Ontario Health Technology Assessment Series 2010; Vol. 10, Suppl. 1

Endovascular Repair of Abdominal Aortic Aneurysms in Low Surgical Risk Patients

An Evidence Update

Presented to the Ontario Health Technology Advisory Committee in October, 2009

January 2010

Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

About this Update

This report updates the following report:

Bowen, J, De Rose, G., Blackhouse, G., Novick, T., Hopkins, R., Tarride, J-E., and Goeree, R. Systematic review and cost-effectiveness analysis of elective endovascular repair compared to open surgical repair of abdominal aortic aneurysms. Hamilton, ON: Program for Assessment of Technology in Health (PATH). 2007 130p. HTA001-0703-02. Available from: http://www.path-hta.ca/Libraries/Reports/EVAR_Final_Report_2007.sflb.ashx

Suggested Citation

This evidence update should be cited as follows:

Medical Advisory Secretariat. Endovascular repair of abdominal aortic aneurysms in low surgical risk patients: an evidence update. Ont Health Technol Assess Ser [Internet]. 2010 January [cited YYYY MM DD]; 10(Suppl. 1) 1-15. Available from:
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/update_EVAR_20100101.pdf

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ISSN 1915-7398 (Online)
ISBN 978-1-4435-4249-4 (PDF)

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Background

Objective

In 2005, the Ontario Health Technology Advisory Committee (OHTAC) made a recommendation to increase the access to endovascular aneurysm repair (EVAR) of abdominal aortic aneurysms (AAAs) for patients at high risk for surgical complications and mortality. This decision was made based on a field evaluation and systematic literature review conducted by the Programs for Assessment of Technology in Health (PATH)[1]. At the time, OHTAC did not recommend EVAR for low and moderate surgical risk patients because of inadequate long-term evidence (see Appendix 1 for the full OHTAC recommendation).

The objective of this Evidence Update is to determine the safety of EVAR for low surgical risk patients.

Clinical Need

An abdominal aortic aneurysm (AAA) is a dilatation and weakening of the wall of the abdominal aorta. The cause of the condition is unknown but risk factors include male sex, smoking, atherosclerosis, and hypertension. A 2004 meta-analysis of population-based screening studies found that the prevalence of AAAs ranges from 4.1% to 14.2% in men and 0.4% to 6.2% in women. (1)

The most serious risk associated with AAAs is aneurysm rupture, which results in death in 80% to 90% of cases. (1) The risk of rupture increases from 1% per year for aneurysms less than 4 cm in diameter to 25% per year when the diameter reaches 6 cm. (2)

Endovascular Repair (EVAR) of Abdominal Aortic Aneurysms

Current treatment options for AAAs include open surgical repair (OSR), EVAR, and best medical treatment (active surveillance and blood pressure management). The choice of treatment depends on the health of the patient, their ability to undergo surgery, whether the patient is symptomatic, and the size, progression rate, and morphology of the aneurysm. (2) For AAAs less than 5 cm in diameter, medical therapy and periodic monitoring with ultrasound are recommended. In Ontario, for those AAAs larger than 5.5 cm, symptomatic, or growing rapidly, OSR is the primary treatment option. Elective OSR has a 4% to 5% mortality rate and factors such as increased age, cardiac, respiratory, and renal comorbidities can double or triple the risk of perioperative morbidity and death. (3)

EVAR is a less invasive catheter-based procedure in which collapsed grafts are delivered to the site of the aneurysm through the femoral arteries under x-ray guidance. The graft excludes the aneurysm from the blood circulation and prevents further expansion. (2;3) At present, seven endovascular grafts for AAA repair are licensed by Health Canada as Class 4 devices.

[1] The final report from PATH is available at: http://www.path-hta.ca/evar1.pdf

Evidence Review

Search Strategy

In July 2009, a non-systematic search of recent peer-reviewed literature related to the safety of endovascular repair of AAAs in low risk patients was conducted. Reference lists of relevant studies were manually searched to identify additional studies.

Inclusion criteria

- English language full-reports
- Studies including: systematic reviews and meta-analyses, health technology assessments, randomized controlled trials (RCTs), observational studies, registry studies

Outcomes of Interest

- Perioperative mortality
- Conversion rate to OSR
- Graft Rupture
- Complication rate
- Re-intervention rate

Results

Five studies were identified including two multicentre RCTs (EVAR-1 and DREAM) that compared EVAR and OSR for AAA repair in low surgical risk patients (see Table 1). (4-7) As some of the safety results were inconsistent in these RCTs, three studies that included patients of both low and high surgical risk were also examined. These additional studies consisted of a retrospective propensity-score matched cohort study based on United States Medicare data (8), a prospective cohort study conducted in Ontario (2), and a European registry study (9).

Complications

The most serious complications associated with AAA repair are perioperative mortality, risk of graft rupture after repair, and conversion to OSR during or after the EVAR procedure (Table 2). Overall, perioperative (in-hospital and 30 day) mortality rates were lower in the EVAR groups compared to the OSR groups. The rate of conversion to OSR after EVAR was similar across the trials and ranged from 0.0% to 2.6%, while the rate of graft rupture was found to be low in both groups with ranges of 0.0% to 1.7% for EVAR and 0.0% to 0.5% for OSR.

Table 1: Characteristics of Included Studies

Study, Year	Study design	Patient population	Location	No. sites	Mean Age, Years		N		Duration of Follow-up
					EVAR	OSR	EVAR	OSR	
EVAR-1, 2005 (4;7)*	RCT	Low surgical risk patients	UK	34	74.2	74	543	539	4 years after randomization; median: 2.9 years
DREAM, 2005 (5;6)*	RCT	Low surgical risk patients	Netherlands, Belgium	30	70.7	69.6	173	178	2 yrs after randomization; mean: 21 months (OSR) and 22 months (EVAR)
Ontario cohort study, 2007 (2)	P. cohort	EVAR: high surgical risk patients; OSR, low and high surgical risk patients	Ontario, Canada	1	75.6	72.3	140	195	1 year
Medicare, 2008 (8)	R. propensity-score matched cohort	High and low surgical risk patients combined	USA.	n/a	76	75	22,830	22,830	4 years
EUROSTAR, 2005 (9)†	Registry	High and low surgical risk patients combined	Europe (19 countries)	181	72	n/a	5,374	n/a	Mean, 21 months (range, 0 – 108 months)

EVAR refers to endovascular repair; N, sample size; no, number, OSR, open surgical repair; P, prospective; R, retrospective' UK, United Kingdom;

*Based on early and midterm results published (trials are not yet complete)

†Only data pertaining to 3rd generation EVAR devices (AneuRx, Excluder, Talent, and Zenith) were extracted from this study.

Table 2: Rates of Perioperative Mortality, Graft Rupture, and Conversion to OSR by Study

Study	Technology	Perioperative All Cause Mortality Rate (%)		Graft Rupture Rate, (%)	Conversion to OSR Rate (%)
		In-hospital	30 Day		
EVAR 1 (4;7)	EVAR (low risk)	2.0	1.7	1.7 (over 4 years)	2.6 (over 4 years)
	OSR (low risk)	5.9	4.6	0.0 (over 4 years)	n/a
DREAM (5;6)	EVAR (low risk)	1.2		0.0 (over 2 years)	1.7 (over 2 years)
	OSR (low risk)	4.5		0.0 (over 2 years)	n/a
MEDICARE (8)	EVAR (combined risk)	0.0		1.8 (over 4 years)	2.0 (over 4 years)
	OSR (combined risk)	0.0		0.5 (over 4 years)	n/a
Ontario cohort study (2)	EVAR (high risk)	0.0	0.7	0.0	0.0
	OSR (low risk)	0.0	1.4	0.0	n/a
	OSR (high risk)	0.0	9.6	0.0	n/a
	OSR (combined risk)	0.0	3.6	0.0	n/a
EUROSTAR (9)	EVAR (combined risk)			0.24 (annual incidence)	1.33 (annual incidence)

EVAR refers to endovascular repair; OSR, open surgical repair; yr, year

Notably, in the EVAR-1 trial, the proportion of patients with at least one complication was substantially higher in the EVAR group compared to the OSR group (Table 3). Of the 186 complications reported in the trial, however, almost half (42%) were type II endoleaks[2]. (4) Type II endoleaks are considered less serious and often do not require further interventions. (11) In contrast to these results, the four other studies reported similar overall complication rates in the EVAR and OSR groups. Furthermore, higher perioperative medical and surgical complication rates were reported in the OSR groups than in the EVAR groups.

Re-interventions

The EVAR-1 trial reported higher re-intervention rates among patients in the EVAR group compared with those in the OSR group (hazard ratio, 2.7; see Table 4). While the DREAM trial also reported a higher rate of complications in the EVAR group during the first nine months of follow-up (hazard ratio, 2.9), this difference was not maintained after nine months. Similarly, the proportion of patients who required at least one re-intervention was similar in the EVAR and OSR groups in the Medicare study and the Ontario cohort study.

[2] Endoleak is defined as persistent blood flow into the aneurysm after the graft has been inserted. (4) There are four types of endoleaks. Type II endoleaks not graft-related and are characterized by retrograde blood flow into the aneurysm sac from surrounding arteries. (4;10)

Table 3: Reported Complications Rates by Study

Study	Technology	Proportion of patients with ≥1 complication (%)	Rate of ≥1 complication	Perioperative Complications (%)			
				Medical Complications	Surgical Complications	During Surgery	≤30 days After Surgery
EVAR 1 (4;7)	EVAR (low risk)	41 (over 4 years)	17.6 per 100 py				
	OSR (low risk)	6 (over 4 years)	3.3 per 100 py				
DREAM (5;6)	EVAR (low risk)		16.8% (over 2 years)*				
	OSR (low risk)		18.5% (over 2 years)*				
MEDICARE (8)	EVAR (combined risk)	13.1 (discharge – 1 year)		23.3 (before discharge)	11.2 (before discharge)		
	OSR (combined risk)	11.4 (discharge – 1 year)		39.9 (before discharge)	26.1 (before discharge)		
Ontario cohort study (2)	EVAR (high risk)	8.63 (discharge – 1 year)				2.1	27.9†
	OSR (low risk)	0.0 (discharge – 1 year)				2.8	46.9†
	OSR (high risk)	0.0 (discharge – 1 year)				3.9	107.7†
	OSR (combined risk)	0.0 (discharge – 1 year)				3.1	63.1†

EVAR refers to endovascular repair; OSR, open surgical repair; py, person years

*Percentage include only moderate and severe complications

†Percentage based on total number of complications reported in each group, so patients could be counted more than once if they reported multiple complications. Thus, some percentages may exceed 100%.

Table 4: Re-Interventions Rates by Study

Study	Technology (Patient Population)	Proportion of Patients with at Least One Re-intervention (%)	Rate of at Least One Re-intervention	Re-intervention Hazard Ratio
EVAR 1 (4;7)	EVAR (low risk)	20 (over 4 years)	6.9 per 100 py	2.7 (95% CI: 1.8–4.1)
	OSR (low risk)	6 (over 4 years)	2.4 per 100 py	
DREAM (5;6)	EVAR (low risk)			≤ 9 mo: 2.9
	OSR (low risk)			> 9 mo: 1.1
MEDICARE (8)	EVAR (combined risk)	13.1 (discharge – 1 year)*		
	OSR (combined risk)	11.4 (discharge – 1 year)		
Ontario cohort study (2)	EVAR (high risk)	0.0 (discharge – 1 year)		
	OSR (low risk)	0.0 (discharge – 1 year)		
	OSR (high risk)	0.0 (discharge – 1 year)		
	OSR (combined risk)	0.0 (discharge – 1 year)		
EUROSTAR (9)	EVAR (combined risk)		5.6% (annual incidence)	

CI refers to confidence interval; EVAR, endovascular repair; mo, months; OSR, open surgical repair; py, person years
*9.0% of these re-interventions are aneurysm-related, most of which are minor re-interventions (7.8%)

Ionizing Radiation Exposure

Following AAA repair by EVAR, patients are monitored regularly with computed tomography (CT) scans. In the first two years after treatment, patients receive two CT scans per year, then one scan per year every year after. (2) EVAR is, therefore, associated with a risk of cancer development due to cumulative ionizing radiation exposure during follow-up monitoring. This risk does not exist for OSR because patients are not monitored after the procedure. Research evaluating the effectiveness of EVAR monitoring by ultrasound imaging (particularly contrast-enhanced ultrasound) instead of CT scans is ongoing, so this risk may be eliminated in the future. (12-14)

Review of EVAR Cost-Effectiveness Literature

Based on a review of six identified cost-effectiveness trial and modeling-based studies of EVAR, the evidence indicates that EVAR is more cost-effective in patients with high surgical risk for complications and mortality, but is not cost-effective when considering low and high surgical risk patients combined (see Table 5). Trials and modeling studies specifically in lower risk patient populations suggest that the poor cost-effectiveness of EVAR in combined patient populations is driven by lower surgical risk patients where EVAR does not appear to be cost-effective.

Table 5: Summary of the EVAR Cost-Effectiveness Literature

Author	Country	Type of CE Study	Patient Population	Cost-Savings	Conclusion
Tarride et al., 2008 (15)	Canada	Trial-based analysis	High surgical risk patients	▪ $24 cost savings ▪ 0.25 gains in QALYs vs. OSR over 1 year follow-up	▪ EVAR is cost-effective (EVAR dominates OSR) in high risk patients
Blackhouse et al., 2009 (16)	Canada	Model-based analysis	Low and high surgical risk patients	▪ EVAR costs an additional $268,337 per QALY gained	▪ EVAR is not cost-effective in low and high (combined) surgical risk patients
Michaels et al., 2005 (17)	UK	Trial-based analysis (EVAR-1)	Low surgical risk patients	▪ EVAR costs £11,449 more ▪ 0.10 gain in QALYs over 10 years (£110,000 per QALY)	▪ EVAR is not cost-effective in low risk patients
Epstein et al., 2008 (18)	UK	Model-based analysis (lifetime projections from EVAR-1)	Low surgical risk patients	▪ EVAR costs £3,800 more ▪ 0.02 loss in QALYs over lifetime,	▪ EVAR is not cost-effective in low risk patients
Prinssen et al., (19)	Netherlands	Trial-based analysis (DREAM)	Low surgical risk patients	▪ EVAR costs €4,293 more ▪ 0.01 loss in QALYs over 1 year follow-up	▪ EVAR is not cost-effective in low risk patients
Chambers et al., 2009 (20)	UK	Review of cost-effectiveness studies (HTA)	Low and high surgical risk patients	▪ n/a	▪ EVAR is not cost-effective at £20,000 per QALY threshold ▪ OSR is likely to be more cost-effective in patients considered fit for surgery ▪ EVAR is likely to be more cost-effective than OSR in the subgroup of patients at higher risk for operative mortality

*CE refers to cost-effectiveness; DREAM; the Dutch Randomized Endovascular Aneurysm Management Trial; EVAR, endovascular aneurysm repair; OSR, open surgical repair; QALY, quality adjusted life year; UK, United Kingdom

Status in Ontario

In fiscal year 2007, a total of 1,327 AAAs were repaired in Ontario. Of these, 888 (66.9%) were performed using OSR and 439 (33.1%) using EVAR.[3]

Conclusions

1. Compared with OSR, EVAR has a lower perioperative mortality rate.
2. While the EVAR-1 RCT reported substantially higher complication and re-intervention rates in the EVAR group, these high rates do not translate into higher conversion to OSR rates as would be expected with serious complications.
3. In contrast to EVAR-1, the other studies included in this analysis reported higher perioperative complication rates in the OSR group, and similar overall complication and re-intervention rates were reported in the EVAR and OSR groups.
4. EVAR is associated with a risk of cancer development from exposure to ionizing radiation during follow-up monitoring with CT scans.
5. A review of the cost-effectiveness literature found that EVAR is not cost-effective in low surgical risk patients.

[3] Source: The Ministry of Health and Long Term Care, Provincial Health Planning Database.

Appendix: 2005 OHTAC Recommendation

Based on the evidence presented by PATH, OHTAC recommended that:

- Hospitals with the required expertise increase access to EVAR for AAA in patients who are at high-risk of perioperative morbidity or death from co-morbidities from OSR. Surgical expertise is critical and a surgeon should do a minimum of 50 EVAR procedures to prepare for this surgery and at least one procedure every two weeks to maintain their skill and expertise in performing the procedure.
- Any recommendation for the provision of EVAR for AAA in low or moderate risk patients will require additional long-term outcome studies. The use of EVAR in these patients is not recommended at this time.
- Based on the London Health Sciences Center (LHSC) protocol, EVAR is considered to be the most suitable treatment for patients falling into one or more of the following 'high-risk' categories:

  (i) High-risk/comorbid diseases
  - Cardiac
    - class II-III angina
    - significant myocardium at risk
    - left ventricular ejection fraction < 30%
    - recent congestive heart failure
  - Pulmonary
    - recent congestive heart failure
    - chronic obstructive pulmonary disease or emphysema
    - severe pulmonary dysfunction
    - home oxygen or forced expiratory flow 25-75 of < 20% predicted
  - Renal
    - creatinine > 250 μmol/L
    - dialysis dependent

  (ii) Hostile abdomen

  (iii) Technical challenges
  - inflammatory aneurysm
  - renal anomalies (e.g., horseshoe kidney, renal allograft)
  - anastomotic aneurysm

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