Necrosis of the left buttock and weakness of the left leg which resolved within one week. (In this case, the endograft occluded the internal iliac artery)
O'Neill et al., 2006 (14)	0	0	0	0	0
Muhs et al., 2006 (15)	1 cardiac arrest that resulted in kidney damage	0	0	0	0
Verhoeven et al., 2004 (16)	1 MI 1 AF	1 pneumonia in patient who had MI	0	0	0
Total	**4**	**2**	**1**	**1**	**2**

NR indicates not reported; COPD, Chronic Obstructive Pulmonary Disease; MI, Myocardial infarction; AF, Atrial fibrillation

Open Surgical Technique for Repair of JRA

A total of 856 patients were included in seven OSR studies. (11;17-22) One study (19) was conducted prospectively, while the other six were retrospective. Some of these studies had two or three arms comparing the results of surgical repair according to the location of the aneurysm. Approximately 80% of the study population was male. The mean aneurysm sizes among studies ranged from 59 to 70 mm. The study and patient characteristics are summarized in Table 17 and the perioperative data are summarized in Table 18.

The mean number of blood units transfused perioperatively ranged from 1.2 to 4.8 units in the OSR studies. The mean operation time for JRA repair among the OSR studies ranged from 215 to 319 minutes. The mean length of hospital and ICU stay after surgical repair of JRA in was recorded in two studies (11;18) that included only patients with JRA. In these the mean hospital stays were 16.7 and 24 days, and the mean ICU stays were 4.6 and 6.2 days. In a third study, length of hospital stay was reported separately for patients with JRA repair, with a reported a median duration of hospital stay of 8 days and a median ICU stay of 3 days (see Table 19).

Table 17. OSR: Patient Characteristics

Study, Year	Study Design	Patients, No.	Male/ Female, No.	Mean Age ± SD (Range), Years	Mean Aneurysm Diameter ± SD (Range), mm
Knott et al. 2008, USA (11)	Retrospective	126 (all JRA) All elective	98/28	73.6* (55-93)	NR
Pearce et al. 2007, USA (17)	Retrospective	All: 150 JRA: 134 SRA: 16 Urgent: 16	108/42	All: 70.8±8 JRA: 71±8 SRA: 69.1±8.2	All: 59±13 JRA: 59±12 SRA: 56±15
Ockert et al. 2007, Germany (18)	Retrospective	35 (all JRA) Urgent: 2	30/5	68.4	67
Illuminati et al. 2007, Italy (21)	Retrospective	21 JRA: 13 SRA: 8 All elective	17/4	78 (76-89)	60 (48-110)
West et al. 2006, USA (22)	Retrospective	247 JRA: 204 SRA: 43 Urgent: 7	203/44	73 (44-96)	64 (30–114)
Chiesa et al. 2006, Italy (19)	Prospective	119 JRA: 85 SRA: 34 Urgent: 4 (all JRA)	NR	All: 67 (60-81) JRA: 66.9 (60-80) SRA: 67.3 (61-81)	58±0.7.2 50±5.5 67±5.5
Back et al. 2005, USA (20)	Retrospective	158 JRA: 78 SRA: 35 TAA: 45 Urgent: 12	132/26	71.1±7.1	70±14

SRA, Suprarenal aortic aneurysm; JRA, Juxtarenal aortic aneurysm; TAA, thoracic aortic aneurysm; NR, Not reported

Table 18. OSR: Perioperative Data

Study, Year	Renal Artery Reconstruction, No. Procedures (%)	Aortic Occlusion Time (mean, SD, Range), min	Mean Renal/Mesenteric Ischemia Time (SD, Range), Min
Knott et al. 2008, USA (11)	23	NR	Renal: 22.5±10.3 (3-90) Mesentric: 9.3±12.7 (3-42)
Pearce et al. 2007, USA (17)	All: 50 JRA: 35 SRA: 15	All: 70* (36) JRA: 69* (36) SRA: 82* (42)	All: 30* (18) JRA: 30* (16) SRA: 42* (21)
Ockert et al. 2007, Germany (18)	17 (51.5)	45.3 (28-110)	30 (14-70)
Illuminati et al. 2007, Italy (21)	8 SRA		Renal: 23 (14-60) Mesentric: 19 (10-45)
West et al. 2006, USA	62		Renal: 23.2±9.7 Mesentric: 25.5±7.8
Chiesa et al. 2006, Italy, (19)	20 (58.8) all SRA		JRA: 26.5±14.2 SRA: 37.5±8 In 83 patients with supraceliac or supra SMA clamp
Back et al. 2005, USA (20)	JRA: 7 (9) SRA: 22 (63) TAA: 18 (40)	NR	NR

*=Reported median; SRA, Suprarenal aortic aneurysm; JRA, Juxtarenal aortic aneurysm; TAA, thoracic aortic aneurysm; SMA, Superior mesenteric artery

Table 19. Open Surgical Repair: Length of Hospital and ICU Stay

Study	Mean Operation time (SD, Range), Min	Mean Hospital Stay (Range), Days	Mean Length of ICU Stay (Range), Days	Blood Transfused (SD, Range), Unit
Knott et al. 2008 (11)	319 (91-648)	16.7 (3-86)	4.6 (1-64)	4.8
Pearce et al. 2007 (17)	All: 300* (120) JRA: 288* (113) SRA: 410* (176)	All: 8* (6) JRA: 8* (5) SRA: 10* (7)	All: 3* (3) JRA: 3* (3) SRA: 5* (5)	NR
Ockert et al. 2007 (18)	215	24	6.2	NR
Illuminati et al. 2007 (21)	NR	11 (9-16)		NR
West et al. 2006 (22)	327 (75-648)	5.2 (2-72)	11.3 (2-372)	5.6
Chiesa et al. 2006 (19)	NR	NR	NR	JRA: 1.2 (1-12) SRA: 2
Back et al. 2005 (20)	NR	NR	NR	NR

*=Reported median; SRA, Suprarenal aortic aneurysm; JRA, Juxtarenal aortic aneurysm; NR, Not reported

Mortality Reported in OSR Studies

The pooled estimate for 30-day mortality after surgical repair of JRA was 3.1% (see Table 20). Only five studies were considered for data pooling as two of the studies did not report mortality for patients who underwent surgical repair for JRA separately from SRA. The most common causes of mortality at 30-days were MI, pulmonary sepsis, MOF, and major bleeding.

Late-mortality after surgical repair of JRA was reported in three studies but only two reported data separately for JRA. The pooled estimate for late mortality was calculated to be 23.7%. Causes of death at follow-up were not stated in OSR studies.

It should be noted that the pooled estimate for 30-day mortality after OSR of JRA in this review is lower than the 30-day mortality rate of 4.7% for AAA reported in the EVAR1 trial (1).

In a recently published study, data on OSR and endovascular repair of 194,507 intact AAA were retrospectively analyzed. (23) The authors reported an overall mortality rate (early and late death) of 4.5% for OSR of AAA over the years 2001 to 2005.

Renal and Visceral Complications Reported in OSR Studies

The rate of temporary and permanent dialysis across OSR studies for the repair of JRA ranged from 0% to 17% and 0% to 3.5% respectively (see Table 21). The proportion of patients who developed renal dysfunction after surgical repair of JRA ranged from 12% to 18%.

The pooled estimate for mesenteric ischemia in patients undergoing OSR for repair of JRA was 2.9%.

Secondary Interventions Reported in OSR Studies

Secondary interventions for non-endoleak reasons were performed for 23 (7.8%) patients across three studies reporting on JRA patients (see Table 22). The pooled estimates for cardiac, pulmonary, and gastrointestinal complications were 10.7%, 13.4%, and 5.9% respectively. For this calculation, only studies reporting postoperative complications separately for JRA were considered (see Table 23).

Table 20. Open Surgical Repair: Duration of Follow-up and Mortality Rate

Study, Year	Mean Follow-up, Months	30-Day Mortality, No, % (Causes of Death)	Late Mortality, No. (%)	Patient Survival (%)
Knott et al. 2008 (11)	48 (9-80)	1 (0.8) (Due to splenic injury during surgery)	NR	1-year: 94 3-years: 78 5-years: 64
Pearce et al. 2007 (17)	17.9*	All: 5 (3) JRA: 4 (3) SRA: 1 (6) (2 had MI, 2 pulmonary sepsis, 3 of 5 developed renal failure requiring acute dialysis)	All: 37 (25) JRA: 33 (25) SRA: 4 (25)	5-years: 69
Ockert et al. 2007 (18)	28 (8-96)	3 (8.6)Ŧ (1 due to MI after postoperative bleeding, 2 due to sceptical MOF)	7 (20)	NR
Illuminati et al. 2007 (21)	27 (2-73)	2 (9.5%) (due to acute mesenteric ischemia)	7 (33) Unrelated to the aneurysm repair	NR
West et al. 2006 (22)	1	6 (2.5) (3 due to significant visceral ischemia, 2 due to intraoperative cardiac arrest, 1 due to MOF resulted respiratory arrest)	NR	NR
Chiesa et al. 2006 (19)	NR	5 (4.2) JRA: 4 (4.7) (1 due to massive MI, 1 due to MOF, 1 due to diffuse bleeding and coagulopathy, 1 due to intestinal ischemia) SRA: 1 (3) (due to MOF associate with coagulopathy) Elective: 2 (1.2) Urgent: 3 (75)	NR	NR
Back et al. 2005 (20)	NR	JRA: 2 (2.6) SRA: 4 (11.4) TAAA: 6 (13.3) (Causes: NR)	NR	5-years: 70
Total		**14 (3.1)**	**40 (23.7)**	

*=Reported median; Ŧ Reported in-hospital mortality; NR, Not reported; MOF, Multi system organ failure; SRA, Suprarenal aortic aneurysm

Table 21. Open Surgical Repair: Post-operative Renal and Mesentric Complications

Study, Year	Renal, No. (%)		Mesentric Ischemia, No. (%)
	Dialysis	Renal Dysfunction	
Knott et al. 2008 (11)	Temporary: 5 (4%) Permanent: 1 (1%)	22 (18%)	3 (2%) One underwent sigmoid resection and colostomy
Pearce et al. 2007 (17)	All: 17 (11.3) JRA: 11 (8.2) SRA: 6 (37.5)	36 (27) Acute tubular necrosis: All: 21 (14) JRA: 16 (12) SRA: 5 (33)	All: 5 (3) JRA: 3 (2) SRA: 2 (13)
Ockert et al. 2007 (18)	Temporary: 6 (17) Discharged on dialysis: 1	6 (17.1)	1 (3)
Illuminati et al. 2007 (21)	0	3 transient serum creatinine increase	3 2 acute mesenteric ischemia (patients died) and 1 hepatic damage
West et al. 2006 (22)	Temporary: 9 (4)	All: 54 (22)	5 (3 died)
Chiesa et al. 2006 (19)	Temporary: 3 (2.5) JRA: 2 (2.3) SRA: 1 (2.9) Permanent: 4 (3.3) JRA: 3 (3.5) SRA: 1 (2.9)	All: 19 JRA: 10 (11.7) SRA: 9 (26)	1 (patient died)
Back et al. 2005 (20)	Temporary: JRA: 0 SRA: 1 (3) TAA: 7 16)	All: 36 JRA: 12 (15) SRA: 8 (23) TAA: 16 (36)	JRA: 3 (4) SRA: 4 (11) TAA: 10 (22)

JRA, Juxtarenal aortic aneurysm; SRA, suprarenal aortic aneurysm; TAA, thoracic aortic aneurysm

Table 22. Open Surgical Repair: Subsequent Procedures (Complication Related)

Study, Year	Subsequent Procedures, No. (%)
Knott et al. 2008 (11)	3 (2.4)
Pearce et al. 2007 (17)	All: 16 (11) JRA: 13 (10) SRA: 3 (19)
Ockert et al. 2007 (18)	7 (20)
Illuminati et al. 2007 (21)	1 (7.7)
West et al. 2006 (22)	NR
Chiesa et al. 2006 (19)	NR
Back et al. 2005 (20)	NR

SRA, Suprarenal aortic aneurysm; JRA, Juxtarenal aortic aneurysm

Table 23. Open Surgical Repair: Post-Operative Complications in Other Organs

Study, Year	Cardiac, No. (%)	Pulmonary, No. (%)	Gastrointestinal, No. (%)	Stroke, No. (%)
Knott et al. 2008 (11)	MI: 7 (6) Arrhythmia: 10 (7.9)	14 (11)	NR	1 (4.8)
Pearce et al., 2007 (17)	All: 24 (16) JRA: 20 (15) SRA: 4 (25)	All: 28 (19) JRA: 24 (18) SRA: 4 (25)	NR	NR
Ockert et al. 2007 (18)	MI: 1 (3)	8 (23)	NR	NR
Illuminati et al. 2007 (21)	0	2 (9.5)	NR	NR
West et al. 2006 (22)	MI: 32 (13)	38 (16)	NR	NR
Chiesa et al. 2006 (19)	4 (3.3) JRA: 4 (4.7) SRA: 0	9 (7.5) JRA: 5 (5.9) SRA: 4 (11.7)	All: 7 (5.8) JRA: 5 (5.9) SRA: 2 (5.8)	NR
Back et al. 2005 (20)	All: Cardiac and pulmonary: 65 (41)		NR	NR

Summary

Short- and medium-term results (up to 2 years) of f–EVAR for the repair of JRA showed that outcomes in f–EVAR series compare favourably with the figures for the OSR series; however, uncertainty remains regarding the long-term results. The following observations are based on low quality evidence.

- F–EVAR has lower 30-day mortality than OSR (1.8% vs. 3.1%) and a lower late-mortality over the period of time that patients have been followed (12.8% vs. 23.7%).
- There is a potential for the loss of target vessels during or after f–EVAR procedures. Loss of a target vessel may lead to loss of its respective end organ. The risk associated with this technique is mainly due to branch vessel ischemia or occlusion (primarily among the renal arteries and SMA). Ischemia or occlusion of these arteries can occur during surgery due to technical failure and/or embolization or it may occur during follow-up due to graft complications such as graft migration, component separation, or arterial thrombosis. The risk of kidney loss in this series of f–EVAR studies was 1.5% and the risk of mesenteric ischemia was 3.3%. In the OSR studies, the risk of developing renal insufficiency was 14.4% and the risk of mesenteric ischemia was 2.9%.
- F–EVAR has a lower rate of postoperative cardiac and pulmonary complications.
- Endoleak occurs in 22.5% of patients undergoing f–EVAR (all types) and about 8% of these require treatment. Most of the interventions performed to treat such endoleaks conducted using a minimally invasive approach.
- Due to the complexity of the technique, patients must be appropriately selected for f–EVAR, the procedure performed by highly experienced operators, and in centers with advanced, high-resolution imaging systems to minimize the risk of complications.
- Graft fenestrations have to be custom designed for each patient to match the anatomy of their visceral arteries. Planning and sizing thus requires scrutiny of the target vessels with a high degree precision. This is important not only to prevent end organ ischemia and infarction, but to avoid prolonging procedures and subsequent adverse outcomes.

Table 24 presents a summary of the characteristics of the reviewed f–EVAR and OSR studies for comparison. Table 25 presents a summary of the outcomes reported in the f–EVAR and OSR studies for comparison.

Table 24. Patient Characteristics: f–EVAR Studies Versus OSR Studies

Technique	Patient, No.	Mean Age (Range), Years	Mean Aneurysm Diameter (Range), mm	Mean Duration of Follow-up (Range)
f–EVAR (5 studies)	274	74 (72-75)	63 (59-68)	9.4 - 25.8
OSR (7 studies)	856: JRA: 675 SRA: 136 TAA: 45	72 (67-78)	62 (50-70)	1 - 48

JRA, Juxtarenal aortic aneurysm; SRA, Suprarenal aortic aneurysm; TAA, Thoracic aortic aneurysm

Table 25. Summary of Outcomes: f-EVAR Versus OSR for the Treatment of JRA

Outcome	f–EVAR	OSR
	Pooled Estimate (Rate)	
30-day mortality	1.8	3.1
Late mortality	12.8	23.7
Permanent dialysis	0-2.5	0-3.5
Loss of kidney	1.5	No report of kidney loss Incidence of post-op renal insufficiency: 14.4%
Mesentric ischemia	3.3	2.9
Aortic rupture	0	0
Post-op cardiac complications	1.5	10.7
Post-op pulmonary complications	0.7	13.4
Post-op GI complications	0.7	5.9
Aneurysm expansion	1.4	0
Secondary intervention (Non-endoleak)	8.8	7.8
Endoleak	Type I: 4 Type 2: 16.8 Type III: 1.8	N/A
Endoleak required treatment	Type I: 2.9 Type 2: 3.3 Type III: 1.1	
Graft migration Graft separation	1.5 0.7	N/A
	Duration (Mean)	
Operation time (min)	240	287
Hospital stay (days)	6	13

Economic Analysis

Disclaimer: The MAS uses a standardized costing methodology for all of its economic analyses of technologies. The main cost categories and the associated methods from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative cost data are used for all in-hospital stay costs for the designated International Classification of Diseases-10 (ICD-10) diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may need to be made to ensure the relevant case mix group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the secretariat normally defaults to considering direct treatment costs only.

Nonhospital: These include physician services costs obtained from the Ontario Schedule of Benefits for physician fees, laboratory fees from the Ontario Laboratory Schedule of Fees, device costs from the perspective of local health care institutions, and drug costs from the Ontario Drug Benefit formulary list price.

Discounting: For all cost-effectiveness analyses, a discount rate of 5% is used as per the Canadian Agency for Drugs and Technologies in Health.

Downstream costs: All costs reported are based on assumptions of utilization, care patterns, funding, and other factors. These may or may not be realized by the system or individual institutions and are often based on evidence from the medical literature. In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions, and the revised approach. The economic analysis represents an estimate only, based on assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied for the purpose of developing implementation plans for the technology.

Economic Literature Review

A literature review was conducted and no economic analyses on f-EVAR were identified. Several economic studies on standard EVAR were identified (24-28) including the Program for Assessment of Technologies in Health (PATH) field evaluation on EVAR versus OSR. (29)

Health Systems Perspective - PATH Field Evaluation

From the PATH report, current costs associated with standard EVAR were identified. (29;29) An expert in the field was consulted and resource utilization was confirmed to be similar for both EVAR and f-EVAR from a health systems perspective (personal communication, clinical consultant, March 2009). F-EVAR, however may require more tests and procedures than EVAR, so costs may be higher than what is reported here. Table 26 describes the resources associated with f-EVAR (assuming a similar resource utilization to EVAR) in the first year of follow-up after surgery from a health systems perspective. Costs are reported in 2006 CAD$. The details of the study can be found in the PATH report. (29)

The costs of f-EVAR devices and stents were included in the total cost. As per communication with the clinical consultant, the average cost of a fenestrated graft is $19,000 (personal communication, clinical consultant, March 2009). Grafts can be further customized to include more branches thus increasing the price of the device. Furthermore, the cost of stents will also increase the total cost per patient, a cost that hospitals are currently absorbing. The average cost of one stent is $2,900 as per communication with its manufacturer (personal communication, manufacturer of stent, March 2009). The cost of two stents was included in the total cost, as per data from one hospital; however, the number of stents does vary based on the individual patient.

Table 26. First-year costs associated with FEVAR.

Direct Costs (2006 CAD$)	Item	f-EVAR cost per patient
Initial hospitalization	Average cost	$34,613
Follow-up medical costs	Hospital admissions	$2,318
	Tests and procedures	$1,372
	ER visits	$115
	GP or FP visits	$349
	Specialist visits	$272
	Other health care professional visits	$755
	Average cost per patient	**$39,794**

Cost reported in 2006 CAD$ from PATH report; Devices costs are current costs reported from manufacturer.

Please note that there is an additional one-time cost for the advanced imaging software required to perform these procedures of $150,000 for a volume of five licenses, as well as an annual support cost of $22,500 with a minimum of a 4-year contract (personal communication, hospital in Toronto, May 2009).

Expenditure by One Toronto Hospital

Presently, hospitals absorb the cost of f-EVAR procedures. Table 27 describes what one hospital in Toronto paid on average for f-EVAR grafts for JRAs in the last fiscal year (2008/09).

Table 27. Description of fenestrated grafts and their costs at one hospital in Toronto.

Graft Description – FY 2008/09	Quantity	Item Cost ($)
AAA Balloon	1	445
Iliac Leg Graft	1	2,400
Covered Stent	2	2,550
AAA Reinforced Fenestrated Device	1	19,000
Total		**$24,395**
AAA Balloon	1	470
Iliac Leg Graft	1	2,400
Covered Stent	2	2,600
AAA Reinforced Fenestrated Device	1	19,000
Total		**$24,470**
AAA Balloon	1	470
Covered Stent	2	2,600
Iliac Bifurcation	1	7,500
AAA Reinforced Fenestrated Device	1	19,500
Total		**$30,070**
AAA Balloon	1	470
Covered Stent	2	2,600
Covered Stent	2	2,700
AAA Reinforced Fenestrated Device	1	19,500
Total		**$25,270**
AAA Balloon	1	470
Covered Stent	1	2,600
Covered Stent	1	2,775
AAA Reinforced Fenestrated Device	1	19,500
Total		**$25,345**

Ontario EVAR Program

The Ministry of Health and Long-Term Care currently funds 550 EVAR patches for AAA annually across six hospitals (personal communication, Ministry of Health and Long-Term Care, March 2009):

1. Sudbury Regional Hospital – 35 patches
2. Hamilton – 125 patches
3. Ottawa Hospital – 100 patches
4. University Health Network – 100 patches
5. St. Michael's Hospital – 20 patches
6. London Health Sciences Centre – 160 patches

The Ministry allocates $7.2M per year at $13,000 per device to hospitals. Eligible patients have to fit certain criteria, the principal one being that they cannot withstand OSR. It's not known whether this funding is currently being used by hospitals to fund f-EVAR procedures (personal communication, Ministry of Health and Long-Term Care, March 2009).

It is important to note that most centers perform more EVAR cases than what they are budgeted for and the newer devices are more expensive than those previously used (personal communication, clinical consultant, March 2009).

Estimate of the Number of f-EVAR Procedures in Ontario

To determine the annual number of patients in Ontario that will require f-EVAR estimates of potential EVAR volume were obtained by an informal survey of existing Divisions of Vascular Surgery possessing the ability to perform the procedure. (29) The survey asked each program to estimate the potential volume of elective and emergency EVAR procedures that could potentially be completed, provided funding was available based on their current case mix. The results of this survey suggest that approximately 635 cases of standard EVAR annually can be expected in Ontario. (29)

Of all AAA cases, 15.5% involve the juxtarenal aortic region. (5) Based on this incidence and the estimate of annual EVAR cases in Ontario, it can be extrapolated that there will be a maximum of 116 patients with JRA in the province. Some of these may be eligible for OSR, therefore, the number of patients who will require f-EVAR is in fact less than 116.

Ontario Cost Impact Analysis

Assuming the average cost range of f-EVAR procedures is $24,395 to $30,070, as per hospital data and assuming that the maximum number of annual cases in Ontario is 116, the average estimated cost impact range to the province for f-EVAR is $2.83M-$3.49M annually.

Appendices

Appendix 1: Literature Search Strategy

Final Search – Fenestrated EVAR

Search date: December 19, 2008
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, INAHTA/CRD

Search Strategy:
---
1 exp Aortic Aneurysm/ (15694)
2 ((aorta or aortic or thoraco?abdominal) adj2 aneurysm*).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (16192)
3 aaa.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4180)
4 or/1-3 (18429)
5 exp Blood Vessel Prosthesis/ (6072)
6 exp Blood Vessel Prosthesis Implantation/ (9206)
7 exp Stents/ (27821)
8 exp Vascular Surgical Procedures/ (52901)
9 (graft$ or implant* or stent* or prosthes* or EVAR or endograft*).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (278270)
10 or/5-9 (304347)
11 4 and 10 (8978)
12 (fenestrat* or branch* or chimney or juxta?renal).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (51500)
13 12 and 11 (668)
14 limit 13 to (english language and humans and yr="2003 - 2009") (333)
15 limit 14 to (case reports or comment or editorial or letter) (98)
16 14 not 15 (235)

Database: EMBASE <1980 to 2008 Week 50>
Search Strategy:
---
1 exp Aorta Aneurysm/ (17689)
2 aaa.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (4674)
3 ((aorta or aortic or thoraco?abdominal) adj2 aneurysm*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (19526)
4 or/1-3 (21339)
5 exp Stent/ or exp Blood Vessel Graft/ (76841)
6 exp Blood Vessel Prosthesis/ (4031)
7 exp Blood Vessel Transplantation/ (44458)
8 exp Endovascular Surgery/ or exp Aneurysm Surgery/ (13579)
9 (graft$ or implant* or stent* or prosthes* or EVAR or endograft*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (448080)
10 or/5-9 (455693)
11 10 and 4 (9204)
12 exp Fenestration/ (1414)
13 (fenestrat* or branch* or chimney or juxta?renal).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (80956)
14 13 or 12 (80956)
15 11 and 14 (554)
16 limit 15 to (human and english language and yr="2003 - 2009") (290)
17 limit 16 to (editorial or letter or note) (3)
18 Case Report/ (1017866)
19 17 or 18 (1017868)
20 16 not 19 (202)

Appendix 2: Grade of Evidence

Grading System

Population	*Outcome*	*Number of studies*	*Study Design*	*Quality of Studies*	*Consistency*	*Directness*	*Other Modifying Factors*
			RCT= High Observational=Low Any other evidence=Low	Serious limitation (-1) Very serious (-2)	Important inconsistency (-1)	Some uncertainty (-1) Major uncertainty (-2)	Defined as*

*=Association: Strong (+1), very strong (+2)
Dose response gradient (+1)
All plausible confounders would have reduced the effect (+1)
Imprecise or sparse data (-1)
High probability of reporting bias (-1)

GRADE Table

Population	*Outcome*	*Number of studies*	*Study Design*	*Quality of Studies*	*Consistency*	*Directness*	*Other Modifying Factors*
Patients who have JRA aneurysm >5 cm, and are at high risk of surgery, and are anatomically unfit for standard EVAR	30-day & late mortality	1	Observational=Low	No change	No change	No change	N/A
		5	Case series=Low	No change	No change	No change	N/A

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