Systematic review and cost-effectiveness analysis of elective endovascular repair compared to open surgical repair of abdominal aortic aneurysms

Interim report

Prepared for the Ontario Ministry of Health & Long-term Care

by

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Disclaimer

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The results and conclusions outlined in this interim report may change following the completion of the ongoing field evaluation study. Additionally, future published scientific findings may influence the final report. The final HTA report is anticipated to be available in the fall/winter of 2006.

PATH takes sole responsibility for the final form and content of this report. The statements and conclusions in this interim report are those of PATH and not of the MOHLTC, OHTAC, McMaster University, University of Western Ontario, St. Joseph's Healthcare, Hamilton or London Health Sciences Centre.

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Abbreviations

AAA	Abdominal aortic aneurysm
AAVS	American Association for Vascular Surgery
ACP	American College of Physicians
ASA	American Society of Anesthesiologists
BCOHTA	British Columbia Office of Health Technology Assessment
BMT	Best medical treatment
CINAHL	Cumulative index to nursing and allied health literature
CCOHTA	Canadian Coordinating Office of Health Technology Assessment
CCTR	Cochrane Central Register of Controlled Trials
CDSR	Cochrane Database of Systematic Reviews
CHF	Congestive heart failure
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CSVS	Canadian Society for Vascular Surgery
CT	Computed tomography
CVD	Cerebrovascular disease
DARE	Database of Abstracts of Reviews of Effects
DSA	Deterministic sensitivity analysis
EBM	Evidenced based medicine
EMBASE	Excerpta Medica database
EQ-5D	EuroQol 5 Dimensions
EVAR	Endovascular aortic aneurysm repair
FE	Fixed effects model
ICER	Incremental cost-effectiveness ratio
LHSC	London Health Sciences Centre
HLD	Hyperlipidemia
HTA	Health Technology Assessment
HTN	Hypertension
ICU	Intensive care unit
IMA	Inferior mesenteric artery
LOS	Length of stay

MAS	Medical Advisory Secretariat
MI	Myocardial infarction
MEDLINE	Medical literature analysis and retrieval system online
MH	Mantel and Haenszel
MRI	Magnetic resonance imaging
MSAC	Medical Services Advisory Committee
MOHLTC	Ontario Ministry of Health and Long-term Care
n.a.	Not applicable
n.d.	Not done
n.r.	Not reported
n.s.	Not significant
NYHA	New York Heart Association
OSR	Open surgical repair
OSR-LR	Open surgical repair – low surgical risk
OSR-HR	Open surgical repair – high surgical risk
OVID	OVID Web Gateway
PATH	Program for Assessment of Technology in Health
PSA	Probabilistic sensitivity analysis
PTCA	Percutaneous transluminal coronary angioplasty
PTSR	Primary technical success rate
PVD	Peripheral vascular disease
QALY	Quality adjusted life year
QoL	Quality of life
RE	Random effects model
RR	Relative risk
s.d.	Standard deviation
SF-36	Short Form 36
SVS	Society for Vascular Surgery
TIA	Transient ischemic attacks
tx	Treatment
VATAP	Veterans' Affairs Technology Assessment Program

1. Introduction

1.1. Statement of the Problem

Abdominal aortic aneurysms (AAA), a pathologic dilatation of a segment of the aorta, are a significant health problem in Ontario. It is estimated that the prevalence of AAA ranges from 4.1% to 14.2% in men and between 0.35% and 6.2% in women.[1] The prevalence of AAA is greater in men, increases with age and also is more common to occur in people with a history of myocardial infarction, peripheral vascular disease, smokers and a family history of AAA.[1,2] Aortic aneurysms can remain asymptomatic for years. When symptoms do present they are characterized by back pain or abdominal throbbing usually as a result of pressure on adjacent tissues. The primary risk with AAA is rupture which is associated with significant mortality rates.[3,4]

Current treatment options for AAA include open surgical repair (OSR), endovascular aneurysm repair (EVAR) and best medical treatment (BMT). The choice of which option to use 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. Open surgical repair is currently the primary method of repair of AAA in Canada, however, in some jurisdictions, EVAR is becoming the predominate method of managing AAA.[5,6] The available clinical literature comparing EVAR to OSR includes some randomized controlled trials but primarily consists of several non-randomized observational studies with some short-term results from randomized controlled trials available.[7-10] However, in the observational trials, the comparability of the baseline characteristics of the patients receiving EVAR versus those receiving OSR may not always be the same as there is a potential for a selection bias towards patients with higher surgical risk receiving EVAR over OSR. Long-term results from ongoing randomized controlled trials are anticipated in 2005.[9,10]

As these interventions are associated with differences in morbidity and mortality, hospital resource utilization, follow-up times and monitoring, re-intervention rates, complications, recovery times and costs of care, it is essential to compare the

relative cost and effectiveness of OSR versus EVAR. Patel et al. have evaluated the cost-effectiveness of endovascular repair versus open surgical repair.[11] This study, using US costing data, found that the use of EVAR was cost-effective. However, results were highly dependent on the potential of EVAR to reduce morbidity and mortality rates as compared to OSR. The authors suggested that the cost-effectiveness of EVAR may not be the same at institutions where OSR can be conducted on patients with a low risk of surgical mortality. While this analysis provides some insight into the cost-effectiveness of EVAR vs. OSR, this evaluation may not be transferable to the Canadian health care setting as morbidity and mortality rates along with the costs associated with the treatment of AAA are different from country to country.[12] In addition, little is known about the long term costs and effects of AAA treatment.

Therefore, there is a need to conduct a Canadian-based economic evaluation of the treatment options for AAA in order to evaluate the short and long-term cost and outcomes (including quality of life implications) associated with the use of open surgical repair vs. endovascular repair of AAA.

1.2. Evaluation of EVAR in Canada

Elective endovascular repair of AAA has been the focus of three health technology assessments (HTA) by Canadian agencies.[5,13,14] The clinical studies reviewed by these HTA's were published prior to 2002. At the time the literature consisted primarily of observational studies with either concurrent or historical control groups. A limited number of randomized controlled trials were incorporated into the analyses and larger randomized controlled trials evaluating EVAR vs. OSR were ongoing.[7]

The first Canadian evaluation of EVAR was completed for the British Columbia Office of Health Technology Assessment (BCOTHA) in 1998.[14] This evaluation was initiated as a result of funding requests for this procedure by clinicians in this province. At the time of the review, no published randomized or non-randomized, controlled trials could be identified that compared EVAR to OSR for AAA. The report did however provide a summary of the best available evidence

which consisted of three case series publications with one of the studies providing a historical control group.[15-17] Based on the review of this evidence, the evaluation found that endovascular graft technology was still considered to be at an investigational stage and that public funding of EVAR as a replacement for OSR must await technology maturity. Furthermore, the technology would continue to be provided on a compassionate basis to patients with contraindications to OSR.

The Medical Advisory Secretariat (MAS) of the Ontario Ministry of Health and Long-term Care (MOHLTC) evaluated EVAR in 2002 by conducting a scientific literature review and descriptive analysis of unique studies published between January 1998 and February 2002. The purpose of the evaluation was to review the evidence concerning the effectiveness and cost-effectiveness of EVAR in comparison to OSR. The report provided a literature update to two previously published HTA's conducted in Australia by the Medical Services Advisory Committee (MSAC) and in the United States by the Veteran's Affairs Technology Assessment Program (VATAP).[18,19] The clinical outcomes that were abstracted by the MAS from the literature were rates of primary technical success, 30 day mortality, conversion to OSR, endoleaks, late adverse events and the need for secondary intervention. In addition, the report provided a synopsis of various issues related to the patient population suitable for EVAR related to anatomical considerations and surgical risk. A review of publications related to the cost and cost-effectiveness of EVAR and OSR was also included in the MAS review. The primary conclusions of the report was that EVAR should be considered as an adjunctive technology to OSR, that no definitive conclusion could be made about the long-term effectiveness of EVAR due to the poor quality of the available evidence and that EVAR may be appropriate for treating a subset of patients with AAA who are unfit for OSR. The report acknowledged the potential of EVAR but stated that the long-term effectiveness and cost effectiveness could not be determined at the time and that further evaluation of the technology was required.

The most recent Canadian review of EVAR was conducted by the Canadian Coordinating Office of Health Technology Assessment (CCOHTA) in 2002.[5] This review had two primary objectives 1) to examine the status of EVAR utilization in Canada, through a postal survey of vascular surgeons and 2) to critically review the literature comparing EVAR, OSR or a "wait-and-see" approach in terms of their relative effects on the mortality and morbidity of patients with abdominal aortic aneurysms. Results are discussed below.

The postal survey (conducted between March – May 2001) of members of the Canadian Society for Vascular Surgery (CSVS) residing in Canada had a response rate for eligible responders of 81% (104/129). Of those responding, 40% (42/104) of the surgeons had repaired an AAA with an endovascular graft and of this group 52% (22/42) were using EVAR as an investigational procedure. The majority of surgeons (98%) primarily used EVAR for patients with moderate to high surgical risk and appropriate anatomy. For those surgeons not performing EVAR, 34% (21/62) stated that a lack of resources was the primary reason for not repairing AAA with this method. The survey also found that for those surgeons performing EVAR about 19% of their elective repairs of AAA were performed using an endovascular graft (341/1842).

This CCOHTA systematic literature review of all comparative studies of EVAR to OSR identified 42 relevant publications. The literature review however identified the potential for significant overlap of data being presented on the same patient in multiple publications. Of the relevant papers, 52% (22/42) were identified as unique studies. The analysis of the comparative efficacy & safety of EVAR vs. OSR in the report was based on these 22 unique publications. The comparative outcome measures that were abstracted in the review were perioperative mortality, primary treatment success, operative blood loss, duration of surgery, length of hospital stay including the time in the intensive care unit (ICU), complication and re-intervention rates including endoleaks, conversion to OSR for patients receiving EVAR and rate of rupture. Due to the heterogeneity of the data reported in the clinical trials with respect to surgical outcomes data was not pooled. Pooled estimates of perioperative mortality and primary treatment

success were however determined. A non-significant difference in perioperative mortality was seen between the patients receiving EVAR or OSR (OR: 0.72; 95% CI: 0.44, 1.17; p=0.18). The primary success rate of EVAR was found to be statistically less than that of OSR (OR: 0.17; 95% CI: 0.08, 0.37; p<0.00001).

The CCOHTA report concluded that EVAR was still a new technology and that the evidence did not suggest that the technology was appropriate for all patients undergoing elective repair of AAA.

In 2003, the Ministry of Health and Long Term Care (MOHLTC) conducted a systematic review of endovascular repair (EVAR) for abdominal aortic aneurysms (AAA). In light of the informational uncertainty associated with the long-term effectiveness of EVAR, the MOHLTC felt that further Ontario-specific evaluation of the technology was warranted. Therefore, based on this review of the literature and in response to requests for funding for EVAR, the MOHLTC provided funding on a one time basis to support a 24 month EVAR evaluation at London Health Science Centre (LHSC). An important condition of this funding was that LHSC would collaborate with the Program for Assessment and Technology in Health (PATH) at McMaster University to design and conduct an observational study or "field evaluation" to support the evaluation of the effectiveness and cost-effectiveness of EVAR compared to open surgical repair (OSR) in Ontario.

This interim report provides an initial analysis of the cost-effectiveness of EVAR compared to OSR using preliminary information from the field evaluation (i.e. patients with 1 year follow-up). An updated systematic literature review and meta-analysis which includes new studies in addition to those published after 2001 identified in the MAS and CCOHTA reports, is also included in this interim report.

1.3. Project Purpose

The purpose of this project was fourfold. First to provide an updated evaluation of the scientific literature related to EVAR. Second to collect Ontario-specific clinical, resource utilization and quality-of-life data related to the use of EVAR and OSR. Third to develop a cost-effectiveness model incorporating data from both the clinical literature & field evaluation study. And finally to evaluate the cost-effectiveness of endovascular repair compared to open surgical repair for the management of non-ruptured abdominal aortic aneurysms in Ontario.

1.4. Report Purpose

The purpose of this report is to present the results of our systematic literature review and an interim analysis to OHTAC to estimate the cost-effectiveness of EVAR versus OSR based 1) on an updated review of the literature, 2) a preliminary analysis of a subset of patients with 1 year follow-up recruited into the LHSC study and 3) a decision analytic model developed to evaluate the cost-effectiveness of EVAR versus OSR.

2. Background

2.1. Abdominal Aortic Aneurysms

The term aneurysm is derived from the Greek word aneurysma, meaning a "widening," and by current reporting standards an aneurysm is defined as a permanent localized dilatation of an artery, having at least a 50% increase in diameter compared with the expected normal diameter.

The aorta is the largest artery of the body. It arises from the heart as the ascending aorta, and receives all the blood pumped by the heart to supply the whole body. The ascending aorta lies just behind the sternum and courses upward toward the neck, then turns toward the back (now called the aortic arch), and gives off the vessels to the head and arms (the arch vessels). It then turns downward and courses downward at the back of the left side of the chest, lying beside the backbone (descending thoracic aorta). It passes through the diaphragm into the abdomen and gives off the vessels to the abdominal organs and kidneys (the visceral or upper abdominal aorta), and then continues to the lower abdomen (the infra-renal aorta), where it divides into the two iliac arteries, and exits the abdomen in the groins (becoming the femoral arteries).

Aneurysms of the abdominal aorta are the most common type of true aneurysm and have a high propensity to rupture, which makes them a significant health care problem. In Canada, ruptured AAAs are the 13th leading cause of death overall, and the 10th leading cause of death in men over age 55 years. The effectiveness of elective AAA repair means that most deaths from AAA's are theoretically preventable.

Aneurysm formation represents the loss of structural integrity of the aortic wall. The cause of aortic aneurysm is multi-factorial, with significant genetic, epidemiological, and behavioral influences. An association between aortic aneurysm formation and generalized atherosclerotic disease has long been recognized. Most patients with aortic aneurysms have evidence of significant atherosclerosis in the coronary arteries, at the carotid bifurcation, and/or in the

lower extremity arteries. Patients with aneurysms and atherosclerotic occlusive disease share similar risk factors.

Atherosclerosis is a degenerative process of arteries comprising a complex series of events involving plaque deposition and artery wall responses. It involves inflammation and necrosis, cellular proliferation and migration, lipid accumulation, and matrix fiber deposition and degradation, as well as dystrophic calcification. For most AAA, aneurysm formation is a manifestation of atherosclerotic artery wall degeneration and appears to be a relatively late phase of the atherosclerotic process. In early phases plaque formation is accompanied by compensatory arterial enlargement; subsequently, the process of plaque regression or resorption may release proteolytic enzymes, resulting in further aortic enlargement and degeneration (hence the term “degenerative aortic aneurysm”). Degenerative aneurysms account for more than 90% of all infra-renal AAA’s; less frequent causes include infection, cystic medial necrosis, arteritis, trauma, inherited connective tissue disorders, and pseudoaneurysm from anastomotic disruption. Once an aneurysm develops, subsequent atrophy and thinning of the aortic wall occurs in association with plaque regression leaving an enlarged aorta with a thinned wall unable to support the elevated mural tensile stress and results in eventual aortic aneurysm rupture.

2.1.1. Prevalence and Incidence

Abdominal aortic aneurysms are generally a disease of elderly white males, with a steadily increasing frequency after age 50 years, and are 5 times more common in men than in women. In men, AAA’s begin to occur at about age 50 years, and reach a peak incidence near age 80 years. In women, AAA onset is delayed, beginning around age 60 years, with incidence continuing to rise thereafter. Overall, the age-adjusted incidence is four-fold to six-fold higher in men than in women for both asymptomatic and ruptured AAA’s.

A significant increase in the incidence of asymptomatic AAA’s has been noted during the 1990’s, in part because of increased aneurysm finding, due to more frequent use of ultrasonography and other abdominal imaging modalities.

Ultrasound screening and autopsy series indicate that the prevalence of AAA's is 3% to 10% for patients over 50 years of age in the western world. Prevalence of AAA's in a given population depends on risk factors that are associated with AAA's, including older age, male gender, white race, positive family history, smoking, hypertension, hypercholesterolemia, peripheral vascular occlusive disease, coronary artery disease, and carotid artery disease. Of these risk factors, however, age, gender, and smoking have the largest impact on AAA prevalence.

Familial clustering of patients with AAA's is well described in the literature. It is estimated that first degree relatives of a patient with an AAA have a 12-fold increased risk of developing an AAA. The likelihood that relatives have AAA's increases if the patient with the AAA is a woman.

2.1.2. Signs and Symptoms

Most AAA's are asymptomatic. Occasionally patients may describe a "pulse" in their abdomen, or may actually palpate a pulsatile mass. Although most clinically significant AAA's are potentially palpable during routine physical examination, the sensitivity of this technique depends on the AAA size, the obesity of the patient, the skill of the examiner, and the focus of the examination. Because of these factors, most AAA's are detected by incidental abdominal imaging studies done for other reasons.

Most AAA's that become symptomatic do so because of rupture or acute expansion. Patients with a ruptured AAA experience abrupt onset of abdominal or back pain that can radiate into the flank or groin. When rupture occurs, extravasation of blood takes place through the disrupted aortic wall. The extent of hemorrhage and cardiovascular compensation then determine the severity of hypotension and shock associated with rupture and the rapidity of frank cardiovascular collapse and death.

Much less frequently, AAA's may present with symptoms unrelated to rupture. Rarely, large AAA's may cause symptoms from local compression of adjacent structures; posterior erosion of AAA's into adjacent vertebrae can lead to back

pain; acute ischemic symptoms can result from the distal embolization of thrombotic debris contained within an AAA or acute thrombosis of the aneurysm itself.

2.1.3. Imaging

Several imaging modalities can be used to diagnose and assess AAA's. Abdominal B-mode ultrasonography is the least expensive, least invasive and most frequently used examination. Diameter measurements are quite accurate; however, visualization of the supra-renal aorta and iliac arteries may be obscured and often the upper extent of an AAA cannot be accurately determined.

Computed tomography (CT) scanning is more expensive than ultrasound, and involves radiation and intravenous contrast exposure, but it provides more accurate diameter measurement. CT scanning precisely defines the proximal and distal extent of an AAA, more accurately images the iliac arteries, and provides other anatomic details important for operative planning.

Spiral CT scanning is a more rapid method of CT scanning that provides excellent resolution of the visceral aortic branches when "thin slices" are obtained. Refinements of spiral CT scanning includes three-dimensional reconstruction which provide images that can be used for accurate measurement necessary for endovascular graft sizing and has eliminated the routine need for pre-operative angiography prior to endovascular aneurysm therapy.

Magnetic resonance imaging (MRI) is comparable to CT scanning in accuracy and avoids radiation exposure. However, this technique is more expensive, less readily available and less well tolerated by the claustrophobic patient. MRI can be of value for patients in whom intravenous contrast is contraindicated, such as in patients with renal failure.

2.1.4. Screening

Since asymptomatic AAAs are often not discovered until they rupture, the potential benefit of the non-invasive ultrasound screening of patients has been examined.

Several studies have indicated that ultrasound screening for AAA's in men over 50 years of age can reduce AAA rupture rate by more than 50% when accompanied by appropriate follow-up and timely elective repair. Other studies have suggested the value of identifying high-risk for AAA screening. In addition to male gender and advanced age, smoking history increases the positive yield of a screening program. Despite ongoing debates regarding the cost-effectiveness of screening programs to detect asymptomatic AAA's, formal cost-effective studies have suggested that ultrasound screening for AAA's is cost-effective if performed once in patients with a reasonably high prevalence of AAA. Earlier this year, the U.S. Preventive Services Task Force has recommended that all men between the ages of 65 and 75 who have ever smoked undergo one-time screening for abdominal aortic aneurysm.[20] The Society for Vascular Surgery and the Society for Vascular Medicine and Biology recommends AAA screening in all men ages 60-85 years, and women of the same age with cardiovascular risk factors. The two groups also advocate screening of both men and women older than 50 years of age with a positive family history for AAA.

Such recommendations are likely to be the only successful method to reduce mortality from AAA rupture.

2.1.5. Rupture Risk

From a hemodynamic perspective, AAA rupture occurs when the forces within an AAA exceed the wall's bursting strength. Theoretically, large AAA diameter and hypertension should increase wall tension and thus rupture risk.

The importance of diameter in determining AAA rupture risk is universally accepted, based initially on a pivotal study reported by Szilagyi in 1966.[21]. The outcome of patients with large (>6 cm by physical examination) AAA were compared with the outcomes of patients with small (<6 cm) AAA managed non-operatively. During follow-up, 43% of the larger AAA's ruptured compared with only 20% of small AAA. This difference in rupture rate contributed to a 5-year survival rate of only 6% for patients with large AAA's compared with 48% for patients with small AAA's.

It is now accepted that AAA diameter is the best predictor of rupture risk, and numerous studies support the impression that the risk of rupture increases exponentially with increasing diameter. The variability of estimates of rupture risk for particular AAA diameters in the literature reflects differences in other factors besides maximal diameter which may vary considerably from series to series, and illustrates that other factors in addition to absolute size must be taken into account in each individual case. It is clear, however, that there is a substantial increase in rupture risk as AAA diameter increases from 5 cm to 6 cm.

Level I evidence for the treatment of small AAA has been provided by two randomized prospective clinical trials conducted in the United Kingdom and the United States.[22-24] Both trials concluded that surveillance of AAA of 4.0 cm to 5.5 cm was safe in compliant patients, and that early surgery did not result in any long-term survival advantage. The risk of rupture, however, was 4 times as high among women as among men.

Thus, although there is agreement that rupture risk is very low for AAA's <5 cm diameter, and increases substantially by 6 cm diameter, there is considerable variation in estimates of actual rupture risks reported in the literature for any specific AAA diameter (Table 1).[25]

Table 1. Estimated annual rupture risk

AAA diameter (cm)	Rupture Risk (%/year)
<4	0
4 – 5	0.5 – 5
5 – 6	3 – 15
6 – 7	10 – 20
7 – 8	20 – 40
>8	30 – 50

The simple observation that not all AAA's rupture at a specific diameter indicates that other patient or aneurysm-specific variables also affect rupture risk. These include female gender, increased initial diameter, hypertension, chronic obstructive pulmonary disease, current smoking and positive family history.

Clinical opinion also holds that eccentric or saccular aneurysms represent greater rupture risk than more diffuse, cylindrical aneurysms. As well, even though not proven conclusively, rapid expansion (>1 cm/year) is generally regarded as a risk factor for rupture and is often used as a criteria for elective repair of small AAA's.

2.2. Management of Non-Ruptured Abdominal Aortic Aneurysms

Surgical treatment of asymptomatic abdominal aortic aneurysms is a prophylactic intervention designed to avoid rupture and prolong life. Thus, for any individual patient, appropriate decision making requires an accurate estimate of AAA rupture risk, elective operative risk and estimate of life expectancy. Thus, not all patients are advised to undergo surgical therapy, as some are best treated medically at any one point in time. Current recommendations for AAA repair are outlined in detail in the Report of Subcommittee of Joint Council of American Association for Vascular Surgery and Society for Vascular Surgery (AAVS/SVS).[25]

2.2.1. Medical Management

For patients with low-risk AAA's (small diameter without other risk factors for rupture) and for patients with co-morbid diseases that are judged to be prohibitive for surgical therapy, attempts are made to reduce both aneurysm expansion rate and rupture risk. Thus, smoking cessation is critical, and hypertension should be aggressively controlled. The use of beta-blockade with propranolol has not been found to decrease the rate of aneurysm expansion.

As well, patients with small, low-risk AAA's should be enrolled in a surveillance program and followed by ultrasonography or CT scanning every 6 months to assess aneurysm size.

2.2.2. Surgical Management

Successful, durable management of AAA's was not achieved until aneurysm resection and aortic graft replacement was first performed in 1951.[26]

Since about 1960, AAA's have been repaired with the technique of endoaneurysmorrhaphy with intra-luminal graft placement, as described by

Creech.[27] This can be accomplished through an anterior transperitoneal incision or through a retroperitoneal approach. Both the transperitoneal and retroperitoneal approaches have advantages in certain patients. The transperitoneal approach, however, tends to be the more frequently used method. The open procedure requires general anesthetic with assisted mechanical ventilation and invasive hemodynamic monitoring.

Most often the transperitoneal approach is carried out through a midline abdominal incision extending from the xyphoid process of the sternum to the pubic bone inferiorly. After the abdomen is entered and the bowel appropriately retracted, the posterior peritoneum is incised to allow adequate aortoiliac exposure. The aorta and iliac arteries are dissected sufficiently to place a vascular clamp proximal and distal to the aortic and/or iliac aneurysm. Most surgeons use heparin anticoagulation during aortic cross-clamping to reduce lower extremity thrombotic complications. Once clamps have been applied appropriately, the aneurysm is opened longitudinally along its anterior surface. Intraluminal thrombotic material and atherosclerotic debris are extracted from the aneurysm sac and this usually discloses several back-bleeding lumbar artery orifices that require suture ligation. Also, the inferior mesenteric artery may or may not require ligation or re-implantation. Once hemostasis within the opened aneurysm sac has been achieved then a prosthetic graft is sutured proximally to the aorta (just distal to the level of the renal arteries), and distally either to the aortic bifurcation or the iliac arteries, or to the femoral arteries in the groin. Prosthetic grafts available for AAA repair include knitted polyester (Dacron), knitted Dacron, and polytetrafluoroethylene (PTFE). After restoration of lower extremity and pelvic blood flow, adequacy of intestinal and lower extremity circulation must be ensured. Finally, the aneurysm wall and retroperitoneal tissues are closed over the graft to provide a tissue barrier between the prosthesis and adjacent intestine; the bowel is returned to the peritoneal cavity and the abdominal wall incision is closed.

2.2.2.1. Perioperative Mortality Rates for Open Surgical Repair

There has been a steady decline in perioperative mortality associated with open surgical repair over the past four decades. This can be attributed to better patient selection, improved pre-operative care, advances in anesthesia, better intra-operative monitoring, refinements in surgical technique, and major progress in perioperative monitoring and critical care. Exemplary results have been obtained in centers of excellence. However, elective surgical repair of an AAA, as documented in the literature, is associated with post-operative mortality rates ranging from 0 to 15%.[25] According to the national multicenter prospective study of non-ruptured abdominal aortic aneurysms in Canada the 30-day post-operative mortality for open aneurysm repair was 4.7%.[28] This is consistent with the findings of the UK Small Aneurysm Trial (5.8%).[22]

A number of risk factors for perioperative mortality in elective AAA surgery have been identified, including age, female gender, history of previous myocardial infarction, congestive heart failure, electrocardiographic abnormalities, and pulmonary and renal disease. In the Canadian Aneurysm Study, the most significant variables were electrocardiographic evidence of ischemia, COPD, and elevated creatinine. If none of these risk factors was present, operative mortality was 1.9 %, whereas if all three were noted in a specific patient, 30-day mortality was 50%. Similar risk factors, as well as the impact of patient-specific variables and the cumulative effect on operative risk have also been documented in other reports.[29-31]

Operative mortality risk is also influenced by anatomic and/or pathologic features of the AAA. Such features (eg. inflammatory aneurysm, extensive atheromatous disease, severe mural calcification) present technical difficulties and lead to potential complications during graft implementation and hence may impact mortality risk.

Thus, by utilizing an individual assessment of risk factors for each specific patient, operative mortality risk can be stratified into low (1-3%), moderate (3-7%), and high (5-10% or greater) surgical risk.[25]

Early complications, following elective AAA repair, may also occur. The frequency of occurrence of each of these complications (Table 2) is estimated below, based on data from two surgical series.[28,32]

Table 2. Early complications after elective AAA repair

Complication	Frequency (%)
All cardiac	15
Myocardial infarction	2 – 8
All pulmonary	8 – 12
Pneumonia	5
Renal insufficiency	5 – 12
Deep vein thrombosis	8
Bleeding	2 – 5
Ureteral injury	<1
Stroke	1
Colon Ischemia	1
Leg ischemia	1 – 5
Spinal cord ischemia	<1
Wound infection	5
Graft infection	<1
Graft thrombosis	<1

Adapted from: Johnston, KW et al. J Vasc Surg 1988; Richardson JD, et al. 1991.[28,32]

2.2.2.2. Late Complications After Open AAA Repair

Late complications after successful AAA repair do occur. These include anastomotic disruption with pseudoaneurysm formation (1 – 4%) at aortic, iliac, or femoral artery anastomoses. One study by Edwards et al has reported an incidence of aortic pseudoaneurysms of only 1% after 8 years, but 20% after 15 years.[33] Hallett and colleagues in their population-based study from the Mayo Clinic reported a 4% likelihood of anastomotic pseudoaneurysm after 10 years.[34]

Graft infection after AAA repair occurs with a likelihood of 1%, usually presenting 3 –4 years after implantation. The development of a secondary aortoenteric fistula after AAA repair is also in the range of 1%, usually developing approximately 5 years after AAA repair. The combined likelihood of graft infection and graft-enteric fistula appears to be 5% after 10 years.[34]

Thrombosis of an aortoiliac graft after AAA repair is unusual, with a likelihood of graft thrombosis estimated to be 3% after 10 years.

In total, even though only up to 10% of patients will experience late complications of open AAA repair during their lifetime, most complications are severe and often fatal.

2.2.3. Endovascular Repair

Endovascular abdominal aortic aneurysm repair (EVAR), using covered stent grafts was introduced in 1991, in two independent publications by Parodi and associates, in Argentina and by Volodos and colleagues in the Ukraine.[35,36]

These pioneering devices were rapidly improved and commercial development of endoluminal stent grafts quickly developed with more than a dozen different devices appearing in the first 12 years. The technique quickly spread worldwide. Currently, in Canada, two devices have been approved and thus are most commonly used. The Talent LPS endograft (manufactured by Medtronic) is a self-expanding modular woven monofilament polyester graft with serpentine nitinol stents inlaid into the fabric and 1 cm bare stent at the proximal attachment site. The Zenith endograft (manufactured by Cook) is a modular woven polyester graft supported by self-expanding Z-stents with a bare proximal stent for supra-renal fixation with hooks.

Briefly, the EVAR procedure can be done with the patient under general anaesthesia, regional anaesthesia, or local anaesthesia. This is due to the fact that the procedure involves incisions in the groins to expose the femoral arteries (sometimes a higher small incision is required to expose the iliac arteries if vascular anatomy is not appropriate to allow use of the femoral artery) through which the sheathed endograft is inserted in a retrograde fashion, with catheters and guide wires, and positioned correctly with x-ray guidance, at the top (at the level of the renal arteries) and bottom (iliac arteries) of the aneurysmal segment of the aorta. The sheath is then removed and usually balloon molding of the endograft is used to allow for thorough apposition of the endograft to the vessel wall and achieve endograft fixation. Proper, correct positioning and attachment

of the endograft allows blood to pass through it and not through the aneurysm and thus remove pressure from the diseased aortic wall.

Successful endovascular repair requires thorough procedural planning, beginning with accurate anatomical vascular assessment with a CT scan of the abdomen, a pre-operative angiogram and detailed measurements of the aorto-iliac arteries in order to select the most appropriate endograft for any individual patient. Some patients due to specific vascular anatomic issues will require custom-manufacturing of the necessary endograft components.

Following successful endovascular repair of the aneurysm, recovery in the intensive care unit is rarely required. Patients are recovered on the ward and usually discharged home on the 3rd or 4th post-operative day. Major cardiopulmonary complications occur less frequently after EVAR than standard open repair. In addition, decreased blood loss, transfusion requirements, hospital stays, intensive care monitoring, and patient discomfort have been documented for EVAR compared to open repair in virtually all studies. Patients return to pre-intervention levels of activity more rapidly with EVAR than with open repair (on average in about half the time).

2.2.3.1. EVAR Reporting Standards

Reporting standards for endovascular aortic aneurysm repair have been set down by the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS).[37]

The reporting guidelines identify and define several aspects that are to be considered when reporting outcomes related to EVAR as well as for the comparison of EVAR and OSR. They are classified by factors contributing to technical and clinical success, secondary outcomes, adjuvant procedures, systemic complications, and local and vascular complications. Outlined below are several definitions of composite outcome measures outlined in the guideline and used in this report for presentation of data from clinical trials.

The composite outcome measure to evaluate EVAR technical success, as defined by the SVS Guidelines is primary technical success rate (PTSR) and is defined on an intent-to-treat basis and requires the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction.[37]

After PTSR, technical success is the other major endpoint used to evaluate EVAR. *Technical* success relates to periprocedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period and it is characterized by the 4 following conditions.

1. Successful access to the arterial system using a remote site (i.e., the femoral, external iliac, common iliac, or brachiocephalic arteries with or without use of a temporary or permanent prosthetic conduit to access these arteries);
2. Successful deployment of the endoluminal graft with secure proximal and distal fixation;
3. Absence of either a type I or III endoleak;
4. Patent endoluminal graft without significant twist, kinks, or obstruction (>30% luminal stenosis or a pressure gradient >10 mm Hg) by intraoperative measurements.

Another endpoint to evaluate EVAR is clinical success in the perioperative period which encompasses the first 30 days post-procedure. Clinical success should be reported on an intent-to-treat basis and requires successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion, aneurysm rupture, or conversion to open repair.[37] Moreover, the presence of graft dilatation of 20% or more by diameter, graft migration, or a failure of device integrity classifies a case as a clinical failure.

Primary clinical success is clinical success without the need for an additional or secondary surgical or endovascular procedure. However, few studies report the

number of patients that have had clinical success without adjuvant procedures. *Assisted primary clinical success* is clinical success achieved with the use of an additional or secondary endovascular procedure. S*econdary clinical success* is clinical success obtained with the use of an additional or secondary surgical procedure (e.g, the performance of a femoralfemoral bypass for treatment of a unilateral limb occlusion of a bifurcated endograft).[37]

Conversely, *clinical failure* includes a failure to deploy the endovascular device at the intended location, the presence of a type I or III endoleak, graft thrombosis or infection, aneurysm expansion (diameter >5 mm, or volume >5%), aneurysm rupture, conversion to open repair, or death as a result of aneurysm rupture or aneurysm-related treatment. Moreover, the presence of graft dilatation of 20% or more by diameter, graft migration, or a failure of device integrity classifies a case as a clinical failure. Aneurysm rupture should be reported as either a *procedure-related aneurysm rupture* (i.e., perforation of the aneurysm during the course of the implantation procedure) or as a *late aneurysm rupture* that follows device deployment.

Primary technical success for open surgical repair (OSR) should be reported on an intent-to-treat basis and should require replacement or bypass of the aneurysmal segment with a prosthetic graft in the absence of mortality or graft thrombosis either during surgery or during the initial 24-hour postoperative period. If an unplanned surgical procedure is necessitated, such as a splenectomy or reexploration for bleeding, the term *secondary technical success* should be used.[37]

To further evaluate OSR is primary clinical success can be determined. The definition of *clinical success for open surgical repair* includes the absence of death as the result of aneurysm related treatment, graft infection or thrombosis, failure of device integrity, including graft dilatation 20% or more by diameter, and paraanastomotic aneurysm formation. Should open repair consist of aneurysm exclusion and bypass grafting, aneurysm expansion (diameter >5 mm, or volume >5%) or rupture would classify a case as a clinical failure.[37]

2.2.3.2. EVAR Patient Registries

Several voluntary registries for the tracking of endovascular aneurysm therapy have been established worldwide over the last decade. The UK Registry for Endovascular Treatment of Aneurysms (RETA) was started in 1996 and the European EUROSTAR initiative in 1997.[38,39]

In North America the LIFELINE Registry of Endovascular Aneurysm Repair (1998) was started shortly thereafter, with participation primarily from U.S. centers and several Canadian centers (including London Health Sciences Centre). The goals of the Registry are to obtain prospective information on endovascular graft recipient survival and to monitor endovascular graft performance.[40,41]

2.2.3.3. Complications of EVAR

The 30-day mortality rate for EVAR has been shown to be consistently less than that of open repair, and appears to be improving. The best example of this is from Australia, May, et al. performed concurrent comparisons of EVAR versus open repair using life table methods.[42] In their first report, the perioperative mortality rate with OSR versus EVAR was 5.6% for both methods, and in the next comparison it was 5% with open repair versus 2.7% for EVAR.[43]

The recent Australian registry report cited a mortality advantage for EVAR of 1.3% versus 2.6% with open repair.[44]

Level 1 evidence now exists for the significantly reduced 30-day mortality following EVAR compared to open aneurysm repair. The EVAR trial 1 from the United Kingdom randomized patients with infra-renal aortic aneurysms (diameter >5.5 cm) deemed fit for open aneurysm repair, and anatomy suitable for endovascular repair, to undergo either EVAR or open AAA repair. Between 1999 and 2003, 1082 elective patients were randomized to either EVAR (n=543) or open repair (n=539) in a total of 41 centers. The 30-day mortality for EVAR was 1.6% versus 4.6% for open repair. In patients with large AAA's treatment by

EVAR reduced the 30-day operative mortality by two-thirds compared with open repair.[9]

The DREAM trial investigators (from the Netherlands) also observed substantial reductions in the primary outcome of operative morbidity and mortality with endovascular repair, as compared with open repair. This multi-center randomized trial compared the two methods in 345 patients who had an abdominal aortic aneurysm of greater than 5 cm in diameter and who were considered suitable candidates for both techniques. The operative mortality rate was 4.6% in the open repair group (8 of 174 patients) versus 1.2% in the endovascular repair group (2 of 171 patients). The authors concluded that endovascular repair is preferable to open repair.[10]

In addition to the significantly reduced 30-day mortality, essentially all reports that have compared the two approaches show that EVAR significantly reduces systemic complications compared with open repair (primarily cardiac and pulmonary complications).

An institutional experience from the Mayo Clinic described elective AAA repair in 355 patients. Cardiac and pulmonary complications were less frequent after EVAR than open repair (11% versus 22%, respectively), but graft-related complications were more frequent (13% versus 4%) with EVAR.[45]

2.2.3.4. Long-term Complications of EVAR

The foremost concern of EVAR long-term has been the potential for graft migration and “endoleak” resulting in persistent blood flow outside the graft and within the aneurysm sac resulting in pressurization of the sac. Endoleaks are classified into five types: Type I is from inadequate attachment of the endograft at the proximal or distal fixation site; Type II is from retrograde collateral blood flow through patent lumbar, intercostals or inferior mesenteric arteries; Type III is from fabric tears, modular disconnection or poor modular seal; Type IV is of undefined origin, usually from graft material porosity or suture holes; and Type V or so-called “endotension,” defined as a state of elevated pressure within the

aneurysm sac but no demonstrable evidence for blood flow into the intact aneurysm sac.[46]

The occurrence of endoleaks after EVAR varies considerably from series to series. At present, the incidence of early endoleak at discharge is in the range of 20% - 30%.[40] Most of these endoleaks are Type II, and more than half of early endoleaks will seal spontaneously within several months of follow-up. However, endoleaks may persist in 10% - 15% of patients, but these persistent Type II endoleaks have been shown to be of no clinical consequence unless the aneurysm sac is expanding. Late endoleaks may develop in 5% - 10% of patients, and these are likely to require re-intervention.[47] Thus, for effective aneurysm therapy, following EVAR, patients require mandatory surveillance involving clinical assessment, plain x-ray of the abdomen, duplex scanning, and/or CT scan of the abdomen with intravascular contrast to assess for aneurysm sac size, endograft migration and endoleak.

Abdominal aortic aneurysm rupture is an infrequent but dreaded complication of EVAR. The incidence of rupture after EVAR has not been well established, and may in part be device-specific. In 2000, the EUROSTAR collaborators reported a cumulative risk of AAA rupture after endograft placement of approximately 1% per year.[48] But a 2004 update of the EUROSTAR data with first and second generation endograft devices excluded, revealed a cumulative annual rupture rate of only 0.4%.[49] As well, late conversion to open repair were reduced in more recent experience (at 4 year follow-up: 4.1% from 1996 to 1998, and 0.5% from 1999 to 2002).

Endograft migration may occur after EVAR. Analysis of five different devices used for endovascular aneurysm repair at the Cleveland Clinic disclosed a 3.6% annual migration rate, but these rates were device-specific.[50]

Migration rates have been significantly reduced with newer endografts that incorporate hooks, barbs or flared ends with supra-renal aortic fixation rather than relying on a self-expanding metal frame and its centripetal forces to provide adequate infra-renal attachment.

Obstruction of the limb of a bifurcated endograft has occurred in all devices, this was most worrisome in those endografts without external structural support (e.g. Ancure).[47] However, with the newer generation of endografts and with proper patient selection (i.e. avoiding small caliber, heavily calcified aortic bifurcations) the occurrence of endograft limb occlusion is rare. If it does occur and is of clinical significance then it can be usually treated by either a secondary endovascular means or an extra-anatomical revascularization of the ischemic limb (e.g. femoral-femoral artery bypass).

Late structural failure has been observed with several of the endograft devices. The Talent stent graft was associated with the development of stent spring fractures (1.4%), and connecting-bar fractures (5.5%) among 416 low-profile stent (LPS) grafts surveyed.[51] The LPS device was modified by burnishing the nitinol to strengthen it and by repositioning the longitudinal connecting bars from a lateral to a medial position to reduce stress from positioning in tortuous iliac arteries. Stent fractures are now rare and none have resulted in a clinical adverse event for a patient.

Barbs are used to improve supra-renal fixation of the Zenith endograft. Fractures were subsequently noted in these barbs. The incidence of barb fractures has been reported at 2.5%.[52] Although no adverse events were reported, the barbs have been made more numerous (10 rather than 4) and larger.

Thus, late structural failures have been observed with most endografts, but design modifications have been made to overcome these. Routine long-term surveillance (to discover such late occurrences) is none-the-less an important mandatory component of successful endovascular aneurysm repair.

2.3. Practice Patterns in Ontario

2.3.1. London Health Science Centre Endovascular Aneurysm Program

The endovascular aneurysm repair (EVAR) program at the London Health Sciences Centre was launched in December, 1997. The rationale for embarking on this endeavour was that this less-invasive method of aneurysm repair would allow for the treatment of patients who (because of associated heart, lung and/or kidney illnesses) might otherwise not be able to have treatment of their life-threatening aortic aneurysm because of prohibitively high perioperative risks associated with standard open repair. The goals for the program were to:

i) Bring together a group of dedicated medical personnel (surgeons, radiologists and nurses) with specialized skills to perform these procedures.

ii) Evaluate this mode of therapy for the most high-risk patients.

iii) Establish an educational program for the training of vascular surgery trainees and other groups of endovascular specialists throughout the province of Ontario and the rest of Canada.

The LHSC endovascular team currently consists of 4 experienced endovascular surgeons, a dedicated interventional radiologist, a group of specially trained operating room nurses, anaesthesiologists and radiology technicians. The patients are initially assessed by the vascular/endovascular surgeon, with the pre-operative planning for each patient being carried out by the surgeon and the radiologist. The endovascular procedures are carried out in the vascular operating room, equipped with appropriate radiologic imaging equipment. Most procedures are done with the patient under general anaesthesia, but depending on the risk factors, the procedure is also done under regional anaesthesia, with the patient awake. Post-operatively the patients are recovered in the regular post-anaesthetic recovery unit (the need for post-operative intensive care is rare), followed by a few days on the regular vascular surgery ward prior to discharge home.

Patients are selected as “high risk” based on selection criteria (Appendix I) that determines high risk on the basis of physiologic parameters and/or anatomical parameters.

As well, the program has established guidelines that help determine the anatomical suitability of patients for endovascular aneurysm repair (Appendix I).

From December 1997 to April 2005 the LHSC endovascular program has performed at total of 451 procedures (Table 3). Of these, 352 have been for the elective treatment of infra-renal aortic aneurysms, and 64 for the treatment of thoracic aortic pathology. (This therapy has become the treatment of choice for patients with thoracic aortic pathology, especially traumatic tear of the thoracic aorta, rupture of the thoracic aorta, and thoracic aortic aneurysms at high risk of rupture).

Table 3. London Health Science Centre Endovascular program volume (December 1997 – April 2005)

Aneurysm Type	**Number**
Abdominal Aorto-iliac	352
Thoracic Aorta	64
Subclavian Artery	3
Other (Iliac, Anastomotic)	32
Total	451

With respect to EVAR for elective repair of infra-renal aortic aneurysms, the LHSC program has treated 352 patients from December 1997 to April 2005. The technical success (defined as successful deployment of the endograft without Type I endoleaks at the end of the procedure) is 98%, and the 30-day mortality has been 2.7% in these high-risk patients (Table 4). The need for conversion to open repair occurred in 8 patients (2.2%), and all of these occurred in the first two years of our experience and were primarily due to poor patient selection (based on anatomic criteria). This has not been necessary in the last five years (highlighting the fact that there is a definite learning curve for these procedures, as documented by the LHSC program).[53]

Table 4. London Health Sciences Centre endovascular program for aorto-iliac aneurysm: clinical & technical outcomes (December 1997 – April 2005)

Outcome	Number (%)
Successful deployment/technical success (342/352)	97.7%
30-day mortality (10/352)	2.7%
Conversion to open repair (8/352)	2.2%
Late graft migration (6/352)	1.7%
Secondary endovascular procedure (8/352)	2.2%
Late aneurysm rupture (1/342)	0.3%

The need for re-intervention has been 2.2% (significantly less than reported in multi-center registries).

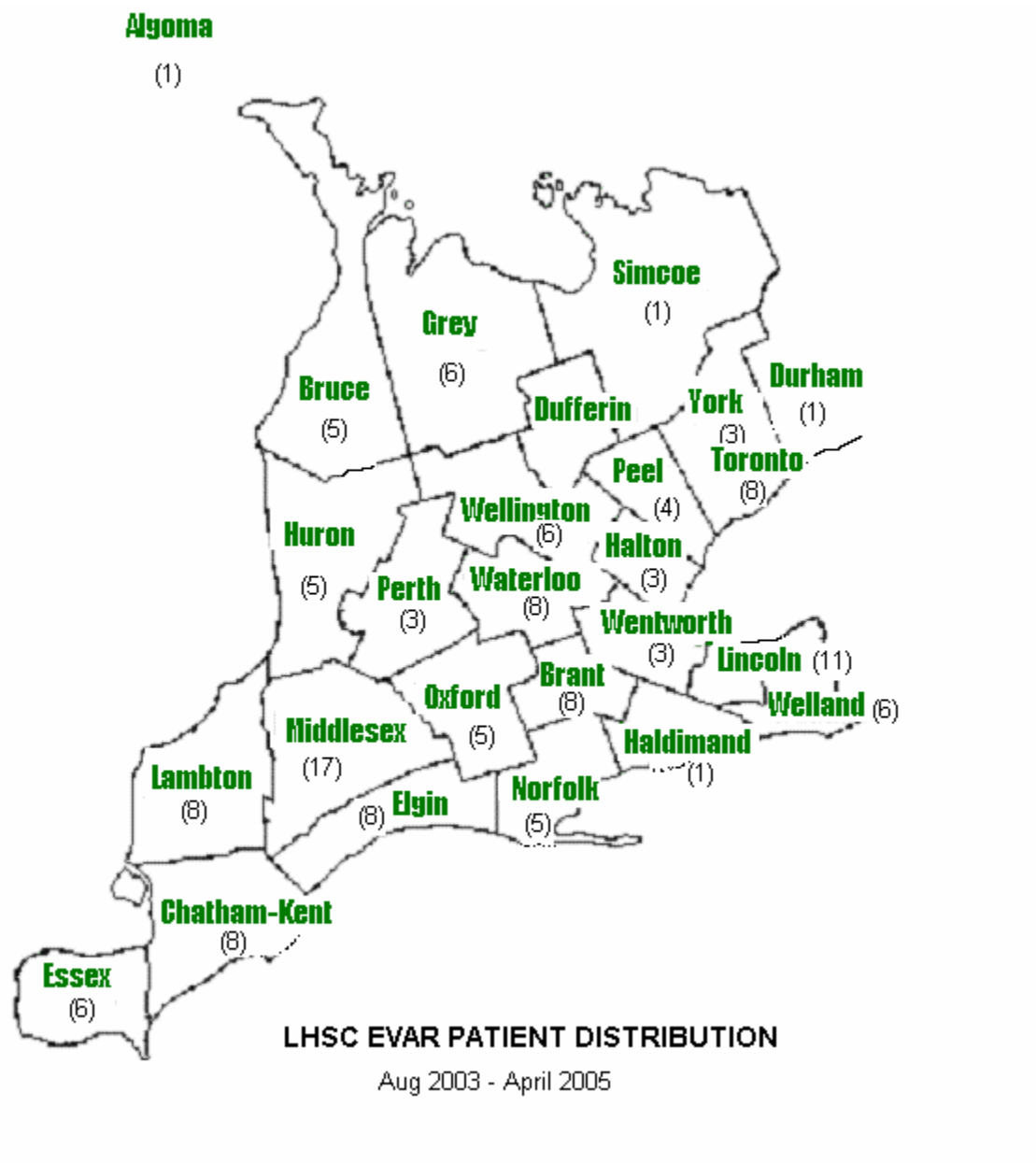
In order to compare the value of EVAR to standard open aneurysm repair, the LHSC group has analyzed the perioperative mortality of all patients undergoing elective repair of an infra-renal aortic aneurysm, by the LHSC team, from September 1999 to December 2004. During this period a total of 871 patients were treated at LHSC, (EVAR – 310 and open surgery – 561). The Leiden Risk Stratification Model was used to stratify patients according to risks factors in order to quantify the prognostic impact of patient's age, gender, cardiac morbidity, renal and pulmonary morbidity.[54] Risk scores are used to estimate surgical mortality. Applying this methodology to the 871 patients treated at LHSC (Table 5) it demonstrates that for all risk categories, EVAR was associated with a significantly reduced 30-day mortality rate than predicted for all categories, whereas patients undergoing standard open aneurysm repair the 30-day mortality was in the expected range. (e.g. for the highest risk patients with an expected 30-day mortality of >10%, open repair patients had a mortality of 11.1%, whereas the EVAR patients had a mortality rate of 3.3%).

Table 5. Comparison of EVAR with open repair: risk stratification per Leiden aneurysm score - LHSC experience (September 1999 – December 2004)

	EVAR (n=310)		OSR (n=561)	
Expected Mortality per Leiden Score	**% of Patients**	**30-Day Mortality**	**% of Patients**	**30-Day Mortality**
<2%	2%	0.0%	13%	0.0%
2-5%	32%	0.0%	61%	3.8%
5-10%	45%	2.9%	20%	8.7%
>10%	21%	3.3%	6%	11.1%

The LHSC endovascular program has treated patients from across the province, but the majority of the patients are from the region of Ontario, traditionally referring patients to the vascular surgery service for a variety of vascular surgical therapy. The 140 patients receiving EVAR at LHSC from August 2003 to April 2005 are listed as to county of origin as per the map in Figure 1.

Figure 1. Referral pattern of patients receiving EVAR at LHSC



The third goal of the LHSC program was to establish an educational and training resource for endovascular specialists in Canada. Over the years, the LHSC team has trained and mentored teams of surgeons, radiologists and nurses from Halifax, Toronto, Hamilton, Sudbury, Sault Ste Marie, Calgary and Victoria. As well, endovascular surgery training is now a mandatory requirement as per Royal College guidelines for vascular surgery trainees. Thus, the LHSC program is fulfilling an academic need as both a provincial as well as a national resource.

2.3.2. Other EVAR Programs in Ontario

In addition to the LHSC program (which has the largest experience in the province), programs exist in Sudbury (Memorial Hospital), Ottawa (Ottawa Civic Hospital), Hamilton (Health Sciences Centre), and Toronto (Toronto General Hospital and St. Michael's Hospital). Current annual volumes (limited by budgetary constraints) in each of these institutions are: LHSC – 40 - 110, (>100 during each of the last two years while the field evaluation was carried out; now limited to only 35 – 40 this year, as per hospital budget), Ottawa – 60, Sudbury – 25, Hamilton – 60, St. Michael's Hospital in Toronto – 15, and Toronto General Hospital had to suspend its activity completely as of February 2004 because of lack of funding.

In the province of Ontario, approximately 1500 elective abdominal aortic aneurysm repairs are performed, and 350 emergency repair of rupture abdominal aortic aneurysms are performed. Following the recommendations of the guidelines for the treatment of AAA, it can be estimated that approximately 40% would best be treated with this currently accepted standard of care.[25,55] Estimating that approximately 40% of patients requiring abdominal aortic aneurysm repair would best be treated by EVAR (due to either physiological and/or anatomical high-risk factors) at least 600 EVAR procedures per year should be performed in Ontario. Each of the six centers that currently possess the aneurysm volumes and expertise to perform these procedures estimate the need to perform the following number of procedures: LHSC (135 elective and 25 emergency procedures); Ottawa Civic (80 elective and 20 emergency procedures); Hamilton (100 elective and 25 emergency procedures); Sudbury (35 procedures); Toronto General (130 elective and 25 emergency procedures); St. Michael's (60 procedures).

2.3.3. Canadian Society for Vascular Surgery Consensus Statement on Endovascular Aneurysm Repair

The Canadian Society for Vascular Surgery (CSVS) recently released their consensus statement regarding the use of endovascular repair for the treatment of AAA.[55] The statement makes four recommendations:

1. The CSVS recommends that EVAR should be the procedure of choice for patients with suitable vascular anatomy who are at intermediate risk (6%-10%) for perioperative morbidity or death with open repair.

2. For patients at low risk (2%-4%), open repair remains the current standard. For those with suitable vascular anatomy for EVAR, the final decision should also take into account the patients wishes. Longer term outcome data are required before EVAR can replace open repair as the treatment of choice for low-risk patients.

3. EVAR procedures require specialized training and cooperation between specialists with complementary areas of expertise. They should be performed in centers experienced with aneurysm repair and with sufficient EVAR volume to enable appropriate data collection and auditing of results.

4. Appropriate training in endovascular therapies and interventional procedures is required for vascular surgery trainees. Training programs are needed for existing vascular surgeons and interventional radiologists currently in practice to allow this procedure to be safely implemented and disseminated across the country.

3. Systematic Review of Literature

3.1. Background

A systematic literature review was conducted to identify comparative studies that describe the clinical efficacy and safety of EVAR versus OSR. The studies identified in the search were then used to fulfill two purposes for this HTA. The initial objective was to describe and compare the clinical efficacy and safety of EVAR and OSR as per the SVS/AAVS reporting standards for EVAR, previously described, through the use of basic statistical analyses.[37] The second purpose of the systematic literature review was to provide estimates of selected parameters to populate the economic model developed to evaluate the cost-effectiveness of EVAR versus OSR.

3.2. Methods

3.2.1. Literature Search

The literature search strategies were developed to identify papers related to the repair of AAA and the health care interventions to treat the condition, as outlined in Appendix II. The surgical interventions of interest were EVAR and OSR. The goals of the search strategies were to identify clinical studies comparing the two surgical interventions. Specific search strategies for the following literature databases were developed and each database was searched individually via OVID Web Gateway (OVID Technologies, Inc. New York, NY): MEDLINE, EMBASE, Cumulative index to nursing and allied health literature (CINAHL), Evidence Based Medicine (EBM) Reviews (Cochrane Database of Systematic Reviews (CDSR), ACP Journal Club, Database of Abstracts of Reviews of Effects (DARE) and Cochrane Central Register of Controlled Trials (CCTR)), and Health and Psychosocial Instruments. English language and human studies between 1990 and 2004 inclusive were selected for review. Identification of duplicate citations was completed using Reference Manager, v.10 (ISI Researchsoft, Thomson Scientific, U.S.A).

The titles and abstracts were screened using predefined criteria to identify publications that discussed the use of EVAR and OSR for the management of

AAA. (Appendix III) Citations were excluded if they reported a mixed patient population including patients with thoracic-abdominal aneurysms, iliac disease, ruptured aorta, emergency aortic repair and patients that received both. Primary clinical reports that discussed EVAR and provided comparative data for elective EVAR versus OSR of abdominal aortic aneurysms were then identified and selected for full text review. Excluded were review articles, comments, editorials, guidelines, letters and case reports. If it was uncertain following the review of the title and abstract as to whether a publication provided comparative information, a full text review of the paper was completed. No restriction based on clinical study design was used and non-randomized trials and patient registries were included.

The full text of the identified comparative studies was then reviewed by three authors (R.B., J.B., J.E.T.) to identify publications with unique patient data using preset criteria (Appendix III). To identify potential overlap in patient data the full text of the articles was reviewed and the authors, institution, period of patient enrollment into study and site characteristics (i.e. single site results of multicentre study) were recorded. Where there was a potential for duplicate reporting of patient results, the most recent publication with the larger sample size was included. At this point, authors were not contacted to verify potential overlap. Clinical studies regarding the FDA approved clinical trials related to the Ancure device (Guidant) were identified and were excluded from further analysis due to 1) the potential of underreporting of device related events and 2) patient complications that were identified following investigation of the study results.[56]

The unique comparative clinical studies were reviewed and those with relevant clinical data including patient characteristics, clinical outcomes (short-term and long-term), complications and re-intervention rates were abstracted manually (Appendix III). The data was then entered into, and managed in, Microsoft Office Excel 2003.

3.2.2. Statistical Analysis

Following the identification of relevant papers, data was extracted from the studies to enable the comparison of EVAR to OSR. Relevant outcomes were

identified and analyzed for two inter-related purposes: 1) to compare the short-term (30 day) and long-term clinical efficacy and safety of EVAR and OSR and 2) to determine estimates of variables to populate the economic model (see Section 5.0 Economic Evaluation).

3.2.2.1. Clinical Efficacy and Safety Outcomes

Abstracted were clinical and safety outcomes related to EVAR and OSR. The outcomes are outlined in this report following, as best as possible, the SVS/AAVS Reporting Guidelines.[37]

Study population weighted means and standard deviations were reported for patient description variables and clinical outcomes. The median value reported of all the studies and the range of the medians was determined. Simple relative risk calculations were calculated by dividing the population weighted means of the two groups. P-values were calculated using simple t-statistics comparing mean reported values.

Of note the inverse variance method, for calculating the population weighted mean, was not used for simple outcome summation due to the high number of zero responses amongst the variables. A rule of thumb adjustment to calculate variance in the presence of zero response rates is needed. The rule of thumb is to add 0.5 to the number of responses and to the number of patients. However, his method over-weights small samples with zero response rates. Another way of dealing with the zeros is to calculate relative risk for each study and then pooling these results. However, this calculation will drop any study with a zero response rate. Only a small number of studies had both response rates greater than zero for most outcomes.

PTSR and technical success, if not reported in the primary study report, were derived based on data provided, when possible, and calculated under the assumption that for each patient, the studies reported mutually exclusive events. For example, if one study reported one conversion and one death and one type of endoleak, then it was assumed that these events occurred in separate individuals.

The definition of clinical success combines technical success with all systemic complications. However, there is a higher likelihood of multiple systemic complications in a single patient. Because of this possible over counting of failures in specific studies, clinical success rates were not reported in this report.

3.2.2.2. Meta-analysis

For the economic model parameters, more advanced statistical methods, as discussed below, were used to determine estimates of the parameters used in the model. Meta-analysis estimates of major outcomes to be used in the economic model were calculated by using the inverse variance method to derive the variance of the estimates. Here, using the rule of thumb method previously discussed, 0.5 can be used because relative risk calculations drop any study that has zero event rates in one arm. When there are studies with many zero events rates, the simple t-statistic comparison of mean reported values may be more relevant. No adjustments were made for random effects (RE) or fixed effects (FE) in the relative risk calculations.

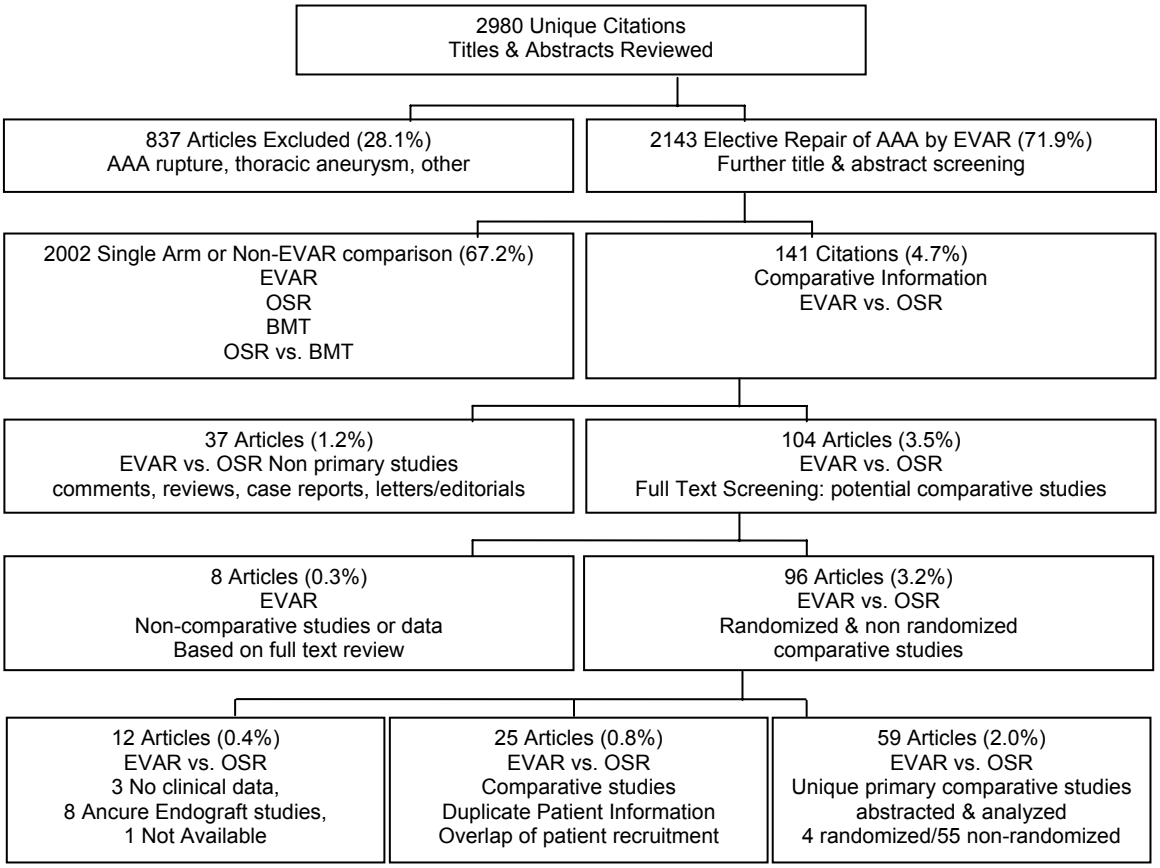
When estimating the outcomes for the economic model, meta-analysis techniques were used. The inverse variance method was used to weight the studies. Test of homogeneity was performed using the Q-statistic. The meta-analysis used RE and FE. If the Q-statistic, a Chi-squared test, rejected homogeneity in the estimation, the RE estimates were used. Random Effects used the method of DerSimonian & Laird, with the estimate of heterogeneity being taken from the Mantel-Haenszel model.[57,58] Fixed Effects used the method of Mantel and Haenszel. In both cases the weights were not standardized. In the absence of heterogeneity in the data, the FE estimates were calculated.

3.3. Results

3.3.1. Literature Search

The literature search, completed on November 6, 2004 identified 2980 unique citations. Upon review of the title and abstracts 837 (28.1%) articles were excluded as they did not focus on elective repair of abdominal aortic aneurysms. The reasons for exclusion are outlined in Figure 2 based on the title and abstract. The remaining 2143 (71.9%) citations included 141 (4.7%) citations with apparent information comparing EVAR to OSR for the treatment for AAA. Excluded were 2002 (67.2%) single-arm studies not providing comparative data related to the interventions of interest. Of the 141 citations, 104 were apparent primary studies comparing EVAR to OSR and were obtained for full text review. The excluded 37 citations were review articles, comments, editorials, letters, guidelines and case reports. The full text review of the 104 citations identified 8 citations that did not include comparative data. The remaining 96 papers (Appendix IV) from the literature search and review were then considered for further evaluation to determine if they consisted of unique patient data, an issue that had been identified in a previous assessment.[5] Upon further full text review, excluded from the analysis were studies that involved only the use of Ancure grafts (n = 8), as well as three studies that did not include relevant clinical data. In addition, one publication was not obtained prior to this interim analysis.[59] A review of the remaining 84 publications identified 59 (70.2%) primary study reports with relevant clinical data and were used for the basis of this analysis. (Appendix IV).

Figure 2. Literature review and evaluation of suitable articles for meta-analysis



3.3.2. Studies Overview & Description

The unique primary studies identified from the literature search consisted of 4 randomized controlled trials and 55 non-randomized trials comparing EVAR to OSR (Appendix V). Three (3) randomized controlled trials were published in 2004 while one trial was published in 2001.[7-10] Of the 55 non-randomized trials 32 (58.1%) were published after 2001 and were not included in the analyses of previous Canadian HTAs.[5,13,14] Enrollment of EVAR and OSR patients in the non-randomized trials was prospective in 65.4% (36/55) and 54.5% (30/55) of the trials, respectively. In both the randomized and non-randomized studies, EVAR was compared primarily to OSR that was performed on patients that were not anatomically suitable to receive EVAR (86.4% = 51/59). Only 19 studies (32.2%) examined only one EVAR device while the majority of trials presenting data related to the use of various endografts in the study. Long-term patient

outcomes (greater than 3 months post surgery) were reported in 39.0% (23/59) of the trials.

3.3.3. Patient Demographics

In the identified 59 unique studies, the average sample size of the patient group receiving OSR was higher than in the EVAR group as many studies provided concurrent information of new or growing EVAR programs, resulting in a larger sample size of OSR at the reporting institution. The provision of patient demographics in the 59 studies was somewhat consistent among studies with 52 studies reporting average age, 49 studies reported percentage males and 38 studies reported mean aneurysm size (Appendix VI &Table 6). The mean age of patients (73.0 vs. 70.1 years) was also higher among EVAR and the percentage of male patients receiving EVAR was also greater (mean percentage males of 87.8% in the EVAR group vs. 81.8% for OSR).

The abdominal aortic aneurysm (AAA) size reported in the studies was however larger for OSR. The mean reported AAA diameter was 5.71 cm in EVAR vs. 5.95 cm in OSR. Four studies reported the median AAA diameter and the mean median AAA size was 5.82 cm in the OSR group and 5.77 cm in the EVAR group.

Table 6. Baseline characteristics of patients and AAA's.

	Studies (n)	EVAR Mean (s.d.)	EVAR Median (min – max)	OSR Mean (s.d.)	OSR Median (min – max)
Patients (n)	59	160.5 (365.4)	53 (6 - 2565)	300.28 (1665)	48.5 (5 - 15589)
Age (years)	52	72.9 (3.6)	73.0 (72 - 83.5)	71.4 (3.3)	70.1 (73 - 83)
Males (%)	49	87.8 (5.7)	88.9 (20 - 100)	81.8 (5.96)	83.0 (56 – 100)
AAA size					
Mean diameter (cm)	38	5.71 (0.43)	5.65 (5.0 - 6.6)	5.95 (0.43)	5.86 (4.99 – 8)
Median diameter (cm)	4	5.77 (0.14)	5.75 (5.4 - 6.5)	5.82 (0.32)	6.15 (5.7 - 7.8)
Minimum diameter (cm)	16	4.19 (0.73)	4.75 (3.0 - 5.3)	4.70 (3.54)	1.69 (3.0 – 4.0)
maximum diameter (cm)	16	9.23 (1.83)	8.30 (6.2 -12.0)	9.85 ± 6.96	4.63 (6.1 - 11.5)

Comparing the patients' baseline surgical risk in the studies, using the American Society of Anesthesiologists (ASA) surgical risk evaluation, 18 studies reported ASA scores (Appendix VI). in these studies, the patients that received EVAR were of higher surgical risk then the OSR patients as more EVAR patients were classified as ASA risk level III and IV than OSR patients, and the difference was statistically significant for level IV (Table 7).

Table 7. Surgical risk assessment according to ASA classification

ASA class	EVAR studies (n)	Mean (s.d.) %	Median (min - max)%	OSR studies (n)	Mean (s.d.) %	Median (min - max)%
ASA I	11	6.8 (9.9)	0 (0 - 21.6)	10	10.4 (11.4)	3.0 (0 - 25.3)
ASA II	11	32.5 (27.7)	19.4 (5.9 - 69.6)	12	32.0 (27.2)	27.1 (0 - 78.9)
ASA III	16	56.6 (24.1)	67.5 (8.2 - 90.6)	16	45.5 (27.3)	59.5 (4.1 - 100)
ASA IV	14	19.6 (12.2)	17.2 (0 - 70.6)	14	9.1 (7.1)	8.3 (0 - 23.6)

The SVS has set classifications for high risk in several categories; age, cardiac, pulmonary, renal, cerebrovascular disease, current tobacco use.[60] According to SVS standards, the presence of any of these existing comorbidities (age, cardiac, pulmonary, renal, cerebrovascular disease, current tobacco use) classifies a patient as high-risk. However, no study provided the percentage of patients that were low risk according to SVS classifications. Only 1 study reported SVS cardiac classification.[61] Instead, studies reported the average number of high risk patients. Deriving from the study reports the SVS risk classifications indicates that 76.2% of EVAR patients were high risk, while 67.8 % of OSR patients were high risk (i.e. ASA levels III and IV).[62]

The reporting of existing comorbidities was variable among studies. Forty-one studies (41) reported cardiac disease, 38 hypertension (HTN), 36 diabetes, 34 chronic obstructive pulmonary disease (COPD) and a few studies reported cerebrovascular disease (CVD) (n=11) (Appendix VI). The mean percentage of comorbidities in the EVAR patients is higher that the OSR patients for the following comorbidities current tobacco use, hypertension, diabetes, hyperlipdemia (HLD), cardiac disease, CVD and COPD (Table 8). Peripheral

vascular disease (PVD) and renal dysfunction occurred more frequently in the OSR patients over the EVAR patients (Table 8).

Table 8. Summary of baseline comorbidities

	EVAR studies (n)	Mean (s.d.) %	Median (min - max)%	OSR studies (n)	Mean (s.d.) %	Median (min - max)%
Current Tobacco Use	24	40.0 (30.9)	49.8 (8.5 - 87.9)	24	36.0 (27.7)	50.6 (7.2 - 100)
Hypertension	38	59.3 (8.7)	58.1 (20 - 87.5)	39	53.8 (11.4)	60 (8.2 - 88.6)
Diabetes	36	11.2 (5.2)	10.4 (0 - 36.4)	36	10.0 (4.0)	9.0 (0 - 29.1)
Hyperlipidemia	15	35.3 (13.0)	46.4 (10.8 - 59.1)	15	29.7 (13.4)	36.7 (12.9 - 60)
Cardiac disease	41	36.9 (18.9)	46.4 (13.3 - 84.2)	40	27.2 (17.8)	45.5 (6.8 - 86.7)
Cerebrovascular Disease	11	4.3 (5.7)	11.8 (0.7 - 18.2)	13	2.7 (4.7)	5.6 (0 - 24)
Chronic Obstructive Pulmonary Disease	34	29.7 (13.2)	29.9 (0 - 79.2)	32	28.7 (7.7)	27.3 (0 - 100)
Peripheral Vascular Disease	9	11.1 (5.3)	17.9 (3.8 - 30.4)	9	11.8 (4.1)	16.9 (2.9 - 25)
Renal Dysfunction	26	7.2 (5.5)	9.5 (0 - 29.6)	26	8.2 (4.8)	7.1 (0 - 50)

3.3.4. AAA Repair: Short-term Outcomes

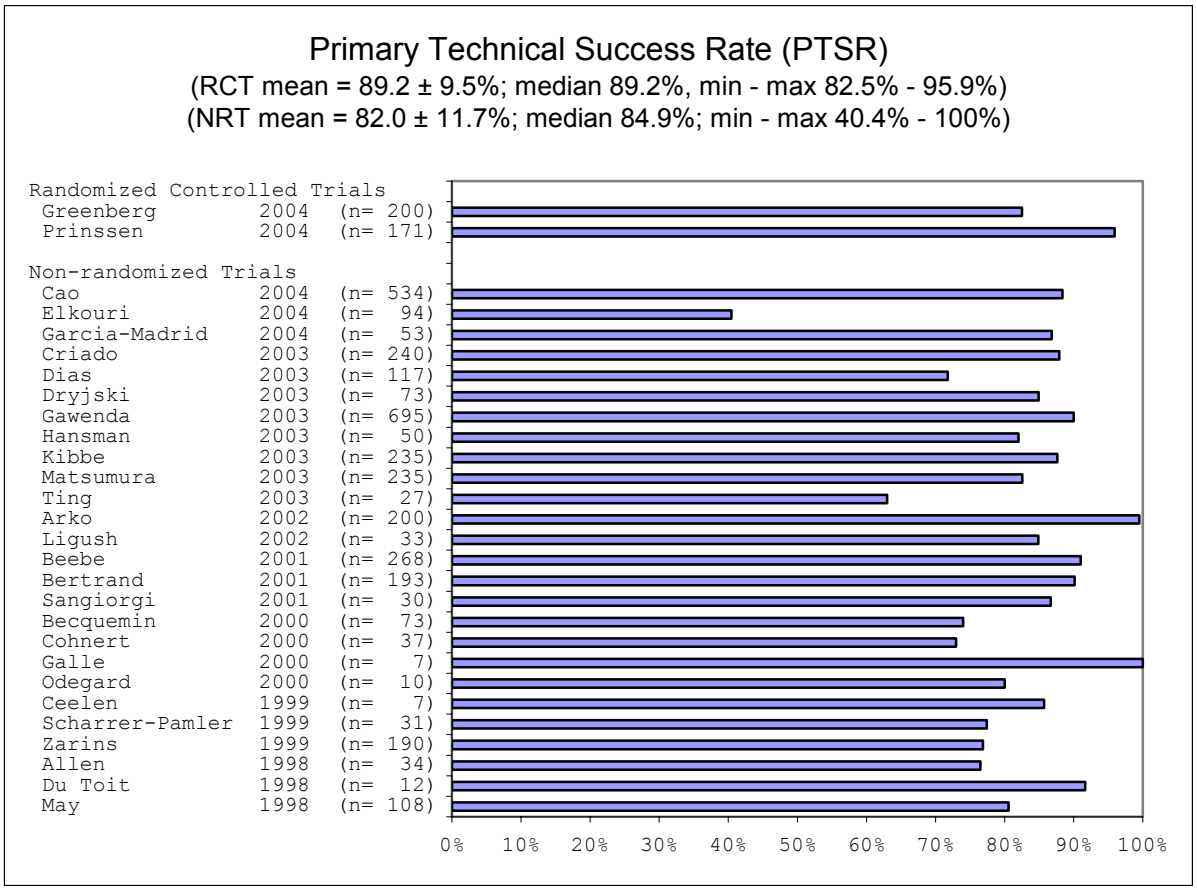
The initial descriptive and comparative analysis is outlined below following the SVS/AAVS reporting guidelines.[37] Due to different definitions of success of EVAR and OSR, the following presents first an assessment of EVAR followed by the assessment of OSR. Common endpoints (e.g., complications) are then contrasted between EVAR and OSR. The short-term outcomes for the composite, clinical and technical outcomes are presented first followed by a meta-analytic estimate of the clinical outcomes to be used in the decision analytic model. Similar evaluation of long-term outcomes (3 months post-operation and more) associated with EVAR and OSR are then provided.

3.3.4.1. EVAR Assessment: Short-term (30 days)

3.3.4.1.1. Primary Technical Success Rate (PTSR)

PTSR was not reported in any of the 59 studies. The reporting of all details required to derive PTSR (e.g., type I endoleak) was also not consistent among studies. For example, some studies reported endoleak totals and not type I or type III endoleaks while few studies reported the presence or absence of graft obstruction. Sufficient information was however available from 29 studies to allow for the derivation of PTSR. The mean PTSR associated with EVAR was from the randomized controlled trials (RCT) was 89.2 ± 9.5% and the median PTSR was 89.2% (min - max: 82.5% -89.2%) (Figure 3). Similarly, the results from the non-randomized trials (NRT) had a mean of 82.0 ± 11.9% with a median PTSR of 84.9% (min - max: 40.4% - 100%). In general, the PTSR increases with the study size, and by year of publication. Simple regression of the effect of study size on PTSR predicts that a PTSR increases 1 percent with every 50 patients increase. Similarly, simple regression of the effect of year of publication on PTSR predicts that PTSR has been increasing 0.51% per year from 1998 to 2004.

Figure 3. Primary technical success rate from 29 studies with available data.



3.3.4.1.2. EVAR Conversion to OSR

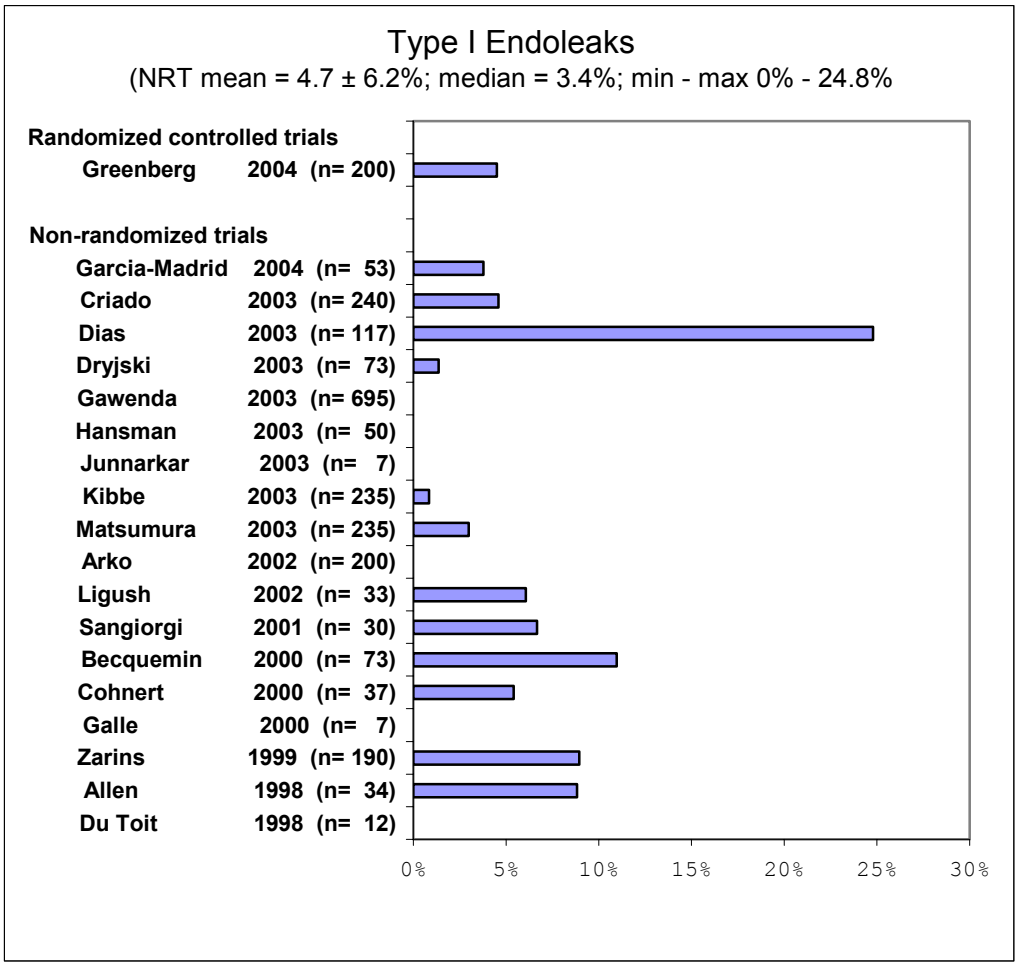
For EVAR patients, the rate of conversion to open surgical repair was on average 1.04% (Table 9). Of the 45 studies that reported the rate of conversion of EVAR patients to OSR, 27 studies reported that no conversions were necessary (i.e. zero conversion rate). The rate of conversion was stable over the studies published between 1998 and 2004, and did not differ with sample size. Aneurysm rupture following repair had zero occurrences in 32 out of 38 studies (84.2%). The aneurysm rupture rate was independent of the year of publication and sample size.

3.3.4.1.3. Endoleaks

Endoleak is a complication unique to EVAR and there are four different types of endoleaks. However, 33 out of 59 (55.9%) unique studies reported total endoleaks (with no further specification), with 5 studies reporting zero occurrences. The mean and median reported values for total endoleaks were 10.8 ± 10.7% and 13.3% respectively, with a range of 0 to 58.5% (Table 9).

Nineteen studies reported type I endoleaks, with 6 studies reporting zero occurrences as outlined in Figure 4. A *Type I endoleak* is indicative of a persistent perigraft channel of blood flow caused by inadequate or ineffective seal at either the proximal or distal graft ends or attachment zones. The mean reported value for type I endoleaks from non-randomized trials was 4.7 ± 6.2% with a median of 3.4% and a range of 0 to 24.8% (Figure 4).

Figure 4. Percentage of EVAR Type I endoleaks



Type II endoleaks were reported in 22 studies, of which 7 studies reporting zero occurrences. A *type II endoleak* is attributed to retrograde flow from lumbar arteries, the inferior mesenteric artery (IMA), or other collateral vessels. The overall mean rate was 9.2 ± 6.4% and the median rate of endoleak type II was 6.6% (range 0 - 26.5) (Table 9).

Table 9. Primary EVAR technical success rate variable components from all trials

Variable	Studies reporting variable (n)	Mean rate (s.d.) %	Median (min - max)
PTSR	29	83.6 (9.9)	84.8 (40.4 - 100)
Conversion to OSR	45	1.04 (1.04)	0 (0 - 6.6)
Rupture	38	0.20 (0.65)	0 (0 - 3.40)
Endoleaks total	33	10.8 (10.7)	13.3 (0 - 58.5)
Type I distal	8	5.6 (6.5)	0 (0 - 19.6)
Type I proximal	8	3.3 (1.7)	0 (0 - 6.6)
Type I unspecified	11	3.1 (2.9)	0 (0 - 10.9)
Type I endoleak total	19	5.5 (6.0)	3.8 (0 - 24.0)
Type II	22	9.2 (6.4)	6.6 (0 - 26.5)
Type III	20	0.6 (1.3)	0 (0 - 5.3)
Type IV	20	1.5 (2.2)	0 (0 - 8.8)

Type III endoleak are caused by fabric tears or disruption, component disconnection, or graft disintegration. Twenty studies reported type III endoleaks, with only three unique studies reporting a type III endoleak (5.3%, 3.0% and 0.7%). The other seventeen other studies reported zero occurrences for type III endoleaks. The overall mean rate of type III endoleak was 0.6 ± 1.3% with a median of 0 % and a range of 0 - 5.3% (Table 9).

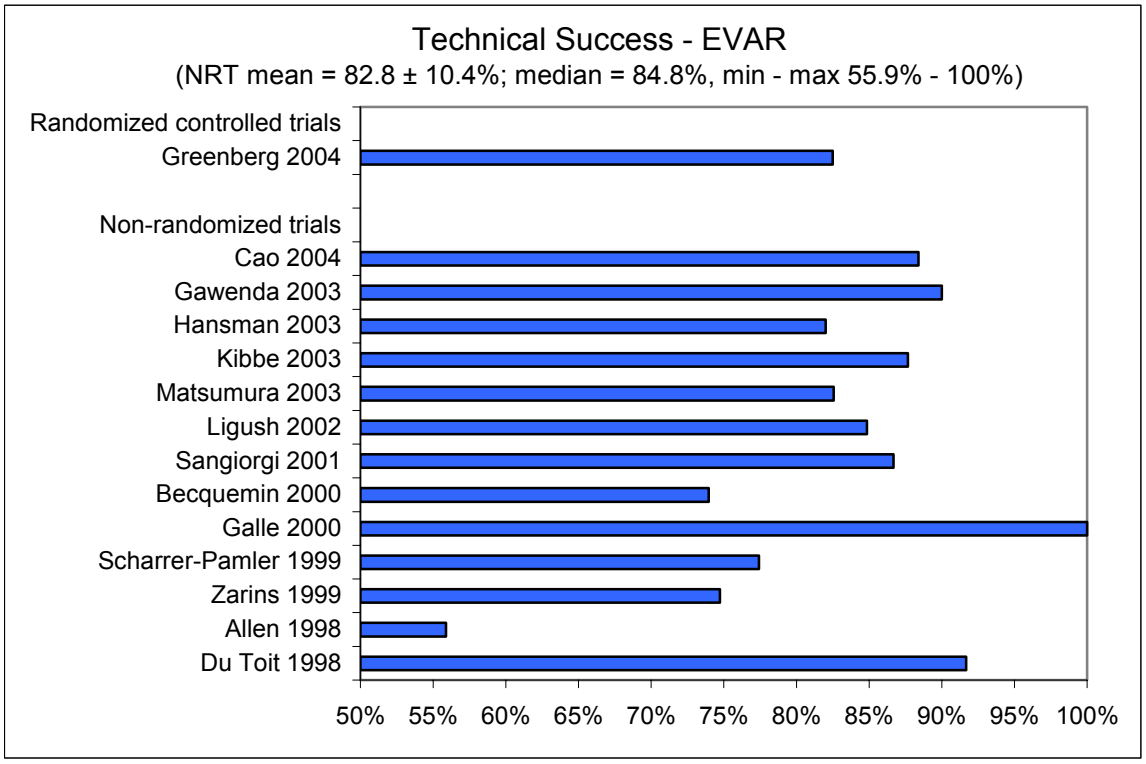
Blood flow through an intact but otherwise porous fabric, observed during the first 30 days after graft implantation, is termed a *type IV endoleak*. This designation is not applicable to fabric-related endoleaks observed after the first 30-day period. The mean reported value for type IV endoleaks was 1.5 ± 2.2% with a median reported value of 0 and a range of 0 – 8.8%. The occurrence of type IV endoleaks was reported as zero occurrences in 80.0% of the studies (16/20) reporting this outcome (Table 9).

Rarely reported is unknown origin endoleaks. If an endoleak is visualized on imaging studies but the precise source cannot be determined, the endoleak is categorized as an *endoleak of undefined origin*. No studies reported unknown origin endoleaks.

3.3.4.1.4. Technical Success - EVAR

While the technical success rate was not provided in the clinical studies used in the analysis, it was possible to derive this outcome in 14 studies (Figure 5). Technical success which also includes graft kinks and folds has a mean rate from the non-randomized trials was 82.8% and a median reported rate of 84.8% (min - max of 55.9% to 100%). Graft kinks and folds had a median of 0% with a minimum and maximum value of 0% to 20.9% as 12 out of 14 studies reported zero occurrences.

Figure 5. Operative technical success rates for EVAR



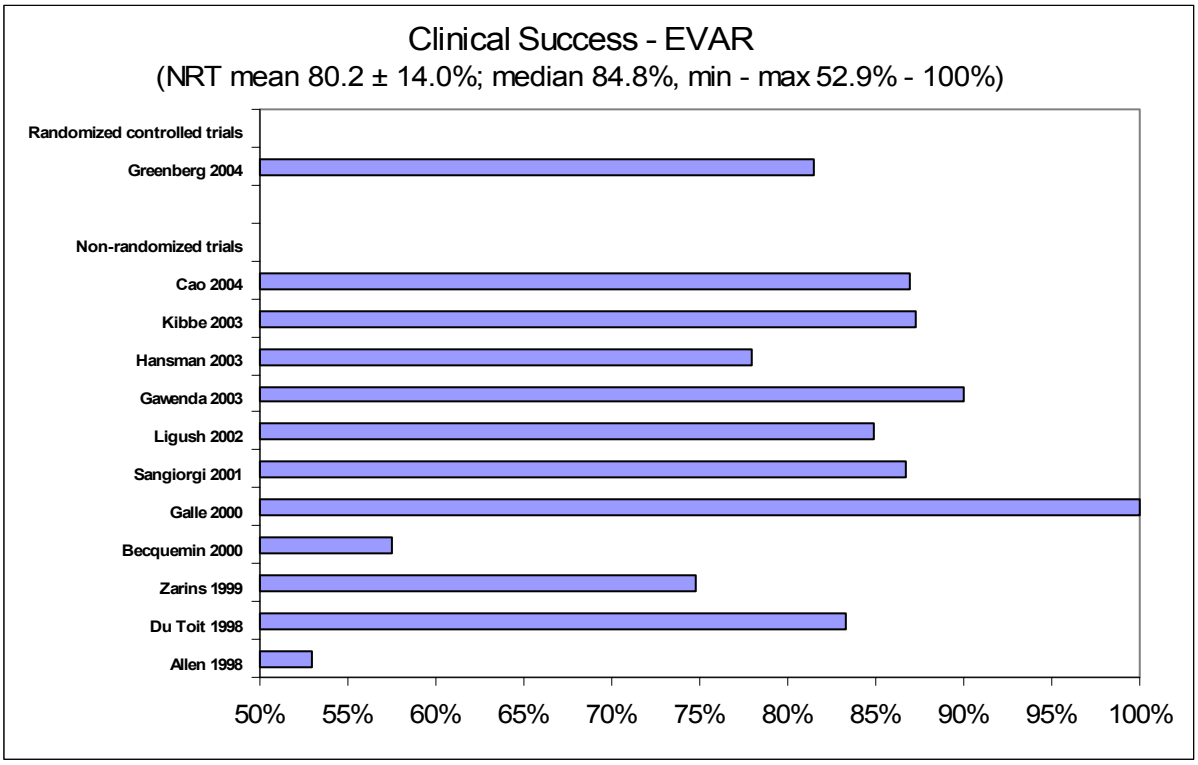
3.3.4.1.5. Clinical Success - EVAR

Clinical success for EVAR includes technical success without graft infection, graft obstruction, rupture, and conversion to OSR. Twelve studies provided enough data to derive clinical success (Figure 6). The mean clinical success rate for

EVAR treated patients in the 11 studies non-randomized studies was 80.2 ± 14.0% with a median clinical success rate of 84.8% and a range from 52.9 - 100%.

The clinical success increases with the year of publication and the number of patients in the study. Simple linear regression predicts that clinical success has rose 2.65% per year from 1998 to 2004 (i.e. publication year). Simple linear regression predicts a 1 % rise in clinical success with every 50 patients.

Figure 6. Clinical success for EVAR



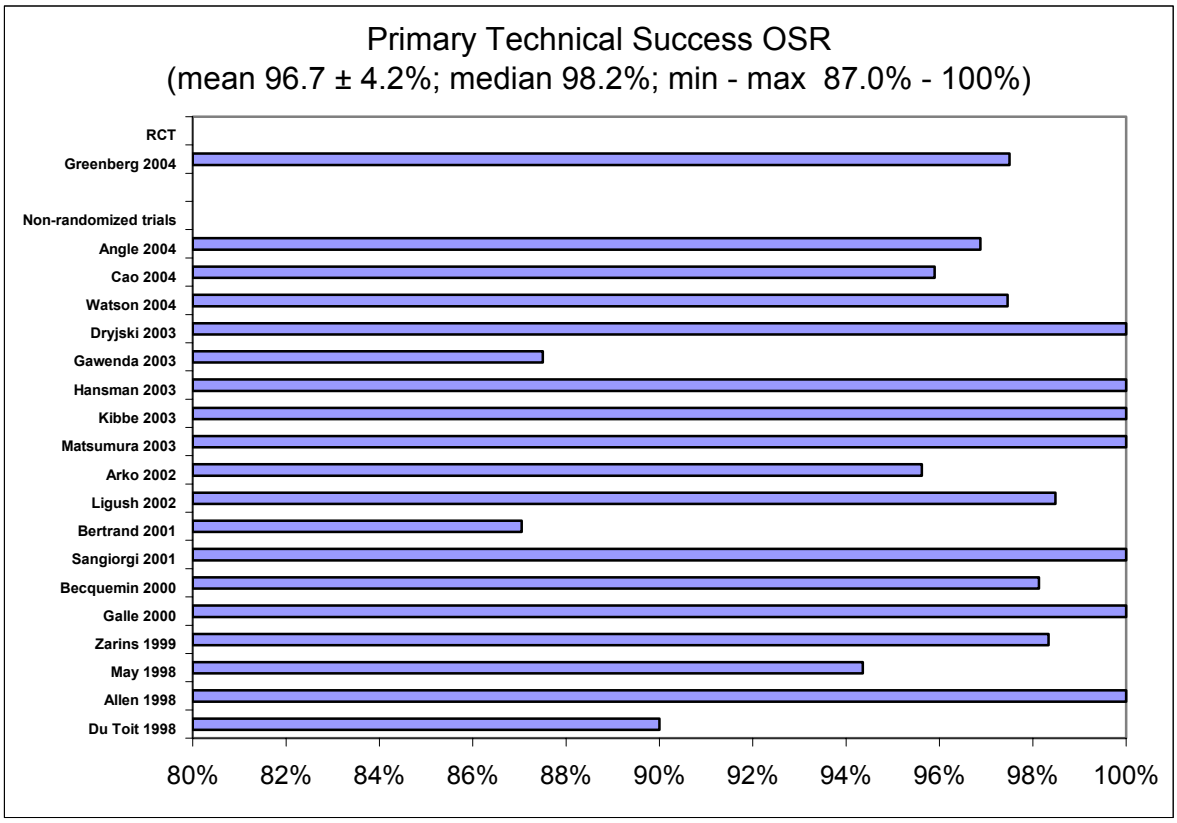
3.3.4.2. OSR Assessment: Short-term (30 days)

3.3.4.2.1. Primary Technical Success

Primary technical success rates for OSR, as shown in Figure 7, were reported in 19 out of 59 studies (15.2%), The mean of technical success rate from the non-randomized studies of OSR was 96.7 ± 4.2% with a median rate of 98.2% (min - max 87.0% - 100%). Based on a simple linear regression analysis, the primary

technical success rate for OSR was independent of trial sample size but has increased 0.25% per year from 1998 to 2004.

Figure 7. Primary technical success rates for OSR procedures

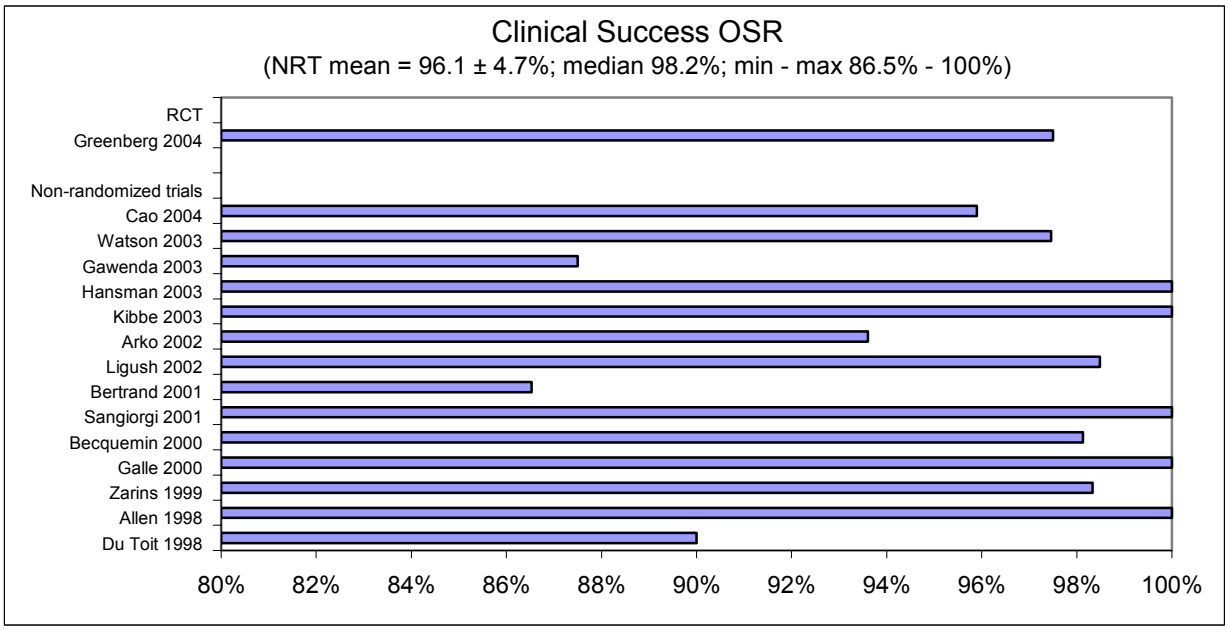


3.3.4.2.2. Primary Clinical Success

Since none of the 59 studies selected for inclusion in the systematic literature review reported directly the primary clinical success rate for OSR, therefore this composite endpoint was derived from those studies that provided sufficient information. Accordingly, 15 studies provided sufficient details to determine this composite outcome (Figure 8). The mean clinical success from the non-randomized trials of OSR was 96.1 ± 4.7% and the median rate was 98.2% with a minimum and maximum rate of 86.5% -100%, respectively. Again, clinical success for OSR was independent of sample size and has only increased 0.02 %

per year for publication years from 1998 to 2004, based on simple linear regression.

Figure 8. Clinical success rates for OSR procedures



The technical and clinical success rates for EVAR and OSR are summarized in Table 10 which summarizes the primary technical and clinical success of EVAR and OSR. As the components and definitions of these composite endpoints differ, comparison of these outcomes needs to be made with an understanding of the variables that are used to derive each outcome as previously outlined.

Table 10. Summary of primary technical and clinical success rates for EVAR and OSR

	Studies (n)	Mean (s.d.) %*	Median (min - max) %
Randomized controlled trials			
EVAR Primary Technical Success	2	89.2 (9.5)	89.2 (82.5 – 95.9)
Non-randomized trials			
EVAR Primary Technical Success	28	83.6 (10.4)	93.3 (40.4 - 100)
EVAR Clinical Success	11	80.2 (14.0)	84.8 (52.9 - 100)
OSR Technical Success	18	96.7 (4.2)	98.1 (87 - 100)
OSR Clinical Success	14	96.1 (4.7)	98.2 (86.5 - 100)

3.3.4.3. Endpoints Common to EVAR and OSR

3.3.4.3.1. Adjuvant Procedures

Primary technical success of EVAR and OSR can also include the use of additional modular components, stents, or angioplasty, and adjunctive surgical procedures. For OSR the reported adjuvant procedures are for the treatment of diseased vessels adjacent to the aorta, and do not relate directly to the OSR procedures. When unplanned endovascular or surgical procedures are necessitated, the terms *assisted primary* or *secondary technical success*, respectively, are used in the literature.

Few studies reported the rate of primary technical success or secondary technical success. Because a single patient may require more than one procedure, the use of adjuvant procedures has to be analyzed and compared between EVAR and OSR. The use of adjuvant procedures (e.g., extension, stent) during the perioperative period seems to be higher following EVAR than OSR (Table 11). The mean percentage use of extensions, used to treat endoleaks, was 6.9 ± 11.7% for and the median use was 2.6% in EVAR, with 11/28 studies reporting zero occurrences, and the difference was significant from OSR ($p<0.01$).

PTCA or PTCA with a stent are often used to treat Type III endoleaks. The mean use of stents was 6.3 ± 14.3% with a median reported stent use of zero, with 16 out of 25 studies reported zero occurrences. The difference in stent use was significantly higher in EVAR ($p=0.04$).

The mean percentage use of PTCA was 0.9 ± 3.3% and the median of PTCA was zero for EVAR, with 20 out of 25 reporting zero occurrences and there was no significant difference in PTCA use between EVAR and OSR. The practice patterns of treating endoleaks might also allow for the use of a coil embolization for type I or type III endoleaks. Similarly, the mean use of coil embolization was 3.2 ± 5.9% and the median reported value for coil embolization was zero, with 15 out of 28 studies reporting zero occurrences. The difference was siginifantly higher in EVAR ($p=0.01$).

Finally, artery bypass is a significant procedure performed in the perioperative period most often when the renal artery is obstructed. The mean use was 0.8 ± 1.8 and the median reported value for Artery bypass was 0 for both EVAR and OSR, with 18 out of 27 studies reporting zero occurrences for EVAR. There was no significant difference in artery bypass for EVAR and OSR.

Table 11. Adjuvant procedures of EVAR and OSR

	EVAR studies (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Mean (s.d.) %	Median (min - max)	P-value
Extension	28	6.9 (11.7)	2.6 (0 - 45.5)	28	0 (0)	0 (0 - 0)	< 0.01
Stent	25	6.3 (14.3)	0 (0 - 68.1)	23	0 (0)	0 (0 - 0)	0.04
PTCA	25	0.9 (3.3)	0 (0 - 16)	23	0 (0)	0 (0 - 0)	0.19
Coil embolization	28	3.2 (5.9)	0 (0 - 55.6)	22	0 (0)	0 (0 - 0)	0.01
Artery bypass	28	0.8 (1.8)	0 (0 - 14.3)	27	1.3 (2.9)	0 (0 - 9.5)	0.45

* means and medians, population weighted estimates
† student t test for comparison of means, unadjusted for differences in baseline characteristics for interim report

3.3.4.3.2. Secondary Technical Endpoints

Secondary technical endpoints common to EVAR and OSR include procedure time, blood loss, length of stay in intensive care, total length of stay in hospital, and recovery time. Recovery time is the duration from the time of procedure until the patient has returned to full activity with discomfort or concern. Forty-one studies provided reported at least one or more of the above endpoints (Appendix VII). Other secondary endpoints recommended to be reported by the SVS, but not available in the data literature, are fluoroscopy time and contrast load. It is important to note that these secondary endpoints do not enter into the consideration of technical success rates for EVAR.

EVAR is statistically associated with less time spent in OR, less blood loss, less length of stay in the ICU, less length of stay in the hospital ($p< 0.01$ for all) and shorter recovery ($p=0.04$) as shown in Table 12. While the majority of OSR and EVAR patients do not require an ICU stay, the length of stay in the ICU has been

decreasing by 7% per year for EVAR while the length of stay in the ICU for OSR has been increasing by 12% per year. The length of stay in the ICU is generally independent of sample size as determined by linear regression.

Table 12. Operative and hospitalization endpoints: EVAR vs. OSR

	EVAR studies (n)	Mean (s.d.)	Median (min - max)	OSR studies (n)	Mean (s.d.)	Median (min - max)	p-value
Operating Time (hours)	34	2.65 (0.51)	2.73 (1.5 - 4.18)	33	3.34 (0.62)	3.33 (2.10 - 5.20)	< 0.01
Blood loss (mL)	28	360 (154)	367 (21 - 810)	27	1609 (538)	1654 (700 - 3476)	< 0.01
Length of stay ICU (days)	26	1.08 (1.67)	0.50 (0 - 6)	25	2.68 (1.32)	2.80 (0.71 - 6.60)	< 0.01
Length of stay Hospital (days)	39	4.01 (1.98)	3.40 (1.43 - 11)	40	9.32 (2.21)	9.8 (4.4 - 22)	< 0.01
Recovery (days)	6	29 (17)	18.9 (290 - 4200)	5	77 (35.2)	92 (8.1 - 99.3)	0.04

* means and medians, population weighted estimates

† student t test for comparison of means, unadjusted for differences in baseline characteristics for interim report

3.3.4.3.3. Systemic Complications

The occurrence of systemic complications in the perioperative period following either EVAR or OSR was abstracted from the studies included in this systematic literature review according to the SVS guidelines.[37] They include cardiac (MI, CHF, arrhythmia, angina, and unspecified), pulmonary complications (permanent failure, edema, pneumonia, pneumothorax, embolism, and unspecified), stroke and ischemia (stroke, transient ischemic attacks (TIA), bowel/colon ischemia, limb ischemia, other ischemia), and cerebrovascular/spinal ischemia.

In all, twenty (20) major medical complications following repair were recorded for both groups in published studies and are outlined in Table 13. The number of studies reporting the systemic complications is also provided in Table 13 as the reporting of these clinical outcomes was not consistent across all studies.

It is important to mention that the literature provided outcomes that could not be properly classified. For example, the use of the term “cardiac problems” was often not well defined or had been recorded as unspecified. The papers that did

classify these as major problems according to SVS guidelines still did not provide enough evidence to isolate the exact nature of the condition. For example, a description of “cardiac major” could be myocardial infraction or congestive heart failure.

The comparison of the difference in the rate of occurrence of systemic complications between EVAR and OSR was based on simple relative risk calculations. Briefly, cardiac complications (myocardial infarction, congestive heart failure, arrhythmia, and angina) are all lower in EVAR, and these differences are statistically significant in when a meta-analysis is conducted (see Meta-analysis section). Relative risks were calculated by comparing overall averages of cardiac problems and results indicate that the occurrence of MI and CHF are not significantly different between EVAR and OSR, while more angina and arrhythmia occur in EVAR ($p=0.01$ for both). Permanent pulmonary failure (COPD onset) is higher in OSR ($p=0.02$), pneumonia and pulmonary embolisms were lower with EVAR but the differences are not statistically significant. Pulmonary edema was similar for both groups, and pneumothorax was absent in both groups (Table 13).

The onset of permanent and temporal renal failure was higher in the OSR group, but the difference was not significant.

The incidence of stroke is equal for both groups. TIA’s, bowel/colon ischemia, and CV or spinal ischemia are less frequent with EVAR, but these differences are not significant. The rate of limb ischemia is higher with EVAR with fewer studies reporting zero occurrences in OSR versus EVAR (12/17 vs 9/17) but this difference is not statistically significant.

Table 13. Perioperative complications: EVAR vs. OSR

	EVAR studies (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Mean (s.d.) %	Median (min - max)	RR	P-value
Cardiac								
Myocardial infarction	21	1.6 (1.5)	0 (0 - 5.2)	20	2.7 (2.4)	0.5 (0 - 7.3)	0.59	0.10
Congestive heart failure	19	0.6 (1.2)	0 (0 - 3.5)	18	1 (1.8)	0 (0 - 16.7)	0.60	0.44
Arrhythmia	18	1.4 (1.6)	0 (0 - 6.4)	17	4.6 (4.3)	2.7 (0 - 20)	0.30	0.01
Angina	10	0 (0)	0 (0 - 0)	9	2 (1.9)	0 (0 - 3.8)	0.00	0.01
Cardiac Unspecified	30	6.6 (5.4)	2.9 (0 - 20)	30	3.2 (3.9)	3.9 (0 - 25.7)	2.06	0.01
Pulmonary								
Pulmonary failure	18	0.7 (0.9)	0 (0 - 4)	17	3.1 (3.8)	0 (0 - 12.9)	0.23	0.02
Pulmonary edema	14	0.1 (0.2)	0 (0 - 0.7)	13	0.1 (0.4)	0 (0 - 2.7)	1.00	1.00
Pneumonia	15	0.9 (1.5)	0 (0 - 14.3)	13	4.5 (6.6)	0 (0 - 40)	0.20	0.08
Pneumothorax	14	0 (0)	0 (0 - 0)	13	0 (0)	0 (0 - 0)	n.a.	1.00
Pulmonary embolism	14	0.1 (0.3)	0 (0 - 1.1)	13	1.3 (2.7)	0 (0 - 7.7)	0.08	0.14
Pulmonary - unspecified	24	1.3 (2.3)	0.6 (0 - 12.9)	24	1.3 (2.7)	0 (0 - 7.7)	0.20	1.00
Renal								
Renal (permanent failure)	19	0.2 (0.3)	0 (0 - 1.8)	19	0.4 (0.5)	0 (0 - 1.6)	0.50	0.15
Renal (temporary failure)	21	1 (1.2)	0.6 (0 - 6.3)	21	1.5 (3)	0 (0 - 17.1)	0.67	0.49
Renal (unspecified)	19	1.2 (2.7)	0 (0 - 19.4)	22	2.8 (5.7)	0 (0 - 45.5)	0.43	0.26
Stroke and Ischemia								
Stroke	26	0.2 (0.4)	0 (0 - 3)	26	0.2 (0.6)	0 (0 - 3)	1.00	1.00
Transient Ischemia Attacks	13	1.2 (5.2)	0 (0 - 26.3)	12	0.8 (6.3)	0 (0 - 52.6)	1.50	0.87
Bowel/colon ischemia	17	0.3 (0.7)	0 (0 - 8.3)	16	1.2 (3.6)	0 (0 - 45.5)	0.25	0.34
Limb ischemia	15	1.6 (2.5)	0 (0 - 8.8)	14	1.1 (1.2)	0 (0 - 2.4)	1.45	0.50
Other ischemia	15	0.1 (0.6)	0 (0 - 2.9)	15	0.1 (0.8)	0 (0 - 5.7)	1.00	1.00
CV impairment or spinal cord ischemia	15	0.1 (0.2)	0 (0 - 0.6)	16	0.3 (2.1)	0 (0 - 27.3)	0.33	0.72

* n.a. not available – denominator is zero
† means and medians, population weighted estimate
‡ RR: simple ratio of population weighted means
§ student t test for comparison of means, unadjusted for differences in baseline characteristics for interim report

3.3.4.3.4. Graft Complications

Table 14 lists graft problems other than endoleaks that were reported in the literature. Graft infection occurs less often in OSR than EVAR. Graft obstruction, kinks or folds, migration, and thrombosis appear only with EVAR. Median reported values are zero for all of the other graft problems. Only graft thrombosis is different, with the rate being higher in EVAR.

Table 14. Other graft complications: EVAR vs. OSR

Graft complication	EVAR studies (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Mean (s.d.) %	Median (min - max)	P-value
Obstruction	15	0.9 (3.6)	0 (0 - 16.4)	13	0 (0)	0 (0 - 0)	0.35
Infection	19	0.3 (0.4)	0 (0 - 2)	18	0.1 (0.4)	0 (0 - 1.7)	0.14
Kinks or folds	15	0.6 (2.9)	0 (0 - 20.6)	14	0 (0)	0 (0 - 0)	0.44
Migration	17	0.3 (0.8)	0 (0 - 8.3)	15	0 (0)	0 (0 - 0)	0.14
Thrombosis	19	0.5 (0.9)	0 (0 - 2.6)	18	0 (0)	0 (0 - 0)	0.03

* means and medians, population weighted estimates
† student t test for comparison of means, unadjusted for differences in baseline characteristics for interim report

3.3.4.3.5. Local and Vascular Complications

Local and vascular complications are listed in Table 15 are in a decreasing order of relative risk of EVAR versus OSR. Thromboembolisms, minor wounds, moderate hemorrhage are treated non-endovascularly and are not a major threat. Arterial of graft obstruction can require a thrombolytic agent or an endovascular treatment. Major wounds such as a hernia require subsequent surgery or major therapy.

Major bleeding problems are higher in OSR (major hemorrhage p=0.02, major thromboembolism p=0.03). Major bleeding problems require vascular surgery, and may be associated with an increased length of stay in hospital, potentially in the ICU, are generally associated with the increased use of blood products. One study reported major groin problems occurring with EVAR and not OSR.[61]. Only one study reported aortoenteric fistulas occurring in the EVAR group and not in the OSR group.[63]

Table 15. Local and vascular complications: EVAR vs. OSR

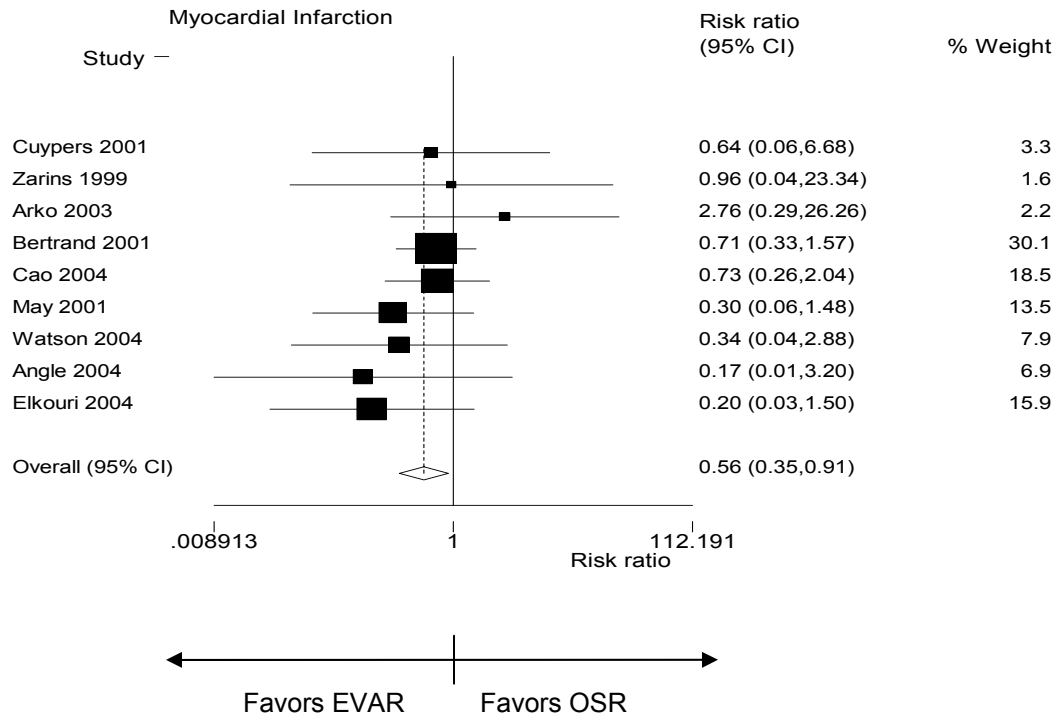
	EVAR studies (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Mean (s.d.) %	Median (min - max)	RR	P-value
Thromboembolism – moderate	15	0.6 (0.9)	0 (0 - 8.3)	15	0.1 (0.3)	0 (0 - 1.1)	6.00	0.06
Groin hemotoma /seroma/lymphoc – minor	18	2.2 (3.8)	1.2 (0 - 20)	18	1.2 (2)	1 (0 - 8.5)	1.83	0.34
Arterial or graft obstruction	13	0.6 (1)	0 (0 - 4.5)	13	0.4 (1.4)	0 (0 - 9.1)	1.50	0.68
Groin/wound infection	21	3.6 (5)	3.6 (0 - 26.5)	19	4.5 (8.7)	1.7 (0 - 37.5)	0.80	0.70
Hemorrhage – moderate	14	0.5 (1.4)	0 (0 - 12.5)	14	0.7 (3)	0 (0 - 20)	0.71	0.61
Wound – major problem (hernia,etc)	16	0.8 (1.4)	0 (0 - 8.3)	16	1.2 (1.6)	0 (0 - 9.1)	0.67	0.46
Thromboembolism – major (need tx)	17	0.6 (1.3)	0 (0 - 6.1)	17	1.6 (1.2)	0 (0 - 3)	0.38	0.03
Hemorrhage – major	25	2.5 (2.9)	0.5 (0 - 11.7)	25	9.1 (13.1)	1.4 (0 - 57.9)	0.27	0.02
Groin – major problem	9	0.5 (0.6)	0 (0 - 1.3)	9	0 (0)	0 (0 - 0)	n.a	0.04
Obstruction of main renal artery	12	0.3 (0.6)	0 (0 - 1.8)	11	0 (0)	0 (0 - 0)	n.a	0.11
Aortenteric fistula	9	0.2 (0.2)	0 (0 - 0.5)	9	0 (0)	0 (0 - 0)	n.a	0.02
Iatrogenic perforation – severe	37	0.1 (0.3)	0 (0 - 1.6)	36	0 (0.1)	0 (0 - 0.6)	n.a	0.06
Pseudoaneurysm – abdominal	10	0.1 (1.1)	0 (0 - 8.3)	10	0 (0)	0 (0 - 0)	n.a	0.78
Pseudoaneurysm – groin	10	0 (0)	0 (0 - 0)	10	0 (0)	0 (0 - 0)	n.a	1.00

* n.a. not available – denominator is zero
† means and medians, weighted by sample sizes
‡ RR: simple ratio of population weighted means
§ student t test for comparison of means, unadjusted for differences in baseline characteristics for interim report

3.3.4.4. Meta-analysis of Short-term Outcomes (30 days)

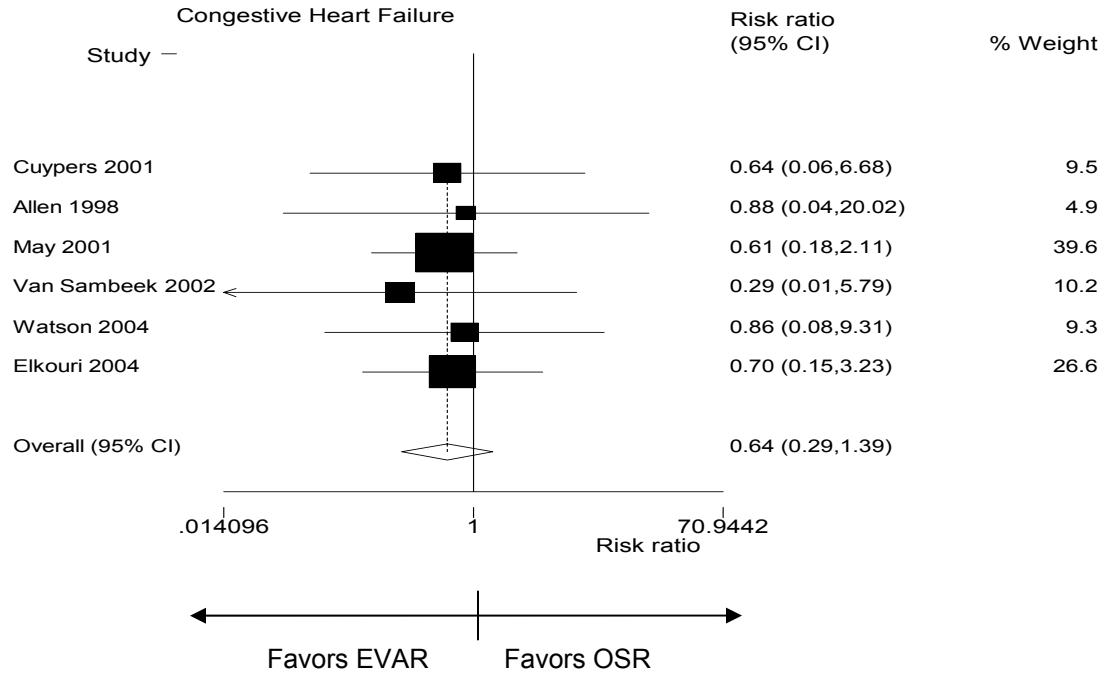
Meta-analysis was performed for input into the economic model the following short-term outcomes: mortality, conversion, rupture, MI, CHF, stroke, renal failure. Relative risks of EVAR versus OSR were calculated and tested for homogeneity using the Q-test. When heterogeneity was present random effects were used. If homogeneity was absent, fixed effects estimates were presented. Forest plots of endpoints used for the economic model are presented below. Relative risk ratio less than 1 favors EVAR (Figures 9 - 12).

Figure 9. Meta-analysis of myocardial infarction rate: EVAR vs. OSR



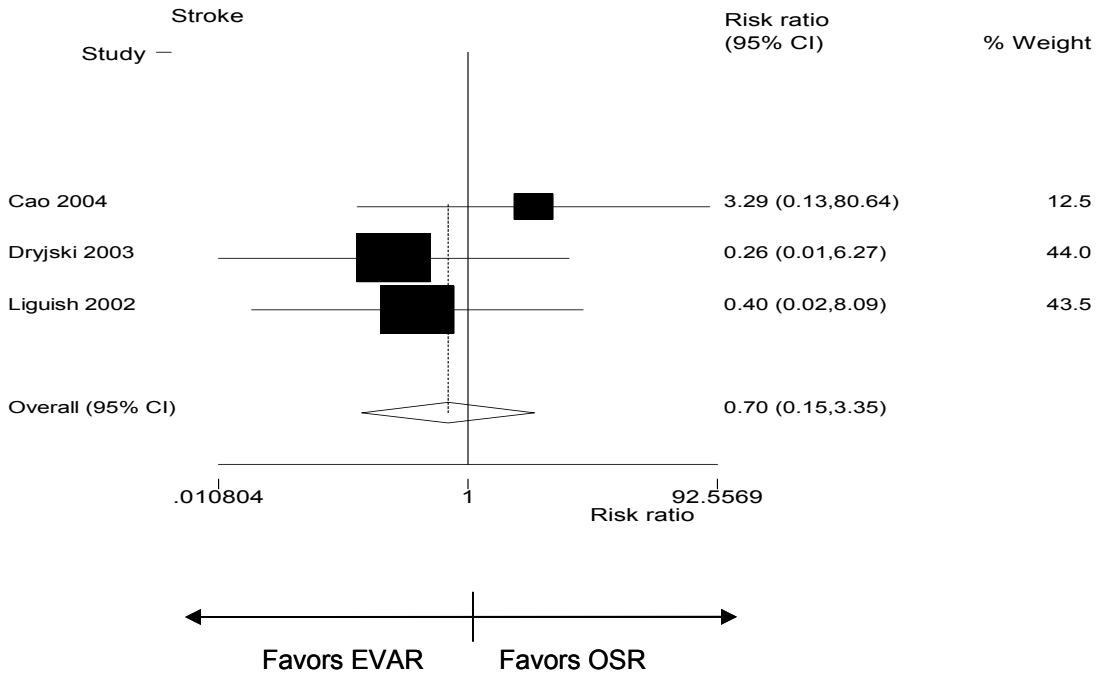
* studies with zero event rates excluded

Figure 10. Meta-analysis of congestive heart failure rate: EVAR vs. OSR



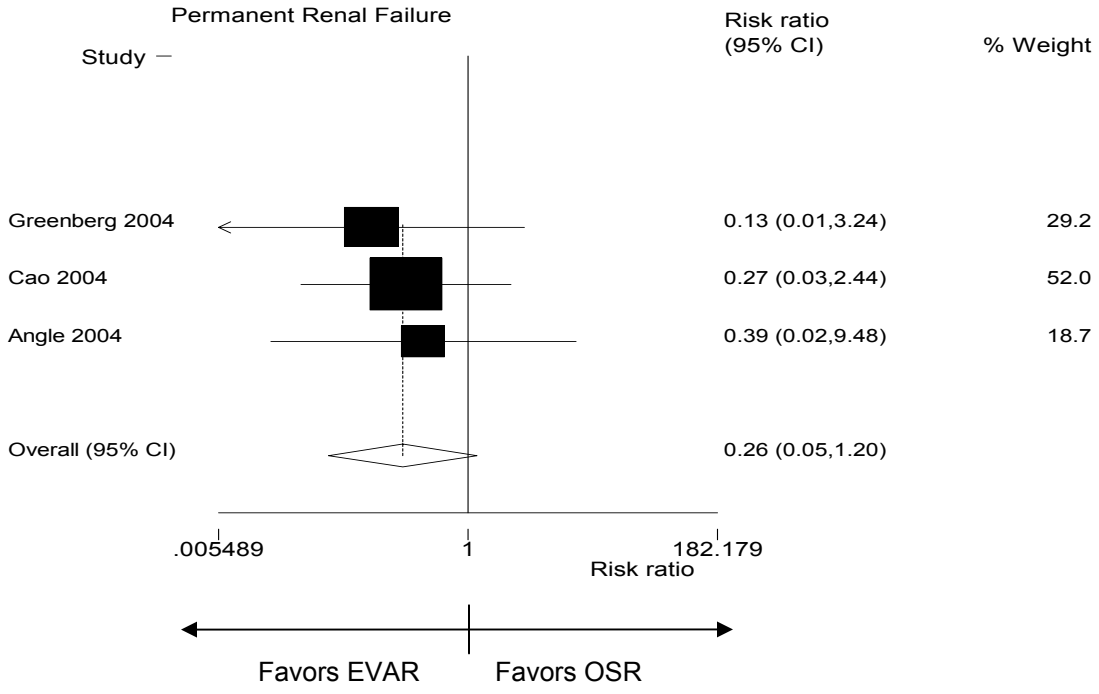
* studies with zero event rates excluded

Figure 11. Meta-analysis of stroke rate: EVAR vs. OSR



* studies with zero event rates excluded

Figure 12. Meta-analysis of permanent renal failure rate: EVAR vs. OSR



* studies with zero event rates excluded

Meta-analysis results indicate that mortality was significantly lower with EVAR than with OSR (p<0.01). The rate of MI was lower in EVAR (p=0.02). Renal failure, CHF, and stroke were lower in the EVAR group but these differences were not significant (Table 16).

Table 16. 30 day Major Complications

	EVAR Mean (s.d.) %		OSR Mean (s.d.) %		RR (95% CI)	p-value
Mortality	2.6 (0.003)	RE	4.3 (0.5)	RE	0.80 (0.70 - 0.91)	< 0.01
Conversion	1.20 (0.2)	FE	n.a		n.a	
Rupture	0.5 (0.2)	FE	0		0	
Myocardial Infarction	1.3 (0.3)	FE	2.2 (0.5)	RE	0.56 (0.35 - 0.91)	0.02
Congestive Heart Failure	2.2 (0.7)	FE	2.6 (0.7)	FE	0.64 (0.30 - 1.39)	0.26
Stroke	0.4 (0.2)	FE	0.7 (0.4)	FE	0.70 (0.15 - 3.35)	0.65
Renal Failure	0.4 (0.2)	FE	0.7 (0.3)	FE	0.26 (0.05 - 1.20)	0.08

* n.a. not applicable
† EVAR & OSR means estimated separately, weighted by inverse variance method
‡ RE/FE estimated EVAR and OSR separately
§ RE estimates used if Q-test for homogeneity is rejected.RR and p-value: pooled study's RR and tested for difference from one. No adjustment for heterogeneity. Unadjusted for differences in baseline characteristics for interim report

3.3.4.5. Mortality Relative Risk Analysis (30 days)

The following meta-analysis is based on outcomes reported in 72.8% (43/59) of the studies. The median mortality rate was 0.50 with a range of mortality rate of 0.06 to 6.09. The calculated meta-analytical relative risk of mortality for EVAR versus OSR is 0.80 (0.70 - 0.91, 95% CI, p-value <0.01).

It is important to note that mortality rates differ according to the type of studies. For example in terms of mortality, four randomized controlled trials (RCT) listed at the top of Table 17, produce relative risks inferior to one implying the risk of mortality with EVAR is less then that of OSR.[7-10] In comparison, results from multi-centre reports (Beebe to Zarins) indicated a mortality rate above 1.00 while two large registries (Anderson 2004 and Lee 2004) reported conflicting results.[6,61,63-67]

Table 17. Mortality Relative Risk

Study	RR	[95% CI]		% Weight
Randomized controlled trials				
Greenberg 2004	0.08	0.00	1.65	0.76
Greenhalgh 2004	0.39	0.18	0.83	4.93
Prinssen 2004	0.29	0.06	1.38	1.48
Cuypers 2001	0.32	0.02	4.88	0.32
Multicentre trials				
Beebe 2003	0.36	0.07	1.77	0.94
Criado 2003	1.59	0.07	38.69	0.14
Kibbe 2003	1.28	0.05	31.07	0.15
Matsumara 2003	1.28	0.05	31.07	0.15
Zarins 1999	3.53	0.20	62.95	0.16
Registries				
Anderson 2004	1.88	1.26	2.81	7.43
Lee 2004	0.33	0.22	0.47	26.89
Non-randomized trials				
Allen 1998	0.88	0.04	20.02	0.17
Arko 2003	0.18	0.02	1.56	1.11
Becquemin 2000	1.47	0.09	23.16	0.17
Berman 2002	0.37	0.02	8.01	0.31
Bertrand 2001	0.46	0.23	0.91	5.13
Cao 2004	0.24	0.09	0.62	4.69
Clair 2000	0.65	0.03	15.70	0.22
Cohnert 2000	5.14	0.26	103.39	0.11
Dias 2003	0.37	0.09	1.51	1.32
Dias 2003	0.09	0.02	0.37	1.18
Du Toit 1998	0.26	0.01	5.65	0.36
Malina 2000	1.00	0.07	14.90	0.21
May 2001	0.52	0.16	1.74	1.56
Rowlands 2001	0.33	0.01	7.62	0.32
Ting 2003	2.78	0.12	65.08	0.11
Treharne 1999	0.40	0.12	1.32	2.17
Turnipseed 2003	1.38	0.20	9.54	0.36
Watson 2004	0.86	0.08	9.31	0.31
Wijnen 2001	1.50	0.10	22.05	0.17
Zeebregts 2004	0.06	0.00	1.01	1.70
de Virgilio 1999	0.50	0.09	2.93	0.73
Akkersdijk 2004	1.42	1.16	1.74	26.49
Angle 2004	1.19	0.08	18.50	0.20
Carpenter 2002	1.09	0.38	3.18	1.32
Dryjski 2003	3.97	0.19	81.14	0.12
Elkouri 2004	0.55	0.03	11.34	0.29
Garcia-Madrid 20	0.56	0.08	3.75	0.55
Gawenda 2003	0.89	0.09	8.50	0.31
Jordan 2003	0.82	0.32	2.10	1.77
Liguish 2002	6.09	0.66	56.29	0.14
Patel 2003	0.16	0.01	2.65	0.91
Teufelshauer 2002	0.44	0.14	1.36	2.13
Mantel-Haenszel pooled RR	0.80	0.70	0.91	
Median 0.50; Range (0.06-6.09)				
* RR < 1 favors EVAR, > 1 favors OSR % weight is study's contributing effect to the overall estimate				

3.3.5. AAA Repair: Long-term Outcomes

The following long-term outcome analysis is based on data available from 22 studies of the 59 studies identified as outlined in Appendix V. Twelve studies of duration of up to 1 year, 7 studies reported results for 13-24 months, 3 studies provided data for 25-36 months are included in this assessment.

3.3.5.1. Long-term Rupture Risk

The risk of subsequent aneurysm rupture was higher in the EVAR and no rupture events were reported in the OSR patients in the studies evaluated (Table 18).

Table 18. Long-term rupture risk at 1 year: EVAR vs. OSR

	EVAR studies (n)	EVAR Sample (n)	Mean (s.d.) %	Median (min - max) %	OSR Sample (n)	Mean (s.d.) %	Median (min - max) %	P-value
Rupture	8	2133	0.09 (0.13)	0 (0 - 0.5)	601	0.0 (0.0)	0	0.09

* Means & medians: weighted by sample sizes
† RR: simple ratio of population weighted means
‡ p-value: from student t test for comparison of means. unadjusted for differences in baseline characteristics for interim report

3.3.5.2. Endoleaks: First Year

Endoleaks in the first year were reported in 6 of the 12 studies, representing a total number of observations of 2224 patients for total endoleaks (Table 19). The event rate for endoleaks has fallen from the perioperative period for all types of endoleaks. Zero type 1 proximal endoleaks appeared in one year. Type 1 distal endoleaks are less common with a median of zero, with 3 out of 4 studies reporting zero occurrences. Type 1 unspecified endoleaks have a lower than perioperative rate, with median zero, with 4 out of 6 studies reporting zero occurrences. Type 2 endoleaks are still present, median 5.9%, with 2 out of 5 reporting zero occurrences. It is not clear in the studies whether these are persistent Type 2 endoleaks (being acknowledged in the perioperative period with continuing monitored) or new Type 2 endoleaks. Type 3 endoleaks are reported in 6 studies, median 0, with 4 out of 6 studies reporting zero occurrences.

Table 19. Classification and rate of endoleaks: First Year

Variable	EVAR studies (n)	Obs	Mean (s.d.)%	Median (min - max) %
Endoleaks (total)	6	2224	17.7 ± 5.0	9.90 (0 - 19.9)
Type I distal	4	344	1.75 ± 1.5	0 (0 - 3.0)
Type I proximal	4	344	0	0
Type I unspecified	6	469	1.73 ± 2.6	0 (0 - 7.0)
Type II	5	438	5.28 ± 3.0	5.9 (0 - 8.0)
Type III	6	2084	.48 ± .51	0 (0 - 2.0)
Type IV	5	438	0	0

3.3.5.3. Adjuvant Procedures: First Year

The rate of adjuvant procedures occurring during the first year in EVAR patients are presented in the Table 20. Conversion to open surgical occurred at the mean rate of 1.54 %, with a median of 0 %. The occurrence of conversion is statistically different from 0 (p=0.05). Extension median was 0.86% with 6 out of 7 studies reporting zero occurrences. Stent use was recorded in 6 studies, with a mean of 2.85% and a median of 0%, with 4 out of 6 studies reporting zero occurrences. Artery bypass was similar for EVAR to OSR, with a mean of median 0.63 ± 1.51 for both, 6 out of 7 studies reporting zero occurrences. The use of extensions, stents, and artery bypass was not significantly different from 0.

Table 20. EVAR adjuvant procedures: year one

	EVAR studies (n)	Obs	Mean (s.d) %	Median (min - max) %	p-value
Extension	7	424	2.17 (4.16)	0.86 (0 - 11.3)	0.21
Conversion	8	658	1.54 (1.84)	0 (0 - 4.2)	0.05
Stent	6	287	2.85 (3.40)	0 (0 - 8.5)	0.09
Artery bypass	7	487	0.63 (1.51)	0 (0 - 1.0)	0.30

* p-value: from student t test for comparison of means. Unadjusted for differences in baseline characteristics for interim report

3.3.5.4. Systemic Complications

Systemic complications rates including cardiovascular events, pulmonary complications, renal failure, stroke and ischemia events (Table 21). There were no statistically significant differences in the rate of systemic complications

between the EVAR and OSR treated patients except for limb ischemia which occurred more frequently in EVAR with a mean rate of 4.50 ± 2.80% and a median rate of 2.69 with a range of 0 – 7.45 ($p<0.01$). Cardiac unspecified, pneumonia, renal unspecified, and bowel/colon ischemia are higher in EVAR. Pulmonary unspecified is higher for OSR. Incidences of MI, arrhythmia, pulmonary failure, and other ischemia were absent in EVAR in the first year.

Table 21. Comparison of systemic complications: first year EVAR vs. OSR

	EVAR studies (n)	Sample (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Sample (n)	Mean (s.d.) %	Median (min - max) %	RR	p-value
Myocardial infarction	4	166	0	0	4	260	0.38 (2.04)	0 (0 - 11.1)	0	0.73
Arrythmia	4	166	0	0	4	260	0.38 (0.46)	0 (0 - 0.93)	0	0.20
Cardiac Unspecified	6	493	1.04 (0.80)	0 (0-1.90)	6	564	0.91 (1.60)	0 (0 - 3.7)	1.13	0.89
Pulmonary (failure)	4	285	0	0	4	392	0.25 (0.41)	0 (0 - 0.94)	0	0.31
Pulmonary (pneumonia)	4	285	1.41 (1.30)	0 (0 – 2.60)	4	392	0.26 (0.35)	0 (0 - 0.74)	5.34	0.19
Pulmonary - unspecified	4	386	0.54 (0.60)	0	4	448	0.93 (1.24)	0.79 (0 - 2.6)	0.58	0.61
Renal (temp failure)	4	412	0.98 (1.27)	0.99 (0 – 4.54)	4	365	1.14 (1.43)	0 (0 - 2.9)	0.86	0.88
Renal (unspecified)	5	586	0.53 (0.82)	0 (0 – 1.80)	5	528	0.20 (0.30	0 (0 - 0.64)	2.70	0.50
Bowel/colon ischemia	4	342	0.88 (0.98)	0 (0 – 1.90)	4	616	0.16 (0.36	0 (0 -0.96)	5.34	0.20
Limb ischemia	4	363	4.50 (2.80)	2.69 (0 – 7.45)	4	638	0	0		< 0.01
Other ischemia	4	342	0	0	4	616	0.34 (0.62	0 (0 - 1.5)	0	0.35

* RR: simple ratio of population weighted means

† p-value: from student t test for comparison of means. Unadjusted for differences in baseline characteristics for interim report

Zero events occurred in the first year in both groups for the following events: amputation, adjuvant procedures (PTCA, Coil embolization), cardiac complications (CHF, angina), pulmonary complications (edema, pneumothorax, embolism), renal complications (permanent renal failure), strokes and Ischemia

(strokes, TIA's, cerebrovascular or spinal ischemia), and other wound problems (major hemorrhage, moderate thromboembolism, arterial or graft obstruction, graft kinks or folds, pseudoaneurysms, or aortoenteric fistulas).

3.3.5.5. Local and Vascular Complications

Local and vascular problems for the first year are presented in Table 22 in order of decreasing relative risk for EVAR versus OSR. Graft obstruction was statically higher with EVAR (p=0.01). Graft migration was also statistically higher with EVAR (p=0.05). In contrast, graft infection, requiring a replacement of the graft, is higher in OSR (p=0.01). Minor wound infections are more prevalent with EVAR while obstruction of the main renal artery and major thromboembolisms are more prevalent with OSR. Present in EVAR but not in OSR are graft obstruction (0.91%), graft migration (1.10%), graft thrombosis (2.70%), and groin major problems (1.26%). Present in OSR but not EVAR ar moderate hemorrhage (1.24%), graft infections (0.22%) and major wounds (0.77%).

Table 22 Local and vascular complications

	EVAR studies (n)	Obs (n)	Mean (s.d.) %	Median (min - max)	OSR studies (n)	Obs (n)	Mean (s.d.)	Median (min - max)	RR	P-value
Groin/wound infection	6	550	2.50 (3.24)	0 (0 - 7.2)	6	788	1.42 (1.38)	0 (0 - 11.1)	1.72	0.49
Obstruction of main renal artery	5	482	0.42 (0.50)	0 (0 - 1.0)	5	444	0.46 (0.99)	0 (0 - 2.6)	0.9	0.94
Thromboembolism - major (need tx)	5	391	0.52 (1.10)	0 (0 - 2.8)	5	555	0.72 (0.76)	0 (0 - 1.5)	0.73	0.76
Groin hemotoma /seroma/lymphoc – minor	5	379	0.26 (0.46)	0 (0 - 1.1)	5	653	1.23 (1.50)	0 (0 - 3.1)	0.22	0.24
Hemorrhage – moderate	3	204	0	0	3	405	1.24 (0.51)	0 (0 - 1.9)	0	0.14
Graft infection	5	482	0	0	5	444	0.22 (0.40)	0 (0 - .93)	0	0.01
Wound - major problem (hernia,etc)	2	247	0	0	2	270	0.77 (0.63)	0 (0 - 1.3)	0	0.33
Graft obstruction	5	1975	0.91 (0.41)	0 (0 - 1.1)	4	303	0	0		0.01
Graft migration	4	1953	1.10 (0.70)	1.46 (0 - 4.2)	3	196	0	0		0.05
Graft thrombosis	3	307	2.70 (4.80)	0 (0 - 11.3)	3	196	0	0		0.43
Groin - major problem	2	247	1.26 (0.82)	0.90 (0 - 1.80)	2	270	0	0		0.12

* RR: simple ratio of population weighted means

† p-value: from student t test for comparison of means. Unadjusted for differences in baseline characteristics for interim report

3.3.6. Meta-analysis of Long Term Outcomes

Meta-analyses of endpoints to be used in the economic model were performed for major systemic endpoints (MI, CHF, COPD, and renal failure) observed for the first, second and third years. Means were obtained from random effects or fixed effect analysis when appropriate (Table 23). No statistical differences were found in any of these events.

Table 23. Meta-analysis of long-term outcomes

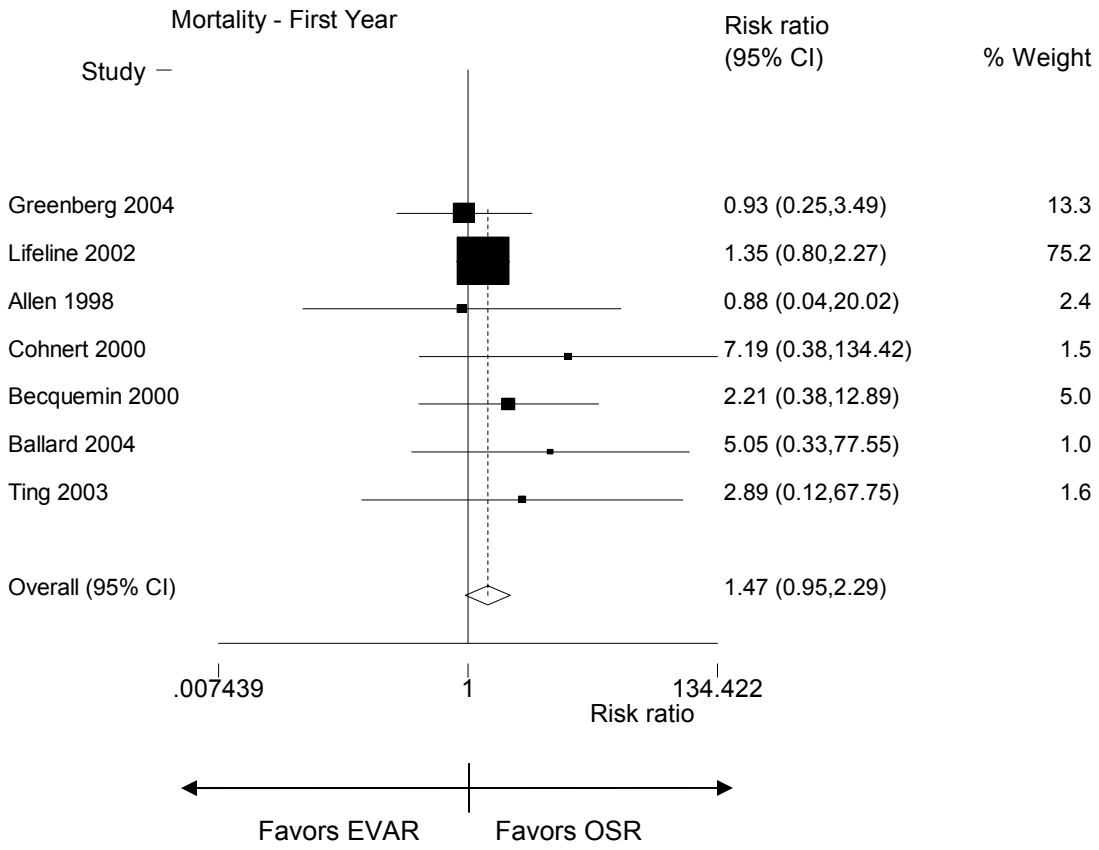
	EVAR		OSR			
	Mean (s.d.) %		Mean (s.d.) %		Relative risk (95% CI)	P-value*
First Year	**12 studies**					
Mortality	0.052 (0.027)	RE	0.027 (0.008)	FE	1.47 (0.95 - 2.29)	0.08
Conversion	0.033 (0.011)	FE	n.a			
Rupture	0.001 (0.001)	FE	0.00 (0.00)			
Myocardial Infarction	0 (0.054)	FE	0.017 (0.041)	FE	0.09 (0.00 - 1.93)	
Congestive Heart Failure	0 (0.054)	FE	0 (0.043)	FE		
Stroke	0.016 (0.022)	FE	0 (0.026)	FE	0.88 (0.04 - 20.02)	
Renal Failure	0 (0.035)	FE	0 (0.037)	FE		
Second Year	**7 studies**					
Mortality	0.065 (0.019)	RE	0.081 (0.019)	RE	0.97 (0.70 - 1.34)	0.12
Conversion	0.018 (0.004)	FE	n.a			
Rupture	0.019 (0.011)	FE				
Myocardial Infarction	0.0 (0.00)		0.0 (0.00)			
Congestive Heart Failure	0.0 (0.00)		0.0 (0.00)			
Stroke	0 (0.029)	FE	0 (0.049)	FE		
Renal Failure	0 (0.058)		0 (0.061)			
Third Year	**3 studies**					
Mortality	0.104 (0.053)	RE	0.118 (0.048	RE	1.25 (0.98 - 1.61)	0.06
Conversion	0.047 (0.009)	FE	n.a			
Rupture	0.011 (0.005)	FE	0.002 (0.002)	RE		
Myocardial Infarction	0 (0.031)		0 (0.029)			
Congestive Heart Failure	0 (0.031)		0 (0.029)			
Stroke	0 (0.026)	FE	0 (0.028)	FE		
Renal Failure	0 (0.03)	FE	0 (0.029)	FE		

RE: Random effects
FE: Fixed effects
* EVAR & OSR means estimated separately, weighted by inverse variance method
† RE/FE estimated in EVAR and OSR separately
‡ RE estimates used if Q-test for homogeneity is rejected
§ RR and p-value: pooled study's RR and tested for difference from one. No adjustment for heterogeneity. Unadjusted for differences in baseline characteristics for interim report

3.3.6.1. Mortality

The first year mortality rate was determined by meta-analysis of seven studies providing information on mortality to 1 year. The relative risk of mortality of EVAR vs. OSR was calculated to be 1.47 (95 CI; 0.95 - 2.29). The Forest plot of mortality is presented below. The randomized control trial (Greenberg 2004) has a slightly lower risk of mortality for EVAR.[8] While the results from the Lifeline Registry (US and Canada) which has the strongest weight provides a relative risk of 1.35 for EVAR versus OSR.[40]

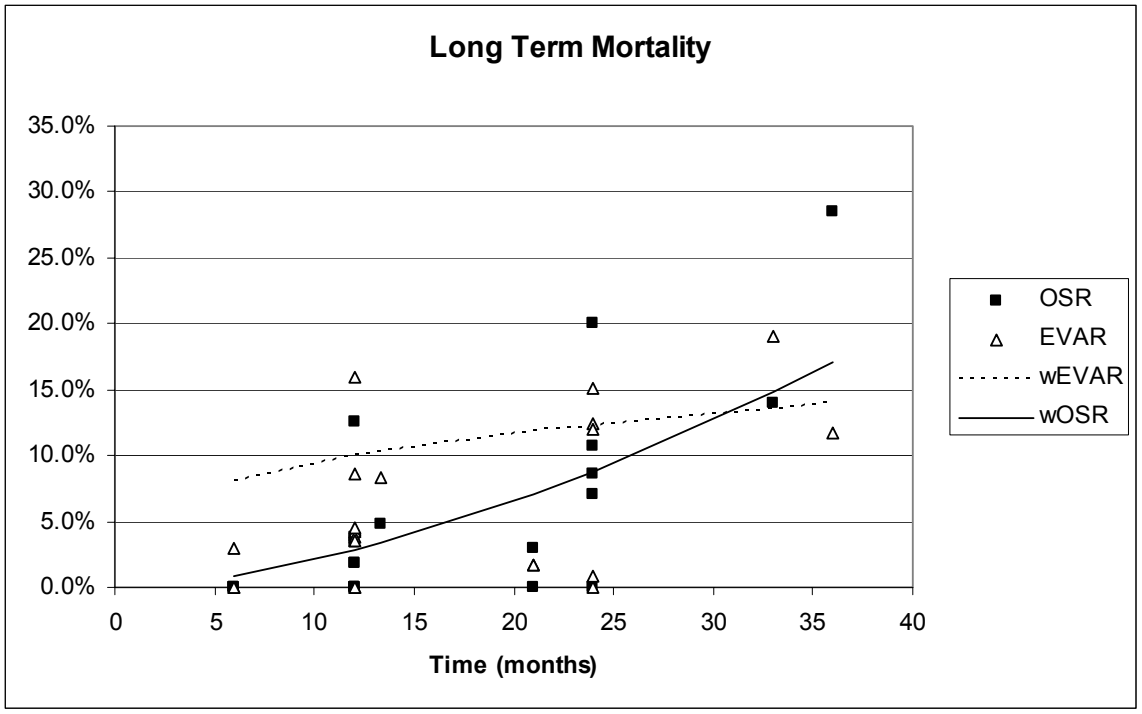
Figure 13. Meta-analysis of mortality within first-year: EVAR vs. OSR



3.3.6.2. Weibull Estimates of Long-term Mortality

In order to estimate relative long-term mortality rates of EVAR vs. OSR, Weibull models were used to estimate the long term effect of mortality for a change in risk over time. The Weibull parameters predict a slowing increase in the risk of mortality for EVAR while the parameters predict a steadily increasing risk of mortality for OSR. When looking at all long term studies, the risk of mortality is higher for EVAR in the first 30 months, but the difference is not significant versus OSR. Beyond 30 months, the risk of mortality is higher for OSR than EVAR, and the difference approaches significance. In the graph below, wEVAR and wOSr represent Weibull estimates of mortality for EVAR and OSR. (Figure 14)

Figure 14. Long-term mortality rates of EVAR vs. OSR: Weibull model



3.4. Summary

EVAR is a relatively new technology. As such, technical success and clinical success rates for EVAR continue to improve with the date of publication. Also, these success rates improve with sample size, suggesting the presence of a learning curve in the use EVAR. Technical and clinical success rates of OSR are also improving with the year of publication but at a slower rate than EVAR. In

addition, technical and clinical success rates for OSR are independent of sample size, suggesting the absence of a learning curve for OSR.

The technical and clinical success rates of EVAR are lower than those of OSR because of the use of adjuvant procedures such as corrections for the type I and III endoleaks in the perioperative period. The use of adjuvant procedures (stents, endovascular extensions, and coil embolization) are required to correct these endoleaks. Even with the correction for the endoleaks, the length of time in the operating room, intensive care, and in the hospital, is less for EVAR. However, the need for conversion to OSR is still present in about 1% of patients and has not decreased in the studies published to date.

The results suggest that EVAR does have other advantages over OSR as systemic complications (cardiac, pulmonary) and surgical complications (thromboembolism, hemorrhage) are more prevalent in OSR.

For the first year post procedure, the risk of endoleaks, limb ischemia, graft migration, graft obstruction are statistically more prevalent in EVAR, requiring more adjuvant procedures but at a much lower rate than in the perioperative period. Graft infection is more prevalent with OSR. Due to these extra vascular concerns for EVAR in the first year, the risk of mortality is higher but the increased risk is not significant. Beyond the first year, the risk of mortality increases with both EVAR and OSR. This risk of mortality rises faster for OSR, and is higher than the risk of mortality for EVAR after 30 months. This difference approaches being significant. In terms of systemic complications in the long term there is no apparent difference between EVAR and OSR.

In the studies evaluated in this systematic review, the pre-existing surgical risk level was higher for EVAR than OSR patients. On average for EVAR, there are more men, an older population, a greater proportion of high anaesthesiology risk patients, and more patients with existing comorbidites (diabetes, hyperlipidemia, cardiac disease, COPD) increasing the risk of potential complications and adverse events during and following surgery. The aneurysm size was larger in

the OSR patients compared to the EVAR patients, from the studies used in this evaluation.

Two large multi-centre randomized control trials will publish their one year results in June 2005.[9,10] These results should allow for a more precise estimate of the long-term benefits/risks associated with EVAR compared to OSR. For results beyond 3 years, no comparable studies that include both EVAR and OSR are available.

4. Field Evaluation Study

4.1. Rationale and Study Objectives

Current treatment options for AAA include OSR, EVAR or best medical treatment (BMT). As these interventions are associated with differences in morbidity, mortality, hospital resource utilization, follow-up procedures, re-intervention rates, complications, recovery times and costs of care, a field evaluation was conducted at London Health Sciences Centre (LHSC) in order to compare EVAR versus OSR.

The objectives of the field evaluation were two-fold: 1) to prospectively collect clinical outcomes, resource utilization and quality of life information on patients undergoing elective repair (i.e. EVAR and OSR) in an Ontario hospital setting, and 2) to compare EVAR patients, who were at high risk for open surgery (OSR) and anatomically suitable for EVAR, to patients receiving OSR both with both low and high surgical risk.

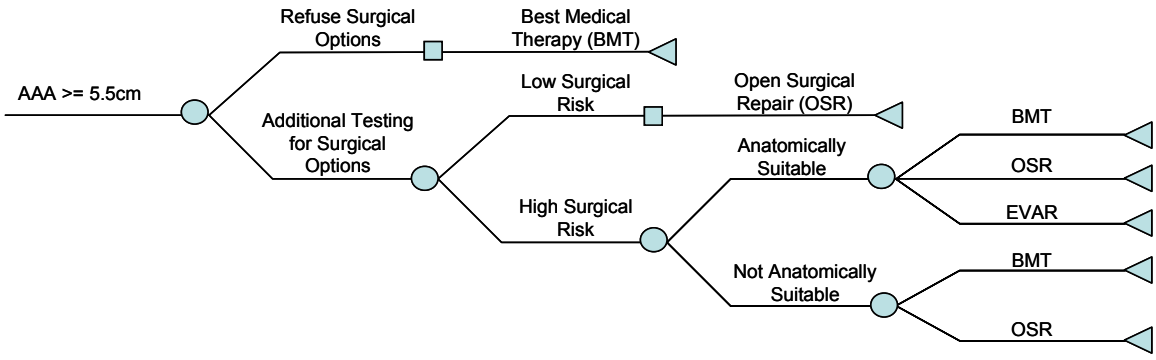
4.2. Methods

All patients requiring elective repair of an AAA (AAA > 5.5 cm) between August 11, 2003 and March 31, 2005 at LHSC, were invited to participate in this non-randomized, prospective observational study. The study, conducted on an intention-to-treat principle, received ethics approval by the University of Western Ontario Ethics Review Board. Informed consent was obtained from the patients before study participation (Appendix IX).

The choice of intervention regarding the AAA repair method was determined as per usual LHSC clinical assessment and with discussion with the patient (Appendix I). Patients refusing surgical options received best medical treatment (BMT). For patients accepting surgical options, surgical risk and suitability were assessed based on cardiac history and risk factors, the classifications of the SVS and the ASA, as well as presence of pulmonary and renal diseases, hostile abdomen, technical challenges and thoracic aortic pathology (Appendix I). [60]

In patients considered to be of low surgical risk, AAAs were treated using OSR. For high risk patients anatomically suitable for EVAR, treatment alternatives included EVAR, OSR or BMT. High risk patients not suitable for EVAR were treated using OSR or BMT. The treatment algorithm for the elective repair of AAAs at LHSC is shown in Figure 15.

Figure 15. Treatment algorithm for elective repair



Demographic, medical, health care resource utilization, cost and quality of life information was collected from participating patients over a period of 1 year following repair (Appendix IX). Data collection was conducted by LHSC research staff during routine clinical visits or over the telephone.

Resource utilization information (e.g., hospital admissions, physician visits, procedures, medications) was prospectively collected using a 'telephone assistance card' and study-specific forms depending on the sequence of the assessment and whether the patient was a medical (BMT) or surgical (EVAR or OSR) patient. For patients that received BMT, resource utilization was collected every 3 months for 1 year following enrollment. For surgical patients, resource utilization data was collected at baseline, 30 days post-surgery and every three months post surgery for 1 year. Patient- specific costing information was also obtained from the Case Costing Centre at LHSC from initial hospitalization to discharge. The case report forms used to collect the data are presented in Appendix IX.

Quality of life was assessed at baseline and at regularly scheduled intervals using two validated quality of life (QoL) instruments. The first QoL instrument, the Short Form-36 Health Survey (SF-36), includes one multi-item scale that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. The RAND 36-Item Health Survey 1.0 was used in this study due to its simplified scoring method.[68] The SF-36 questionnaire is included in Appendix IX.

The second QoL questionnaire, the EQ-5D, has been designed to complement other quality of life measures such as the SF-36. In the EQ-5D, 5 dimensions describe health status: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The EQ-5D provides a simple descriptive health profile and generates a single utility value for heath status on which full health is assigned a value of 1 and death a value of 0. The scoring method given in Drummond was used to compute utilities.[69] The EQ-5D questionnaire is included in Appendix IX.

Once the EQ-5D utilities were generated over time for each patient by treatment group, Quality Adjusted Life years (QALYs) were calculated. QALYs are a composite measure of outcome where utilities for health states (on 0-1 scale) act as qualitative weights to combine the quantity and quality of life. QALYs take one year of perfect health-life expectancy to be worth 1, but regards one year of less than perfect life expectancy as less than 1. For example, 10 years in perfect health (1.0 quality) is equivalent to 20 years at 0.5 quality.

QALYs can therefore provide an indication of the benefits gained following repair by EVAR or OSR. To derive QALYs, the difference in the areas under the curves representing the utilities over time for EVAR and OSR patients were calculated.

Statistical significance was conducted using Chi-square tests for categorical variables and t-tests for continuous variables.

4.3. Study Status

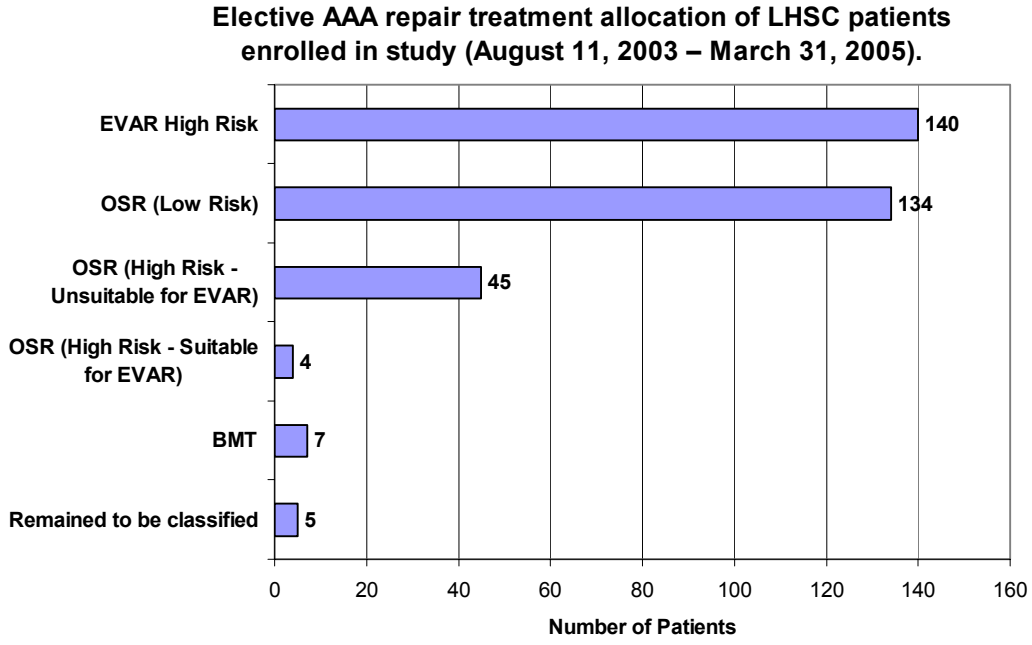
4.3.1. Study Recruitment

Study recruitment started on August 11, 2003 and will end after April 1, 2005. To date, 350 patients have been approached to participate in this field evaluation and 341 patients have been enrolled. Seven patients declined to participate, 2 patients had their aneurysm rupture prior to enrollment. Six patients have dropped out. Risk levels for five patients remained to be classified.

4.3.2. Treatment Allocation

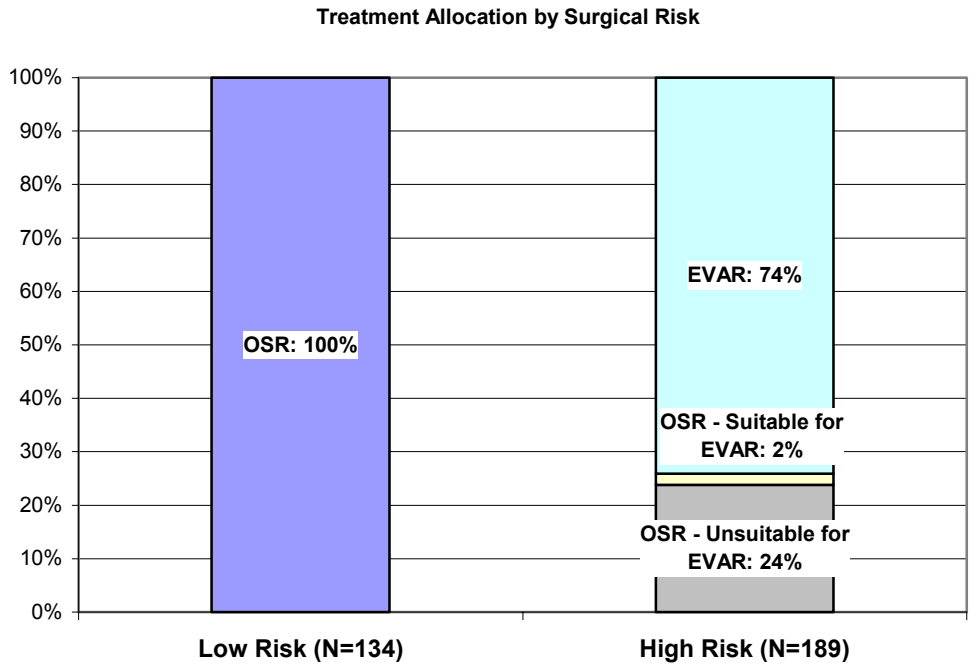
One hundred and eighty three patients (183) underwent OSR, 140 EVAR and 7 received BMT. Allocation by treatment and surgical risk is presented in Figure 16.

Figure 16. Treatment Allocation



Patients at high risk and low risk of surgery represented 59% and 41% of all patients, respectively. All patients at low risk of surgery (N=134) were treated with OSR as shown in Figure 17. Among high risk patients, more than three-quarters were suitable for EVAR and the vast majority received EVAR. Only 2% of these high risk patients suitable for EVAR decided to undergo OSR. Almost one out of four high risk patients (24%) were not suitable for EVAR and therefore underwent OSR.

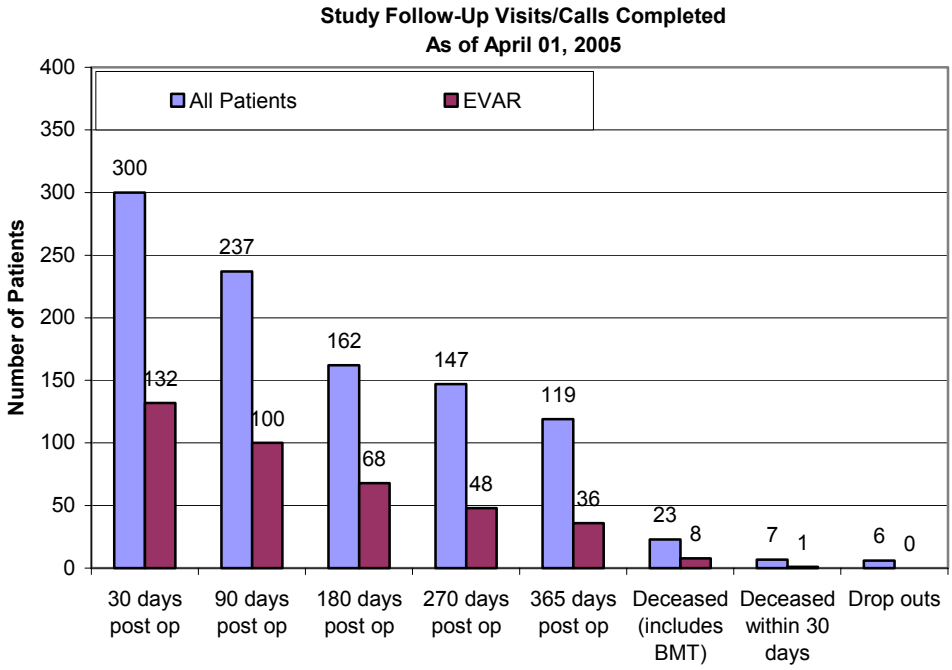
Figure 17. Treatment Allocation per Surgical Risk



4.3.3. Study Termination

Study termination is scheduled at the end of April 2006 when 1 year follow-up will be completed for all participants. As of April 01, 2005, one year follow-up was available for 119 patients as shown in Figure 18.

Figure 18. Study Status



4.4. Interim Results

The interim results are based on 79 patients enrolled up to December 30, 2003 (23.1% of all enrolled patients) and for whom 1 year follow-up data was available when the data was sent on April 01, 2005 to PATH by LHSC.

Of those 79 patients, 24 patients were allocated to EVAR and 55 to OSR. The majority of patients in the OSR group were patients with a low surgical risk (n=30). All high risk patients who underwent OSR (n=23) were not suitable for EVAR. At time of the analysis, two OSR patients were not classified by their surgical risk. Results for patients refusing surgical treatments and who received BMT are not discussed in this report due to the small sample size with one-year follow-up data available for analysis.

4.4.1. Baseline Characteristics

As shown in Table 24, the mean age of patients was 76 (range: 57-93) in the EVAR group and 72 (range: 59-85) in the OSR group and there were more men than women in both groups (83% and 78%, respectively). Twenty-one percent of EVAR patients and thirty-six percent of OSR patients were smokers at time of repair. Few patients were employed at the time of the study, only 4.8% off the EVAR patients and 13.2 % of the OSR patients were either employed full or part time. The mean AAA size was similar between the 2 groups (EVAR: 6.1 cm and OSR: 6.3 cm). None of these differences between groups in terms of age, gender, employment and smoking status or mean AAA size were significant.

Statistical significance was observed in the SVS grade between low and high risk OSR patients. The majority of OSR high risk patients (60.1%) had a SVS grade of II which compared with 16.7% among OSR low risk patients. In total, 36.6% and 54.2% of all OSR and EVAR patients were classified as SVS grade II but this difference was not significant.

In terms of assessment of fitness for anaesthesia and surgery with the ASA grade, there were no statistically differences between EVAR and OSR groups, with approximately half of the patients being classified as ASA grade III (severe systemic condition limiting activity but not incapacitating) and the other half as ASA grade IV (incapacitating systemic disease which is constantly life threatening).

However, statistical significance in the ASA grade was observed between low and high risk patients who underwent OSR. Not surprisingly, high risk patients not suitable for EVAR and who underwent OSR surgery were at more risk of surgical mortality due to anesthesia and surgery (i.e. ASA grade IV: 69.6%) than low risk patients who underwent OSR (i.e. ASA grade IV: 22.6%) as shown in Table 24.

Table 24. Patients' Characteristics

	EVAR (n=24)	OSR (n=55)	EVAR vs. OSR*	OSR Low Risk (n=30)	OSR High Risk (n=23)	OSR Low vs. High Risk*
Age	76.5	72.4	n.s	71.5	73.4	p=0.06
Gender (male)	83.3%	78.2&	n.s	84.4%	69.6%	n.s
Work full or part time	4.8%	13.2%	n.s.	17.2%	9.1%	n.s.
Smoking Status			n.s.			n.s
Current	20.8%	36.3%		46.7%	26.1%	
Ever	62.5%	58.2%		46.7%	69.6%	
Never	16.7%	5.4%		6.7%	4.3%	
Mean AAA size in cm (median)	6.3 (6.0)	6.1 (6.0)	n.s.	5.9 (6.0)	6.3 (6.0)	n.s.
SVS Grade			n.s.			P<0.05
I	44.8%	63.6%		83.3%	39.1%	
II	54.2%	36.4%		16.7%	60.1%	
ASA Grade			n.s			P<0.01
I	0	0		0	0	
II	8.3%	0		0	0	
III	50.0%	54.5%		73.3%	30.4%	
IV	41.7%	45.5%		22.6%	69.6%	

*: ns means not statistically different

The baseline comorbidities in the patients enrolled in the study are provided in Table 25. Many patients participating in this field evaluation had a cardiac history such as angina (41.7% EVAR vs. 32.7% OSR), MI (41.7% EVAR vs. 31.4% OSR), arrhythmia (20.8% EVAR vs. 11.1% OSR), valvular heart disease (12.5% EVAR vs. 5.5% OSR), congestive heart failure (4.2% EVAR vs. 1.8% OSR). However, none of these differences were statistically significant.

With respect to previous cardiac interventions, CABG was the most frequent intervention (25% EVAR and 12.7% OSR), followed by angioplasty/stent (8.3% EVAR vs. 9.1% OSR) but again no statistical differences were observed between the two treatment groups.

Similarly, no statistical differences were found in terms of the New York Heart Association (NYHA) classification, a functional and therapeutic classification for prescription of physical activity for cardiac patients. According to NYHA classification, approximately 90% of all participants are classified as Class 1 (patients with no limitation of activities; they suffer no symptoms from ordinary

activities) and a few patients in class 2 (patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion).

Regarding vascular history, the majority of the participants were hypertensive (75% EVAR and 71% OSR) and 4% (OSR) and 13% (EVAR) had suffered a previous stroke. Previous transient ischemic attack was reported by 4% of EVAR patients and by 6% of OSR patients. Peripheral disease was only observed in OSR patients (11.9%). None of the differences observed between the different groups were significant with the exception of transient ischemic attack and peripheral vascular disease for which a significant difference was observed between the low and high risk groups who underwent OSR. More than 20% of those high risk patients not suitable for EVAR who underwent OSR had a peripheral vascular disease prior to repair (versus 3.3% for OSR low risk patients) and 13% had a transient ischemic attack (versus 0% for OSR low risk patients).

The other statistically significant difference between treatment groups was related to the presence of COPD between EVAR (12.5%) and OSR (32.7%) and between low (20%) and high risk (48%) OSR patients. No other statistical differences were observed between EVAR and OSR in terms of emphysema, asthma, diabetes history, renal and liver functions or other (i.e. hematologic disease, previous abdominal surgery and hostile abdomen).

Table 25. Baseline characteristics

	EVAR (n=24) %	OSR (n=55) %	EVAR vs. OSR*	OSR Low Risk (n=30) %	OSR High Risk (n=23) %	OSR Low vs. High Risk*
Cardiac History						
Angina	41.7	32.7	n.s	26.7	39.1	n.s
MI-<6 months previous	41.7	29.6	n.s	23.3	34.8	n.s
MI->6 months previous	0	1.8	n.s	0	4.4	n.s
Valvular Heart disease	12.5	5.5	n.s	3.3	8.7	n.s
Congestive Heart Failure	4.2	1.8	n.s	0	4.3	n.s
Arhrythmia	20.8	11.1	n.s	10	13.6	n.s
Previous Cardiac Interventions						
Angioplasty/Stent	8.3	9.1	n.s	3.3	8.7	n.s
CABG	25	12.7	n.s	10	17.3	n.s
Valve Surgery	4.2	1.8	n.s	3.3	0	n.s
Vascular History						
Hypertension	75	70.9	n.s	70	69.5	n.s
Stroke	12.5	3.6	n.s	0	8.7	n.s
Transient Ischemic Attack	4.2	5.5	n.s	0	13.4	p=0.04
Peripheral Vascular Disease	0	11.9	n.s	3.3	21.8	p=0.02
Diabetes History						
Diagnosed diabetes	8.3	16.4	n.s.	10	26.1	n.s
Insulin Dependent	0	1.8	n.s.	3.3	0	n.s
Renal Function			n.s			n.s
Normal	91.7	96.3		96.7	95.7	
Abnormal>250mmol	4.2	1.8		3.3	0	
Liver Function			n.s			n.s
Normal	100	100		100	100	
Pulmonary History						
COPD	12.5	32.7	p=0.06	20	47.8	p=0.03
Emphysema	0	3.6	n.s	0	8.7	n.s
Asthma	0	7.2	n.s.	3.3	13.6	n.s
Other						
Hematologic Disease	16.7	5.5	n.s	6.9	4.3	n.s
Previous Abdominal Surgery	39.1	27.3	n.s	23.3	34.8	n.s
Hostile Abdomen	0	1.8	n.s	0	4.4	n.s

*: n.s. means not statistically different

4.4.2. Clinical Outcomes

As part of this interim analysis, several outcomes were analyzed from the 79 patients for whom one year of data were available: 1) characteristics of EVAR and OSR procedures, 2) hospital length of stay, 3) endoleak and additional procedures, 3) complications at time of surgery and 4) post-operative complications.

As shown in Table 26, almost 100% of EVAR patients had a general anaesthesia alone prior to the procedure. In contrast, general anesthesia with epidural was

given to the vast majority of OSR patients (90% low risk OSR and 78% high risk OSR). These differences in the use of general anaesthesia with or without epidural were significant between EVAR and OSR patients and between EVAR and high risk OSR patients but not between OSR patients.

The mean procedural time in minutes was statistically significantly lower for EVAR patients (147.8 minutes) than for OSR patients (184.2 minutes) and when EVAR patients are compared with high risk OSR patients. Among OSR patients, no statistical differences in procedural time were observed between surgical risk groups.

On average, 27% of OSR patients received a blood transfusion (16.7% low risk and 43.5% high risk). No EVAR patients required a blood transfusion during surgery. All of these differences were statistically significant.

Primary technical success was 100% for EVAR and 100% for OSR patients, respectively. Three definitions had to be met all together for primary technical success for EVAR: 1) successful introduction and deployment of the device, 2) absence of surgical conversion or mortality and 3) absence of type I or III endoleaks, or graft limb obstruction.[37] There were no surgical conversions, deaths, type I and III endoleaks or graft limb obstructions reported in EVAR patients evaluated in this field evaluation, Therefore the primary technical success of EVAR was 100% (24/24).

For OSR patients, primary technical success required replacement or bypass of the aneurysmal segment with a prosthetic graft in the absence of mortality or graft thrombosis either during surgery or during the initial 24-hour postoperative period.[37] Based on these criteria the primary technical success of OSR was 100% (55/55).

Table 26. Treatment characteristics

	EVAR (n=24)	OSR (n=55)	OSR Low Risk (n=30)	OSR High Risk (n=23)	EVAR vs OSR	OSR: Low vs. High Risk	EVAR vs. OSR High Risk
Anesthesia type					p<.05	n.s	p<.05
General	22 (95.7%)	9 (16.4%)	3 (10%)	5 (22%)			
General with Epidural	1 (4.4%)	46 (83.6%)	27 (90%)	18 (78%)			
Epidural/Spinal	0	0	0	0			
Local	0	0	0	0			
Surgical Procedure							
Mean Procedural Time (minutes)	147.8	184.2	184.3	185.2	p<.05	n.s	p<.05
Blood Transfusion (%)	0	15 (27.3%)	5 (16.7%)	10 (43.5%)	p<.05	p<.05	p<.05
Primary Technical Success	100%	100%	100%	100%	p<.05	n.s	p<.05

n.s. not significant

As shown in Table 27, only Type II endoleaks were reported in the EVAR population with 37.5% of EVAR patients developing type II endoleaks. It is important to note that according to LHSC experience, type II endoleaks do not require an immediate corrective procedure.

One EVAR patient had to undergo an endovascular procedure. In comparison, more “other” additional procedures (e.g., inguinal hernia repair) were performed among OSR patients. However, no statistical differences were observed between the two OSR groups in terms of other additional procedures.

Table 27. Endoleaks and additional procedures

	EVAR (n=24)	OSR (n=55)	OSR Low Risk (n=30)	OSR High Risk (n=23)
Endoleak				
Type I	0	n/a	n/a	n/a
Type II	9 (37.5%)	n/a	n/a	n/a
Type III	0	n/a	n/a	n/a
Type IV	0	n/a	n/a	n/a
Additional Procedures				
Conversion to OSR	0	n/a	n/a	n/a
Endovascular Procedure	1(4.2%)	n/a	n/a	n/a
Surgical Procedure	0	n/a	n/a	n/a
Other	0	11 (20%)	6 (20%)	5 (21%)

n/a not applicable

Table 28 shows that complications at time of surgery were only observed among OSR patients with 5.5% of all OSR patients having blood loss. These differences were not significant between OSR patients (i.e. low and high risk). In addition, 3.6% of OSR patients experienced other complications (e.g., respiratory compromise) which compared to 0% among EVAR patients. This difference was significant as well as the difference in terms of incidence of “other” complications between EVAR and high risk OSR patients.

Table 28. Complications at time of surgery

	EVAR (n=24)	OSR (n=55)	OSR Low Risk (n=30)	OSR High Risk (n=23)	EVAR vs OSR	OSR: Low vs High Risk	EVAR vs OSR High Risk
Complications at Time of Surgery							
Blood Loss	n/a	3 (5.5%)	2(6.7)%	1 (4.6%)	-	n.s	-
Graft Thrombosis	n/a	0	0	0	-	-	-
Nerve Injury	n/a	0	0	0	-	-	-
Vein Injury	n/a	0	0	0	-	-	-
Failed Access	0	n/a	n/a	n/a	-	-	-
Access Vessel Complications	0	n/a	n/a	n/a	-	-	-
Failed Deployment	0	n/a	n/a	n/a	-	-	-
Misplaced Deployment	0	n/a	n/a	n/a	-	-	-
Covered Renal Artery	0	n/a	n/a	n/a	-	-	-
Imperfect Seal	0	n/a	n/a	n/a	-	-	-
Twist/Kink/Obstruction	0	n/a	n/a	n/a	-	-	-
Complications-Embolisation	0	n/a	n/a	n/a		-	-
Other	0	2(3.6%)	1 (3.3%)	1 (4.6%)	p<.05	n.s	p<.05

n.s. not significant

As shown in Table 29, post-operative complications were more frequent among OSR patients than EVAR patients but most of these differences were not statistically significant. The only statistically significant differences were the rate of blood transfusion among EVAR (4.2%) and OSR high risk patients (30.4%) as well as the incidence of “other” complications between EVAR (12.5%) and OSR (38.2%) and between EVAR and high risk OSR patients (43.5%).

Table 29. Post-operative complications

	EVAR (n=24)	OSR (n=55)	OSR Low Risk (n=30)	OSR High Risk (n=23)	OSR vs EVAR	OSR: Low vs High Risk	EVAR vs OSR High Risk
Post Operative Complications							
Death	0	1 (1.8%)	0	1(4.3%)	n.s	n.s	n.s
MI	0	3 (5.5%)	1 (3.3%)	2(8.7%)	n.s	n.s	n.s
Stroke	0	0	0	0	n.s	n.s	n.s
Pneumonia	0	4 (7.3%)	1(3.3%)	3(13.0%)	n.s	n.s	n.s
Renal Failure	0	5 (9.1%)	2(6.7%)	3(13.0%)	n.s	n.s	n.s
Blood Transfusion	1(4.2%)	11 (20%)	4(13.3%)	7 (30.4%)	n.s	n.s	p<.05
Wound Infection/Lymphocele	0	1 (1.8%)	0	1 (4.3%)	n.s	n.s	n.s
Hemmorrhage/Hematoma	n/a	4(1.8%)	0	1(4.3%)	-	n.s	-
Graft Occlusion	n/a	0	0	0	-	n.s	-
Paralytic Ileus	n/a	3 (5.5%)	2 (6.7%)	1 (4.4%)	-	n.s	-
Sepsis	n/a	3 (5.5%)	0	3 (13.0%)	-	p<.05	-
Vascular Reoperation	n/a	1 (1.8%)	0	1(4.4%)	-	n.s	-
Embolization	0	n/a	n/a	n/a	-	-	-
Other	3(12.5%)	21 (38.2%)	11 (36.7%)	10 (43.5%)	p<.05	n.s	p<.05

n.s. not significant
n/a not applicable

4.4.3. Resource Utilization and Costs

As shown in Table 30, EVAR patients analyzed in this interim report spent statistically significantly less time in the hospital (6.7 days) than OSR patients (13.27 days) or OSR high risk (17.9 days) patients. No EVAR patients attended an intensive care unit (ICU). In contrast, between 10% (low risk) and 40% (high risk) OSR patients were admitted to an ICU. Differences in terms of attendance to an ICU were significant between EVAR (0%) and OSR patients (22%) and between EVAR and high risk OSR (40%) patients. Length of stay (LOS) in the ICU was also statistically different between low (0.3 days) and high (5.08 days) risks OSR patients.

Table 30. Hospital Length of Stay

	EVAR (n=24)	OSR (n=55)	OSR Low Risk (n=30)	OSR High Risk (n=23)	EVAR vs OSR	OSR: Low vs High Risk	EVAR vs OSR High Risk
Length of Stay (LOS)							
Mean length of stay (days)	6.7	13.3	10	17.9	p<.05	n.s	p<.05
Attendance to ICU	0	12 (22%)	3 (10%)	9 (40%)	p<.05	n.s	p<.05
Mean ICU LOS (days)	0	2.29	0.3	5.08	n.s	p<.05	n.s

As shown in Table 31, in terms of one year resource utilization after the initial hospitalization, EVAR patients visited specialists (i.e. vascular surgeons and other specialists) more often than OSR patients and had more diagnostic tests (i.e. CT scan) than OSR patients. These differences were statistically significant when compared to all OSR patients or high risk OSR patients. No other significant differences were observed between EVAR and OSR patients in terms of initial hospitalization and follow-up resource utilization. Among OSR patients, high risk patients had significantly more ER visits than low risk patients.

In terms of loss of productivity following AAA repair, the mean number of days taken off work among all employed patients was 45 days (range 0-134) and there was no statistical difference between the treatment groups. However, for the purpose of this analysis, the number of days taken off from work was averaged to all patients and thus the mean paid days off work for the EVAR group was 6.83 days and for the OSR group 12.2 days. The second measure used to capture productivity losses, the average number of hours of care provided by others, indicates that 14 (OSR high risk) and 19 hours (EVAR and OSR low risk) of care were provided by relatives or others. None of these differences were significant across treatment groups.

Table 31 also summarizes the utilization of selected resources between EVAR and OSR groups. For convenience, differences are given in this table between 1) EVAR and OSR (all); 2) OSR low and high risk patients and 3) EVAR and OSR high risk patients not suitable to EVAR.

Table 31. One-year resource utilization

	EVAR	OSR			Differences		
	All (n=24)	All (n=55)	Low Risk (n=30)	High Risk (n=23)	EVAR vs. OSR (all)	OSR: High vs. Low Risk	EVAR vs. OSR High Risk
Initial Hospitalization							
Mean Length of Stay	6.70	13.27	10.00	17.90	-6.57*	7.90	-11.20*
Mean ICU days	0	2.29	0.30	5.08	-2.29	4.78*	-5.08
Follow-Up. Mean Number of:							
Hospital admission	0.45	0.29	0.27	0.30	0.16	0.03	0.15
ER visits	0.75	0.54	0.77	0.26	0.21	-0.51*	0.49
GP visits	7.75	6.07	6.36	5.43	1.68	-0.93	2.32
Specialist visits	4.54	1.69	1.86	1.39	2.85*	-0.47	3.15*
Vascular Surgeon Visits**	3.20	1.09	1.30	0.83	2.11*	-0.47	2.37*
CT Scans	2.91	0.07	0.03	0.09	2.84*	0.06	2.82*
Follow-Up (Productivity Costs)							
Mean paid days taken off work	6.83	12.20	17.90	5.82	-5.37	-12.08	1.01
Mean hours of care provided by others	18.70	19.30	18.70	13.90	-0.60	-4.80	4.80

*Indicates significance at 5% level

**: Vascular surgeons visits are included in specialist visits

Table 32 lists selected unit costs that were applied to resource utilization data to calculate the mean one year cost of EVAR and OSR in this preliminary report. Costs related to initial hospitalization and follow-up were derived from LHSC while the unit cost of a vascular surgeon was from the Ontario Schedule of Benefits. The Canadian national hourly wage was used to cost out productivity losses.

Table 32. Unit costs

Resource Item	Unit cost	Source
Initial Hospitalization	Varies per patient	London Health Science
Follow-up hospitalization		
Angina	$1,509 per day	London Health Science
CHF	$1,213 per day	London Health Science
Ischemic Gangrene	$768 per day	London Health Science
ER visit	$122.95	London Health Science
CT Scan	$285.75	London Health Science
X-ray	$53.42	London Health Science
Vascular surgeon-consult	112.35	Ontario Schedule of Physician Benefits
Vascular surgeon -assessment	47.20	Ontario Schedule of Physician Benefits
Hourly wage	16.75/hour	Statistics Canada

Although EVAR patients spent statistically less time in hospital (Table 31) and seemed to have less complications at the time of surgery than OSR patients (Table 28), the initial cost of hospitalization between EVAR ($23,525) and OSR patients ($22,129) was similar due to the cost of EVAR procedure, primarily the cost of the endograft. The only statistical difference in initial hospitalization costs was observed between OSR patients when stratified by their surgical risk levels ($13,491 for low risk versus $34,308 for high risk).

Due to a higher number of medical resources consumed during the one-year follow-up (Table 33), the cost of follow-up was greater for EVAR patients ($7,885) than OSR patients ($4,623) but this difference was not statistically significant. Similarly there was no statistical difference in terms of total cost of follow-up between OSR patients stratified by surgical risk level. However, statistical differences were found between EVAR and OSR patients (all and high risk OSR patients) with respect to the cost of tests/ procedures and specialist visits. A greater cost of follow-up with respect to these items was observed with EVAR when compared to OSR (all and high risk OSR patients). Productivity losses were estimated at $1,229 for EVAR (4% of total cost) and $1,961 for OSR

(7% of the total cost). No statistical differences were observed in productivity costs between treatment groups.

As shown in Table 33, the total mean 1 year cost of EVAR patients ($32,639) was not statistically different of the cost of OSR patients ($28,713). However, the mean 1 year cost associated with OSR patients at low risk ($19,221) was statistically lower than the 1 year cost of OSR high risk patients not suitable for EVAR ($42,056).

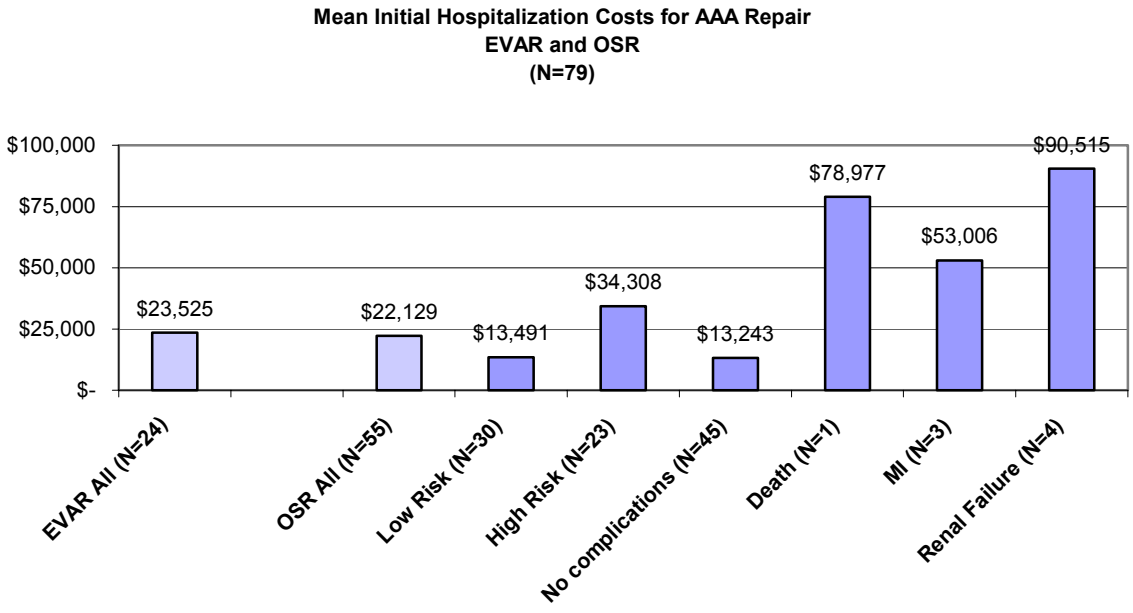
Table 33. Total Average One Year Cost of EVAR and OSR

	EVAR	OSR			Differences		
	All (n=24)	All (n=55)	Low Risk Risk (n=30)	High Risk Risk (n=23)	EVAR vs. OSR (all)	OSR High vs. Low Risk	EVAR vs. OSR High Risk
Initial Hospitalization Costs							
Mean Length of Stay	$23,525	$22,129	$13,491	$34,308	$1,396	$20,817*	-$10,783
Follow-Up Medical Cost							
Hospital admissions	$5,636	$3,618	$2,028	$5,731	$2,018	$3,703	-$95
Tests and procedures	$1,035	$202	$257	$97	833*	-$160	938*
ER visits	$92	$67	$94	$32	$25	-62*	$60
GP visits	$424	$333	$349	$298	$91	-$51	$126
Specialist visits	$235	$114	$128	$89	121*	-$39	146*
Other Health Care Professionals	$463	$291	$164	$481	$172	$317	-$18
Sub-Total	*$7,885*	*$4,623*	*$3,018*	*$6,728*	$3,262	$3,710	$1,157
Total Healthcare Costs	**$31,410**	**$26,752**	**$16,509**	**$41,036**	**$4,658**	**$24,527**	**-$9,626**
Follow-Up. Productivity Costs							
Mean paid days taken off of work	$916	$1,637	$2,399	$786	-$721	-$1,613	$130
Mean hours of care provided by others	$313	$324	$313	$234	-$11	-$79	$79
Sub-Total	*$1,229*	*$1,961*	*$2,712*	*$1,020*	-$732	-$1,692	$209
TOTAL	**$32,639**	**$28,713**	**$19,221**	**$42,056**	**$3,926**	**$22,835***	**-$9,417**

*: Indicates significance at 5% level

Figure 19 depicts the average costs of initial hospitalization derived from the first 79 patients for whom 1 year follow-up was available. In this figure, results are presented for all EVAR patients. This figure also presents the average initial hospitalization costs of all OSR patients and the costs of OSR patients when stratified by surgical risk (i.e. low and high). The initial hospitalization costs of OSR patients with no complications are also presented in this graph as well as the cost of complications following OSR (i.e. death, MI and renal failure). Even based on a small sample size, the complications following OSR seems to be very expensive.

Figure 19. Mean initial hospitalization cost of EVAR and OSR by complications



4.4.4. Quality of Life and QALYs

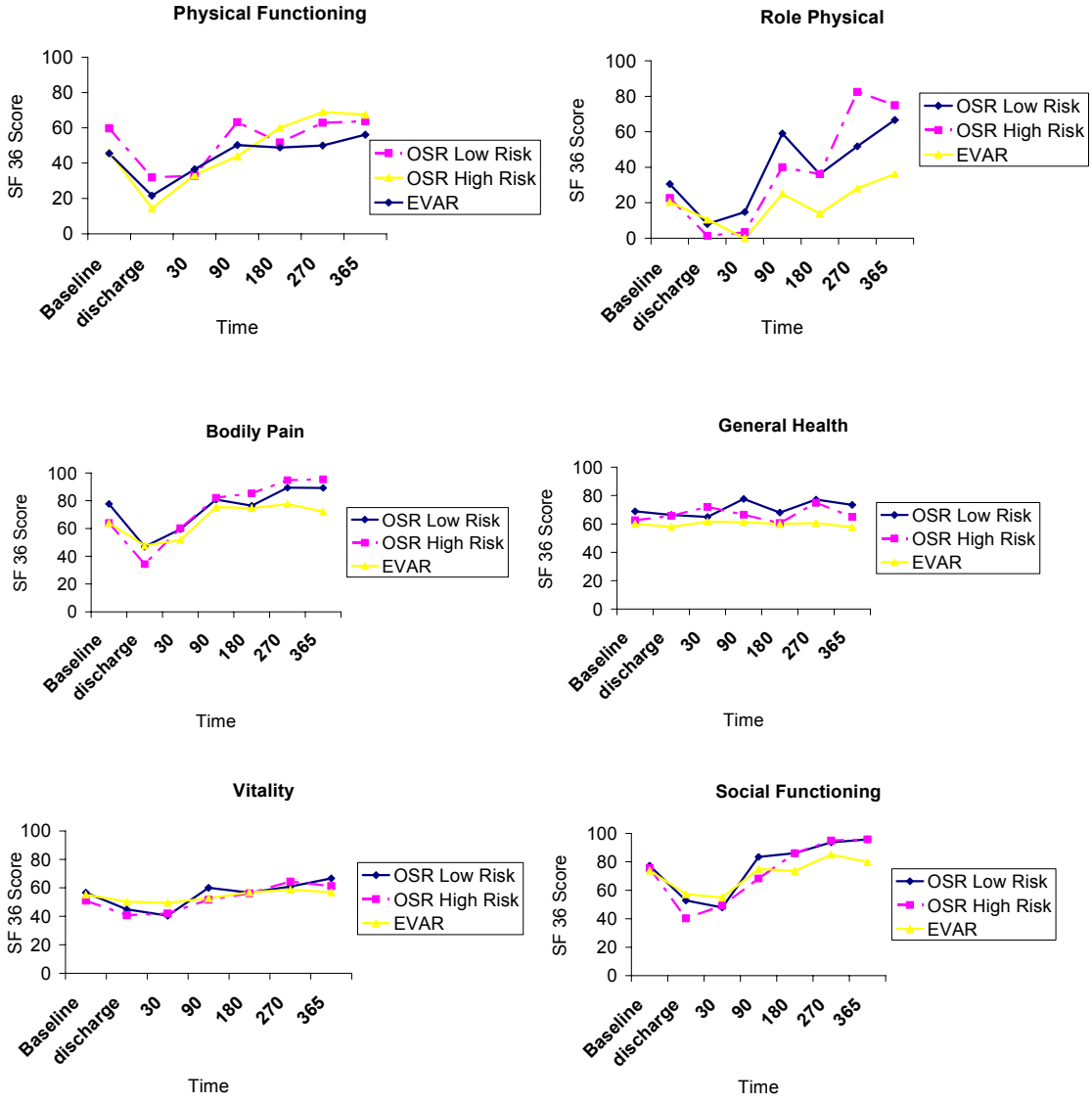
4.4.4.1. SF-36

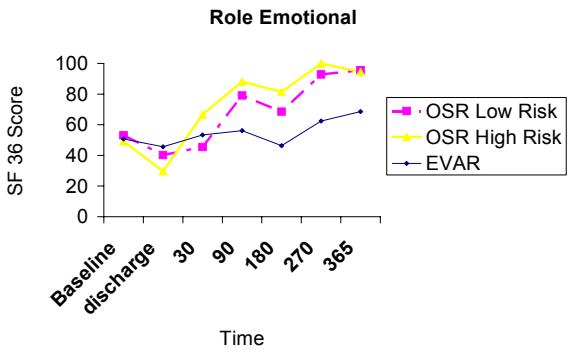
The first quality of life instrument to be analyzed was the Short-Form 36 (SF-36). Using the scoring method of the SF-36, the eight dimensions of this instrument were computed at every time point (e.g. baseline, discharge) and for each type of

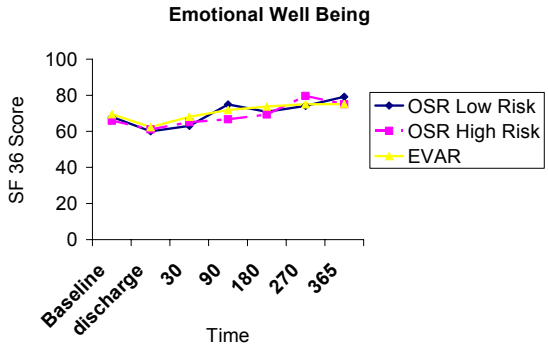
patient (e.g., EVAR, OSR). The eight dimensions are depicted in Figure 20 for EVAR patients and for low and high risk OSR patients. The higher is the score, the better is the quality of life for the patient.

For 5 dimensions (physical functioning, role physical, bodily pain, social functioning and role emotional), a U-shaped curve was observed with the lowest scores obtained after discharge. After discharge, the scores increase overtime

Figure 20. SF-36 Dimensions




Role Emotional
SF 36 Score
100
80
60
40
20
0
Baseline
discharge
30
90
180
270
365
Time
OSR Low Risk
OSR High Risk
EVAR


Emotional Well Being
SF 36 Score
100
80
60
40
20
0
Baseline
discharge
30
90
180
270
365
Time
OSR Low Risk
OSR High Risk
EVAR

and tend to surpass at the end of the one-year period the initial scores at time of initial hospitalization. Differences among EVAR and OSR patients can be observed in physical functioning, role physical, bodily pain, social functioning and role emotional with lower one-year scores for EVAR. Interesting, the scores of the remaining 3 domains (general health, emotional well being and vitality) were not affected over time or by type of patients.

4.4.4.2. EQ-5D

The second quality of life questionnaire used in this evaluation was the EQ-5D. From the answers to the five questions of this questionnaire, it is possible to compute a utility score comprised between 0 (death) and 1 (full health) and then to derive QALYs to assess EVAR and OSR.

The first analysis undertaken was to calculate the EQ-5D utilities over time for EVAR and OSR patients. As observed for the SF-36, the utility is lower at discharge and then increases over time. However, since both groups of patients have different utilities at baseline, it is necessary to adjust the utilities to have comparable baseline values in order to be able to calculate QALYs. A similar approach was used to derive the utility for low and high risk OSR patients. Figure 21 presents the observed utilities and Figure 22 presents the adjusted utilities of the EQ-5D.

Figure 21. EQ-5D Observed Utilities

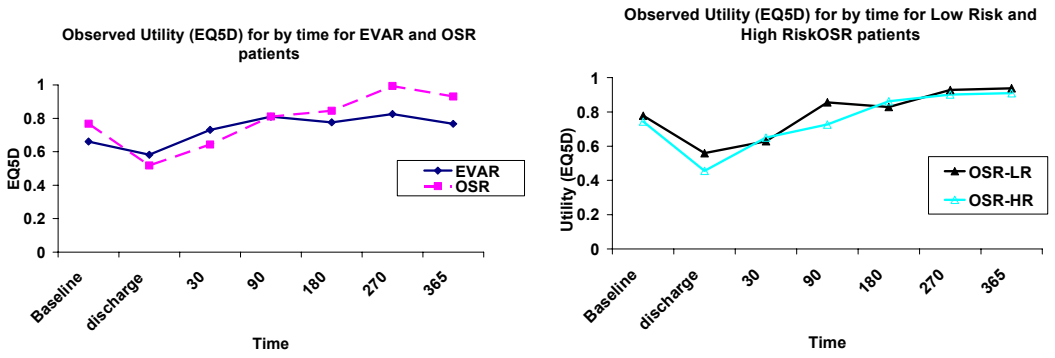
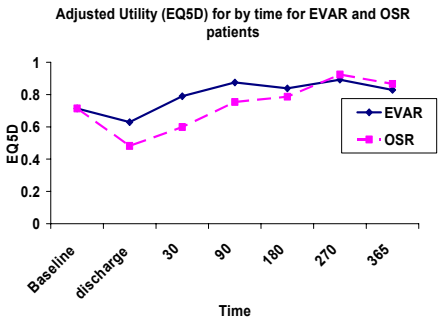
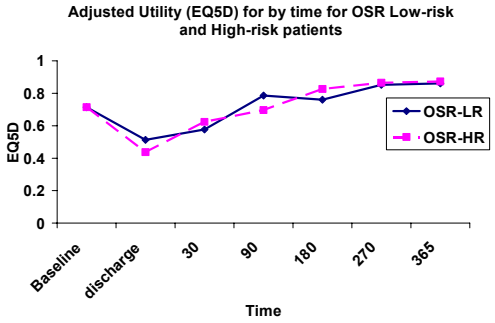


Figure 22. EQ-5D Adjusted Utilities





4.4.4.3. QALYs

Once the utilities over time were adjusted to have similar baseline values, the area under the curves (e.g., difference between EVAR and OSR curves) was computed to derive unadjusted and adjusted QALYs.

As shown in Table 35, before adjustment, the QALYs associated with EVAR and OSR were 0.780 and 0.85, respectively. After adjustment for differences in baseline, EVAR had a higher QALYs (0.843) than OSR (0.777). When the analysis is conducted for OSR patients, it is important to note that at time of analysis, 2 patients remained to be stratified by their risk levels.

Table 34. Unadjusted and adjusted QALY

	QALY's by patient group and differences between groups	
	Unadjusted	Adjusted
EVAR	0.782	0.843
OSR	0.832	0.777
OSR Low Risk	0.839	0.771
OSR High Risk	0.810	0.777
EVAR vs. OSR	- 0.069	0.066
EVAR vs. OSR High Risk	- 0.028	0.066

4.5. Field Evaluation Interim Cost-Effectiveness Analysis

4.5.1. Incremental Cost-Effectiveness Analysis

Using the preliminary results from the field evaluation, an incremental cost-effectiveness ratio was calculated to compare EVAR versus OSR.

Based on the preliminary data collected from these 79 patients, the difference in the mean annual costs of EVAR versus all OSR was estimated at $3,926 ($32,639-$28,713). The difference in adjusted QALYs between EVAR and all OSR patients was 0.066 (0.843-0.777). This led to an incremental cost-effectiveness ratio of EVAR versus OSR of $59,485 per QALY ($3,926/0.066).

Comparing specifically the high risk patient populations, the difference in the mean annual cost of EVAR versus OSR was estimated to be -$9,417 ($32,639-$42,056) and the difference in the adjusted QALYs between the two interventions is 0.066 (0.843-0.777). Therefore, in patients with high surgical risk OSR is dominated by EVAR, costing more and providing less QALY benefit.

Although these results are in support of the use of EVAR in high surgical risk patients, it should be noted that the OSR cost estimates in the high risk patients may be over-estimated due to the higher complication rate and extended length of stay for a few patients and this may result in EVAR being the dominant treatment strategy. Cost estimates for a larger sample of patients (i.e. full patient sample) will help quantify the magnitude of complication rates and costs of complications for high risk OSR patients.

4.5.2. Discussion

While this interim evaluation provides a lot of information necessary for the evaluation of EVAR versus OSR, caution should be used in over interpreting these preliminary results.

The small number of patients for whom one year of follow-up data was available at time of analysis (n=79) limits the generalizability of these results. The final

analysis of the field evaluation (n=341) will provide more information in terms of baseline characteristics, success rates, complications, mortality, utilization of resources, quality of life and costs associated with EVAR and OSR.

Even when the data from all the patients are available and analyzed, it should be emphasized that this field evaluation conducted at LHSC is not a randomized controlled trial and there is a potential issue of selection bias as characteristics of patients may be different at time of repair. This may in turn bias the results of a comparative clinical and economic evaluation of EVAR and OSR.

Another concern with relying solely on the LHSC patients for clinical efficacy data for the economic analysis is that this data reflects the clinical experience and practice of only one centre. An alternative approach for comparing the cost-effectiveness of EVAR versus OSR is to develop a global economic model which integrates clinical endpoints from the systematic literature review and specific cost and utility information from the field evaluation. This approach is described in the next section.

5. Economic Evaluation

A decision analytic model was developed to evaluate the one-year costs and Quality Adjusted Life Years (QALYs) associated with EVAR and OSR. The population of the model cohort is composed of 70 year old male patients with 5.5 cm AAA's who are medically suitable to undergo either OSR or EVAR. The model consists of two treatment arms: EVAR and OSR.

The overall approach will be to first determine if one treatment strategy is dominated by another (i.e. higher costs and lower QALYs) or if there is a trade-off between higher costs but better outcomes between the two treatments. In the absence of dominance, an incremental cost-utility ratio will be calculated and expressed as an incremental cost per QALY gained. The cost per QALY gained is the ratio of the difference in costs to the difference in effects (QALYs).

5.1. Decision Analytic Model

5.1.1. Model Design

All the relevant outcomes following EVAR and OSR were modeled using a Markov state transition model. The Markov model is preferred for the purpose of this study as a traditional decision tree modeling long-term outcomes of EVAR and OSR would become very large and unmanageable.

The Markov model represents the patient as being in one of a finite number of discrete states of health (i.e. alive, dead, etc.) over time which are called Markov states. Changes in patient's health states are represented as transitions from one state to another. The probability that a patient moves from one state to another is called a transitional probability. The model is set up in 2 stages; the first 30 days post repair of the AAA and every 3 months thereafter. The time horizon for the model is 13 months (30 days plus four cycles of 3 months).

5.1.2. Clinical Pathways

The decision tree given in Figure 23 represents the possible clinical pathways occurring within 30 days following EVAR or OSR. Both strategies share common health states such as operative death, alive with no complications following

AAA's repair or alive with complications (stroke, myocardial infarction, renal-dialysis and congestive heart failure). Two additional outcomes may also occur after EVAR: endoleak and conversion to OSR following rupture. When patients are converted to OSR, three health states are possible: operative death, alive with no complications or alive with complications.

Figure 24 presents for the EVAR arm the general structure of the one-year Markov model following the initial 30-day period. In the model, patients move from one health state to another one every 3 months as a function of transitional probabilities. For example in this tree, following EVAR and in absence of complications during the initial 30-day time period (i.e. branch "post evar – no events"), five health states are possible at the beginning of each 3-month cycle: 1) no further events, 2) conversion of OSR, 3) endoleak intervention, 4) rupture and 5) death. In the case of an endoleak intervention, costs and outcomes are modeled to the endoleak intervention arm (2nd branch of the tree) as per Markov modeling. For the disease states arising from surgical complications (i.e. stroke, MI, renal dialysis, CHF), patients either die or remain in these particular states.

Figure 25 presents the one-year Markov model for OSR patients following the initial 30-day period. The structure of the OSR decision tree is similar to the EVAR tree. However, the OSR decision tree does not include the arms associated with endoleak, conversion to OSR or no events following OSR conversion.

Figure 23. One-Month Decision Tree for Patients with AAA Receiving EVAR or OSR

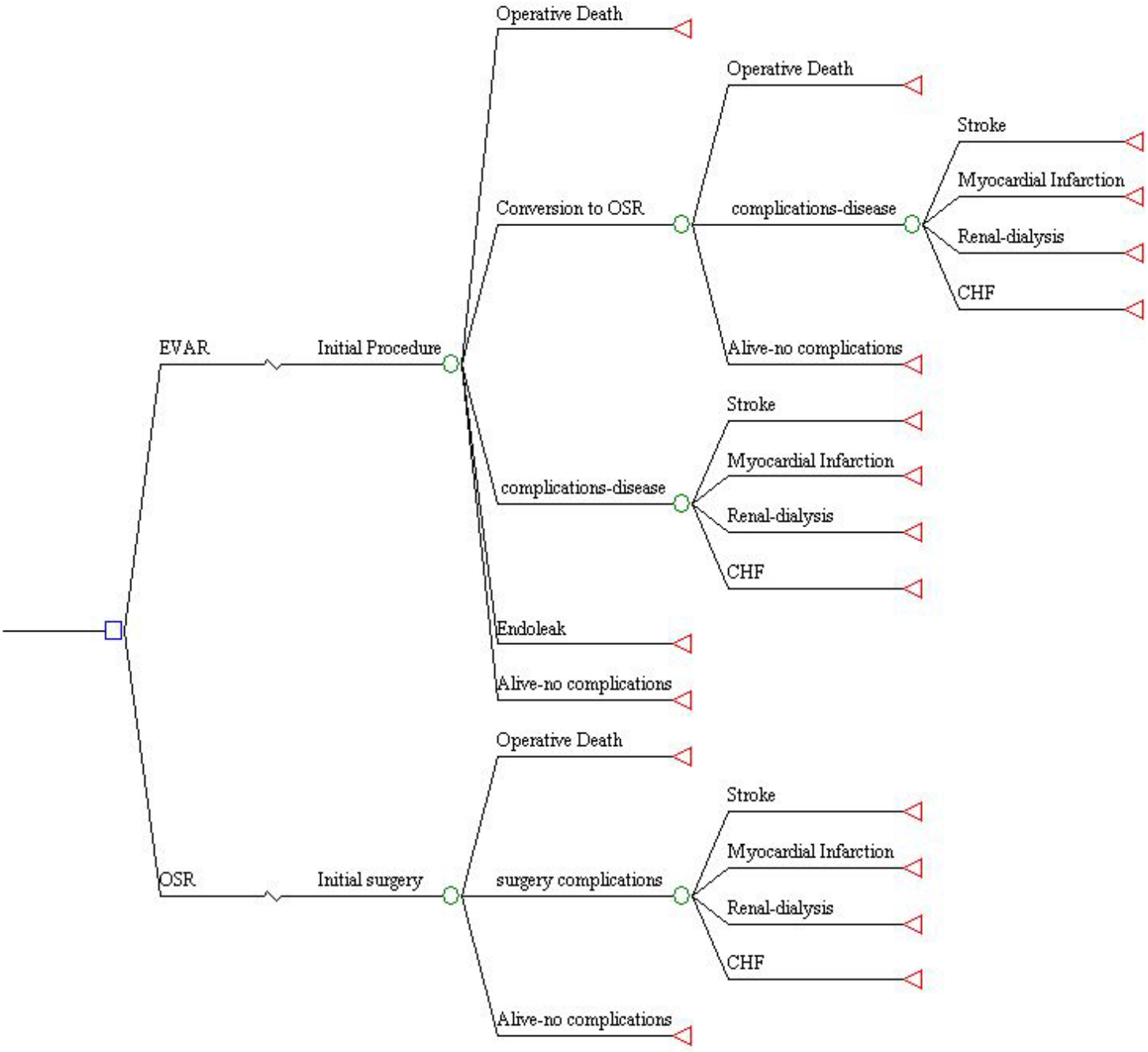


Figure 24. One-Year Markov Model for EVAR

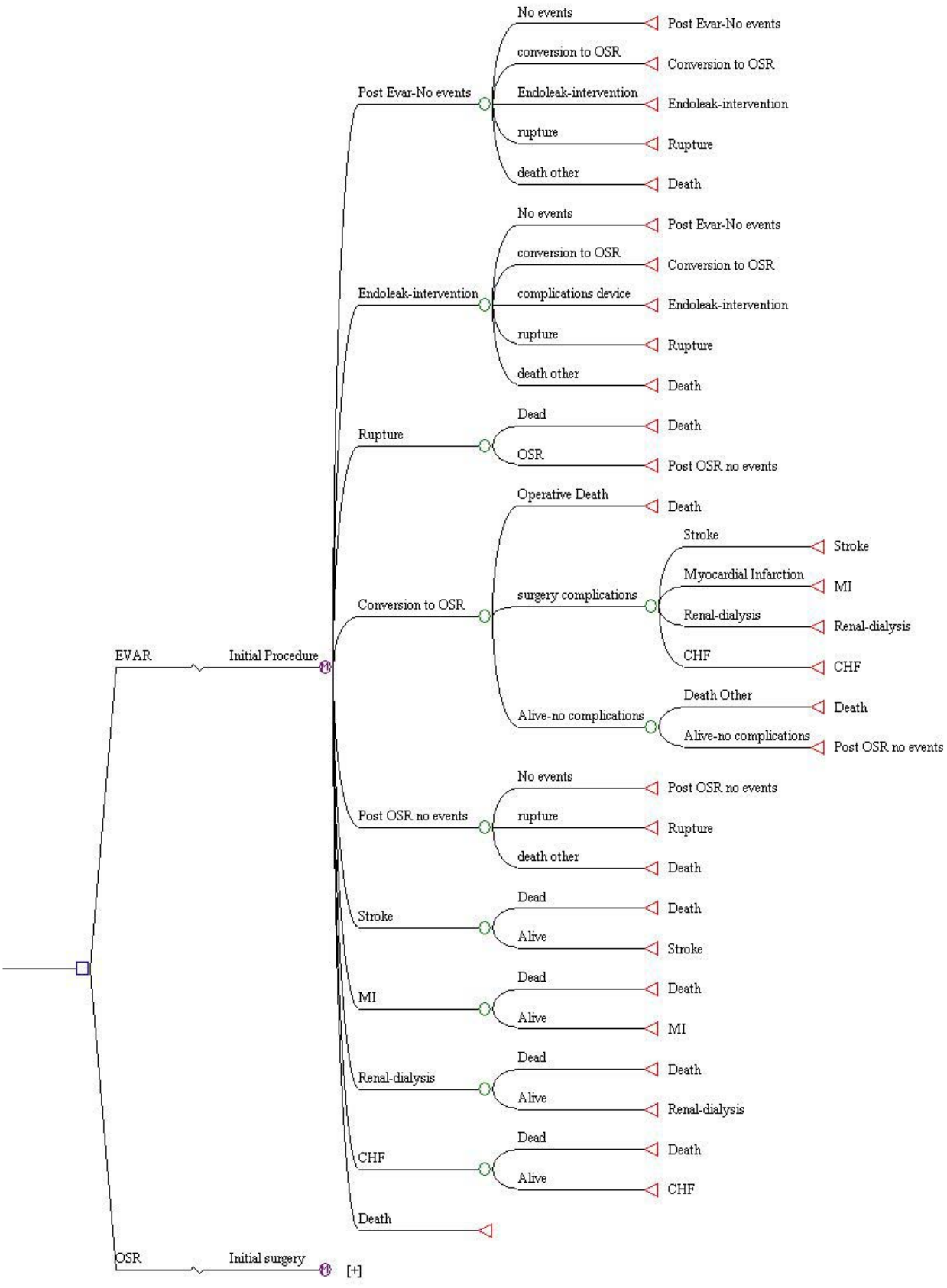
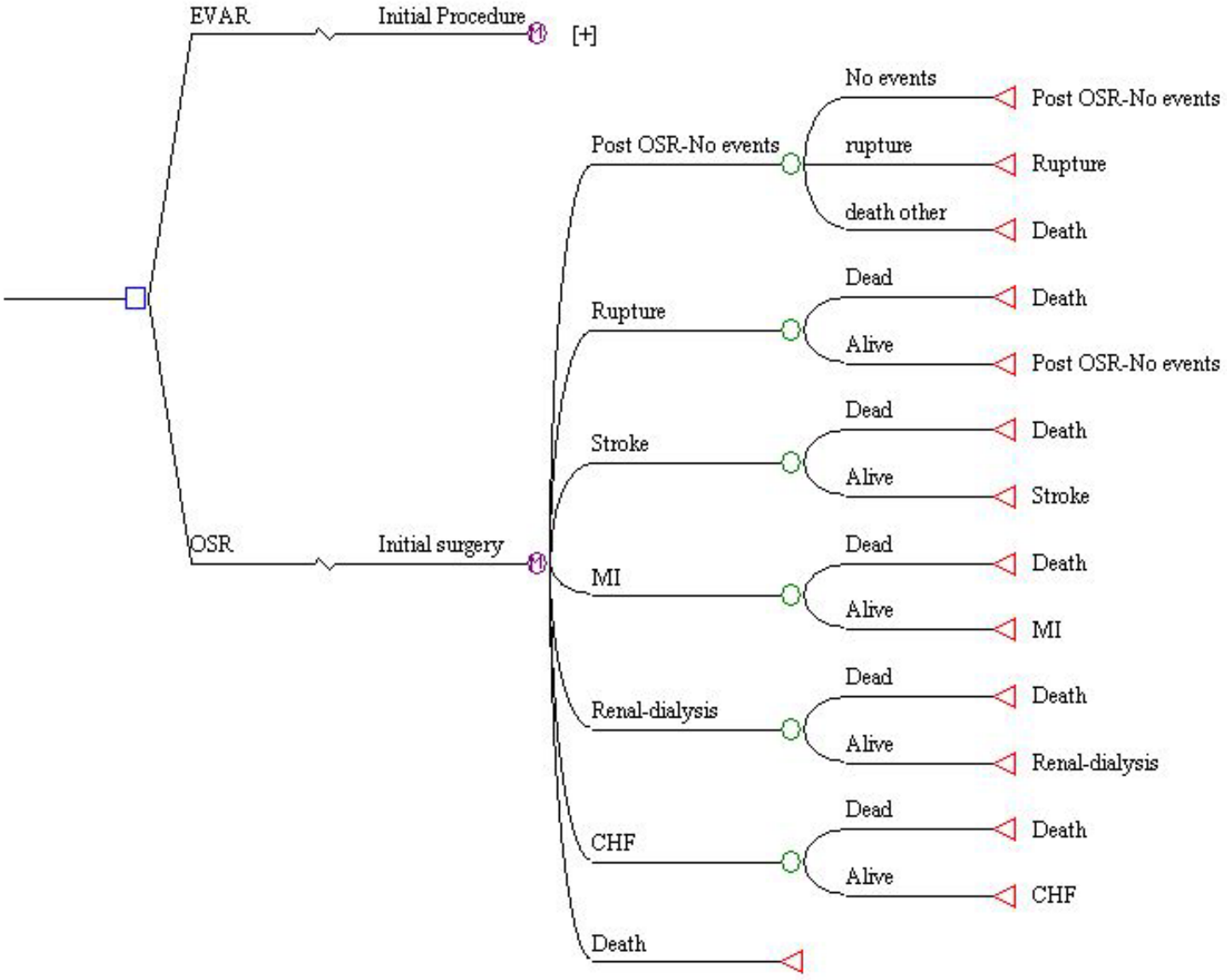


Figure 25. One-Year Markov Model for OSR



5.1.3. Data Sources and Assumptions

Various sources of data were used in the model. These include results observed from the field evaluation and the results from the systematic literature review discussed earlier in the report, along with data from other published sources. Input parameters into the model can be classified into the following categories: 1) Transitional probabilities including mortality variables, 2) Utility input variables and 3) Cost input variables. A summary of the input parameters used in the model is provided in the following three subsections.

5.1.4. Transitional Probabilities

Due to the structure of the model, two sets of transitional probabilities were used: initial 30 days following repair (Table 35) and one-year probabilities following the initial 30-day period (Table 36).

The transitional probabilities for the initial 30-day period following repair were derived from the systematic literature review and meta-analysis conducted by PATH. The transitional probabilities used in the one-year model following the initial 30-day period, were also derived from the systematic literature review and meta-analysis for the following probabilities: conversion to OSR, endoleak and rupture following EVAR or OSR. Mortality rates after 30 days were derived from various sources as described below.

The annual probability of death for all causes was derived from the life tables of Statistic Canada for the years 1995-1997.[70] The annual probability of death following rupture was based on a study of Harris in which 2,464 patients who underwent endovascular repair were evaluated as part of the EUROSTAR (European Collaborators on Stent/graft techniques for aortic aneurysm repair) registry.[48] The relative risk of death following a congestive heart failure was derived from a study of Herzog et al. in which a cohort of 1,136,201 patients in the 5% Medicare database were followed for 2 years.[71] The absolute risk of death post MI was derived from Rouleau et al. In this study, all patients (< or =75 years of age) presenting with a acute MI between July 1, 1990 and June 30,

1992 at nine Canadian hospitals were prospectively evaluated and followed-up for 1 year. [72] Finally, the absolute risk of death post-stroke was derived from a study by Kapral et al. conducted to evaluate the impact of socio-economic status on mortality from ischemic heart disease among all patients with acute stroke admitted to hospitals in Ontario between April 1994 and March 1997.[73]

Table 35. Transitional Probabilities: Initial 30-Day Period

Initial 30-day period		
	Value	**Source**
Mortality		
Probability of death immediately following EVAR	2.6%	Table 16
Probability of Death immediately following OSR	4.3%	Table 16
Conversion to OSR		
Probability of early conversion from EVAR to OSR	1.2%	Table 16
Peri-operative complications – EVAR		
Probability of CHF complication post EVAR	2.2%	Table 16
Probability of Stroke complication post EVAR	0.4%	Table 16
Probability of Renal Failure complication post EVAR	0.4%	Table 16
Probability of MI complication post EVAR	1.3%	Table 16
Peri-operative complications-OSR		
Probability of CHF complication post OSR	2.6%	Table 16
Probability of Stroke complication post OSR	0.7%	Table 16
Probability of Renal Failure complication post OSR	0.7%	Table 16
Probability of MI complication post OSR	2.2%	Table 16

Table 36. Transitional Probabilities: One-year Period Following the Initial 30-day Period

One-year Period Following Initial 30-day			
		Value	**Source**
Conversion to OSR			
	Probability of conversion from EVAR to OSR in long term	3.3%	Table 23
Endoleaks			
	Probability of Endoleak causing intervention in long term	2.2%	Table 19
Rupture			
	Annual probability of rupture post EVAR	0.1%	Table 23
	Annual probability of rupture post OSR	0	Table 23
Mortality			
	Annual probability of death for all causes	3%	Stats-Can
	Annual probability of death following rupture	65%	Harris/Eurostar
	Annual probability of death post MI	5.3%	Rouleau
	Annual probability of death post stroke	12%	Kapral
	Relative risk of death post Congestive Heart Failure	2.25	Herzog et al
	Relative risk of death post dialysis	1.64	Herzog et al

5.1.5 Utilities

The utility values assigned to EVAR and OSR treatment arms in the model were based on the adjusted estimates of EQ-5D utilities reported in the Field Evaluation results. A summary of the utility weights used for the two groups by time period of the model are shown in Table 37. Both the OSR and EVAR arms are assumed to have a starting baseline utility value of 0.71. For each period of the model, average utility values were estimated by dividing the area under the curve for each period by the length of the time. As shown in Table 37 , OSR is assigned a lower utility value then EVAR for the short term 30-day portion of the model and the first two 90 day cycles of the model, but has as slightly higher utility value than EVAR in the last two 90 day cycles of the model.

Table 37. EVAR and OSR Utilities Values

	OSR	EVAR	Source
Baseline	0.71	0.71	Field Study
Short Term-30 day model	0.56	0.70	Field Study
1st 90-day cycle of 1-year model following initial 30 days	0.67	0.83	Field Study
2nd 90-day cycle of 1-year model following initial 30 days	0.77	0.85	Field Study
3rd 90-day cycle of 1-year model following initial 30 days	0.82	0.86	Field Study
4th 90-day cycle of 1-year model following initial 30 days	0.91	0.91	Field Study

Patients who are in a disease state (MI, CHF, stroke, renal failure) as a result of a major complication were assigned a disease specific utility weight. Table 38 shows the utility weights applied to patients who are in the disease state arms of the model. These utility weight values were derived from several sources identified in the literature. The utility weight for CHF was taken from a study by Lewis in which 99 patients with advanced heart failure completed time trade-off and standard gamble questionnaires.[74] The utility weight for MI was taken from a study by Oldridge who compared quality of life over 1 year post MI for patients with and without comprehensive cardiac rehabilitation.[75] The utility weight for renal failure was derived from a study that compared health utility and psychometric health status measures based upon responses by 79 chronic renal patients with anemia.[76] The utility weight assigned to stroke was taken from a study by Schleinitz.[77]

Table 38. Utility Weights for Disease States

	Weight	Source
Stroke	0.39	Schleinitz
CHF	0.64	Lewis
MI	0.77	Oldridge
Renal Failure	0.63	Revicki

5.1.6 Cost of Health Resource Utilization

Costs used in this analysis were derived from a variety of sources. Table 39 shows the various cost input variables used in the model. The costs for the initial hospitalization for each treatment arm were derived primarily from the costs observed in the interim field evaluation. For each treatment group the mean cost

amongst individuals in the field study that did not experience a major complication (OSR: $13,243, EVAR: $23,525) was applied. For the proportion of the model cohort who experienced a major complication (MI, CHF, stroke, renal failure), disease specific costs were added to the initial hospitalization costs. These additional costs were based on mean hospital costs for each condition (CMG) found in the Ontario Case Costing Initiative (OCCI) database.

The 1 year follow-up costs applied to EVAR and OSR treatment arms were also based on the field evaluation costing results. Specifically, the one year follow-up direct medical costs estimated for each group (OSR: $3,266 OSR, EVAR: $7,885) were applied in the 90 day follow-up cycles of the Markov model. Other costs were derived from the literature as described below.

The cost applied to aneurysm rupture repair was based on the mean cost of rupture repair hospitalizations found in the OCCI database. The cost for an endoleak intervention was based on the cost for an embolization reported in a recent Canadian study.[78] The annual costs post major complications (MI, CHF, stroke, renal failure), were derived from Canadian literature sources. The annual cost of CHF was based on a study by Tsuyuki in which the 6-month cost of hospitalized patients with heart failure was estimated.[79] The annual cost following MI was derived from an unpublished study of Coyle.[80] The annual cost following renal failure and stroke were derived from Kroeker and Riviere, respectively.[81,82]

Table 39. Cost inputs used in the model

	Value	Source
Hospitalization for OSR-no major complications	$13,243	Field Study
Hospitalization for EVAR-no major complications	$23,525	Field Study
Additional cost of CHF	$5,055	OCCI
Additional cost of MI	$6,372	OCCI
Additional cost of Renal Failure	$6,990	OCCI
Additional cost of Stroke	$6,084	OCCI
Cost of Rupture Repair	$17,122	OCCI
Cost of Endoleak Repair	$900	Forbes
Annual Follow-Up Costs		
post-OSR	$3,266	Field Study
post-EVAR	$7,885	Field Study
post-CHF	$9,096	Tsuyuki
post-MI	$5,566	Coyle
post-Renal Failure	$57,314	Kroeker
post-Stroke	$15,690	Riviere

5.2 Results

Using the systemic complication rates derived from the systematic literature review, the 13-month expected cost of EVAR and OSR (low and high risk) were estimated at $32,079 and $17,503, respectively. The incremental cost of EVAR versus OSR was therefore $14,576. The expected QALYs calculated by the model were 0.863 for EVAR and 0.772 for OSR, representing an incremental QALY gained of 0.091 for EVAR over a 13-month time period. As shown in Table 40, this yielded an incremental cost-effectiveness ratio of EVAR versus OSR of $160,176 per QALY gained.

Table 40. Costs, Effects and Incremental Cost-Effectiveness of EVAR versus OSR

	Expected Costs	*Incremental Cost*	Expected QALYs	Incremental QALYs	Incremental Cost-Effectiveness Ratio
OSR	$17,503		0.772		
EVAR	$32,079	*$ 14,576*	0.863	*0.091*	$ 160,176

Since randomized controlled trials comparing high risk EVAR and OSR patients directly could not be identified, there is concern that the results from the systematic literature review and meta-analysis may not be representative of the true event and complication rates that would be observed in head-to-head controlled trials. This is a particular concern for peri-operative complication rates which may be different between OSR and EVAR treated patients. The 30-day rates of peri-operative complications (CHF, stroke, renal failure and MI) used in the model, from the systematic literature review, totalled 4.3% for the EVAR and 6.2% for OSR. (see Table 16 & 35 for individual rates). However, for these same complications (CHF, renal failure, stroke and MI) different rates were observed in the interim field evaluation with none of these peri-operative complications occurring in the 0% of the EVAR treated patients 0% and in 14.5% of the OSR patients, respectively (Table 29).

There is also concern that the general costs used for peri-operative complications from OCCI may not be accurate costs of complications for this particular patient group. For these reasons, the calculated costs and effects based on complication rates and costs of complications from the field evaluation were determined. The 13-month expected cost of EVAR and OSR were estimated at $31,986 and $29,242, respectively yielding an incremental cost of EVAR versus OSR of $2,744. The expected QALYs calculated by the model were 0.8749 for EVAR and 0.7531 for OSR patients, representing an incremental QALY gained of 0.1218 for EVAR over a 13-month time period. This yielded an incremental cost-effectiveness ratio of EVAR versus OSR of $22,528 per QALY gained (Table 41).

Table 41. Costs, Effects and Incremental Cost-Effectiveness of EVAR versus OSR Patients: Field Evaluation Complication Rates and Costs.

	EVAR		**OSR**		**Incremental**		**ICER**
	Costs	QALYs	Costs	QALYs	Costs	QALYs	
Model Results using cost & complication rates form the field evaluation	$31,986	0.8749	$29,242	0.7531	$2,744	0.1218	$22,528

5.2.1 Sensitivity Analysis

Sensitivity analysis is typically used to assess both parameter uncertainty and variability in patient cohorts or model assumptions. It is common practice today to assess parameter uncertainty using probabilistic sensitivity analysis (PSA) where distributions are used to represent the uncertainty around parameter values and simulation techniques makes random draws from these distributions. Variability in patient cohorts (e.g. low risk versus high risk or different starting ages) or in modeling assumptions (e.g. discount rates) are assessed using traditional deterministic sensitivity analysis (DSA) where alternative values are substituted into the model and cost-effectiveness re-calculated. Since this is an interim report, PSA was not conducted and results from PSA will be fully explored in the final report.

6. Budget Impact Analysis

In order to estimate the budgetary impact of introducing EVAR as an insured medical service in Ontario, three pieces of information are needed. First, an estimate of the total annual number of AAA patients in Ontario is needed. Second, the number of AAA patients (or percent of total) where EVAR may be considered as the alternative treatment to OSR is needed. And third, the incremental cost of EVAR over OSR is needed.

The volume of both elective and emergency AAA repair in Ontario has been recently published.[83] The volume of elective AAA repair in 1999 was estimated to be 1538 cases and for emergency repair of AAA the estimate was 319 cases. Assuming that the volume of AAA has not increased significantly since 1999, the total potential case volume in Ontario would approximately be around 1900 cases.

To estimate the potential volume of EVAR that could potentially occur in the province, based on current case mix, each of the centres in Ontario with the ability to perform EVAR were contacted (Personal Communication, Dr. G. De Rose, April 2005) and were asked to provide an estimate of their current procedure volume for fiscal 2004/05. The centres were then asked to provide an estimate of the number of both elective and emergency EVAR procedures that they would perform based on the current AAA case mix seen at their institutions, if resources were available. The results from the survey are presented in Table 42. The results of this survey suggest that approximately 635 cases of EVAR annually may be expected if EVAR was an insured and funded medical service in Ontario.

Table 42. Current and estimated volume of EVAR repair with funding

	Current total annual volume (2004/05)	Elective procedure volume (estimated)	Emergency procedure volume (estimated)	Total annual volume (estimated)	Estimated annual volume increase
London Health Sciences Centre	110*	135	25	160	50
Hamilton Health Sciences Centre	60	100	25	125	85
Ottawa Civic Hospital	60	80	20	100	40
Sudbury Memorial Hospital	25	35	nr	35	10
St. Michael's Hospital	15	60	nr	60	45
Toronto General Hospital	0	130	25	155	155
Total	270	540	95	635	365

* Funded volume as part of EVAR study. Volume for 2005/06 estimated to be 40 procedures due to decreases in funding as insufficient funding from global hospital budget

nr not reported

These estimates of the annual volume of EVAR procedures were applied to the incremental cost estimates derived from the field evaluation and economic model to provide a range of possible budgetary impact for the Ontario Ministry of Health (Table 43). The incremental cost of EVAR in high surgical risk patients compared to all OSR patients, calculated by using the field evaluation complication rates in the economic model, was $2,744 per patient. Based on an annual case volume of 635 cases the resulting the budget impact of treating high surgical risk patients with EVAR is estimated at $1.74 million.

The budgetary impact results derived from the model and the field evaluation however range from a savings of $6.11 million (using the incremental cost results from the interim field evaluation for high risk OSR patients) to a cost increase of $9.26 million (using the incremental cost results from our base case economic model considering OSR treated patients with complication rates and risk profile equivalent to the published literature).

This broad range of potential budgetary impact highlights the importance of addressing the issue of conducting an analysis of the literature that adjusts for potential imbalances in patient baseline characteristics and for increasing the sample size of patients in the field evaluation to obtain more reliable estimates of

complication rates and costs of managing complications. Both of these issues will be addressed in the final report from PATH due in 2006.

Table 43. Potential budgetary impact of introducing EVAR in Ontario

Source of Incremental Costs	Estimated Annual Healthcare Cost ($)	Incremental Healthcare Cost (EVAR-OSR)	Potential Budgetary Impact (based on 635 cases per year)
Field Evaluation			
EVAR	31,410		
OSR – All Patients	26,752	4,658	+$2.96 million
EVAR	31,410		
OSR – High Risk Patients	41,036	-9,626	-$6.11 million
Economic Model			
EVAR	32,079		
OSR	17,503	14,576	+$9.26 million
EVAR*	31,986		
OSR*	29,242	2,744	+$1.74 million

* using complication rates and cost of complications from interim field evaluation

7. Discussion

When the rate and cost of complications from the sample of patients included in the interim field evaluation are used in the cost-effectiveness model, the cost-effectiveness of EVAR compared to OSR is $22,528 per QALY gained and suggests that EVAR is a cost-effective strategy. The cost-effectiveness results, derived from the Markov model using literature rates and OCCI hospitalization costs (i.e. $160,176 per QALY gained), indicate however EVAR may not represent good value for money when used in all AAA repair patients. These results suggest that whether EVAR is considered cost-effective is very sensitive to the rate and cost of complications.

Several limitations associated with this interim analysis need to be considered when interpreting the results of this evaluation and a few important cautionary notes are warranted that may significantly affect these interim results and conclusions.

First, these interim results are based on a deterministic, as opposed to probabilistic, cost-effectiveness model. The standard today for conducting cost-effectiveness analyses of models is to represent parameter uncertainty using probability distributions and to use simulation techniques to sample from these distributions in arriving at cost-effectiveness estimates. By structured the decision problem in this way, the full range of uncertainty in model parameters and the impact of joint uncertainty are built into the base case analysis. Variability assumptions (e.g. different patient cohorts or modeling assumptions) are then tested using sensitivity analysis on the probabilistic model. These interim results are based on a deterministic cost-effectiveness model and the final model (due 2006) will be a fully probabilistic model.

Second, not included in this report is an extensive sensitivity analysis around the base case deterministic cost-effectiveness estimates to fully explore the impact of uncertainty on our results. There are two reasons for this. First, the final model will be a probabilistic model that incorporates parameter uncertainty and as a result extensive sensitivity analyses around these parameters are not needed.

And second, it was felt there were too few patients and too much uncertainty around our results for the patients included in our interim analysis to conduct extensive sensitivity analyses. The final analysis, due in 2006, based on a larger sample of patients will help refine the estimates for the rate and cost of complications.

And finally, there is concern over the comparability of EVAR and OSR patients available from the systematic literature review. The comparison of EVAR versus OSR has been studied using a randomized trial design in 4 unique studies.[7-10] All other study reports are non-randomized and compare EVAR with either concurrent or historical OSR comparison groups. The OSR patients used as a comparison to EVAR patients generally do not present with the same prevalence of co-morbidity conditions and thus may not have similar surgical risk profiles. Furthermore, the ability to abstract data from the literature by patients' surgical risk is not always possible. The analysis of the clinical literature therefore represents a mixed population of patients with high and low surgical risk. The mixed patient population in the OSR arms of the trials may have resulted in an under estimate of the rate of major systemic complications used in the economic model (EVAR: 4.3% versus OSR: 6.2%) (Table 16). As a comparison, the rate of major complications from patients in the interim field evaluation is substantially different (EVAR: 0% versus OSR: 14.5%) (Table 29).

These differences in major systemic complications between the meta-analysis results and the interim field evaluation could potentially be due to several reasons. The studies identified in the literature search did not include any randomized controlled trials of EVAR versus OSR in high risk patients. The lack of randomization and the reporting of non-randomized studies may have led to a selection bias towards the higher surgical risk patients receiving EVAR and the remaining lower risk patients receiving OSR, especially in studies that provide details concerning consecutive series of patients. Second, a limitation of the meta-analysis reported is that it provides an unadjusted estimate of complication rates and does not account for baseline co-morbidities. The OSR patients generally had a lower surgical risk and the difference between the OSR group

and the EVAR group with respect to systemic complications may be artificially low. Third, the field evaluation site may have a slight referral bias as it is a regional tertiary care centre and may have a higher surgical risk case mix thus resulting in higher baseline morbidity in the OSR group, especially in the high risk OSR group. Finally, the expertise and experience of the LHSC team have an important impact not only on technical success rates, but on the rate of complications for OSR and EVAR procedures that may influence the generalizability and comparability of the LHSC experience to other centers. The final report (due 2006) will include an adjustment for base line imbalances between OSR and EVAR patients in the systematic literature review.

Endovascular repair of the aneurysm can be done safely and recovery in the intensive care unit is rarely required with patients usually discharged home sooner than the OSR patients. Major cardiopulmonary complications also occur less frequently after EVAR than OSR. In addition, the use of hospital resources are decreased with EVAR including transfusion requirements, hospital length of stays, and intensive care monitoring. Patients return to pre-intervention levels of activity more rapidly with EVAR than OSR. Current recommendations for the repair of AAA in intermediate to high surgical risk patients support the use of EVAR.[25,55] Further long-term results from randomized controlled trials comparing EVAR to OSR are scheduled to be published in the summer of 2005.[9]

8. References

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9. Appendices

Appendix I Clinical Criteria for Endovascular Aneurysm Surgery

LHSC Clinical Criteria for Endovascular Aneurysm Surgery

Endovascular repair is considered to be the most suitable treatment for patients falling into one or more of the 'high-risk' categories outlined below:

I: High-Risk/comorbid diseases*

- **Cardiac:**
  - Class II-III angina
  - Significant myocardium at risk
  - Left Ventricular Ejection Fraction (LVEF) < 30%
  - Recent Congestive Heart Failure (CHF)

- **Pulmonary:**
  - Chronic Obstructive Pulmonary Disease (COPD) or emphysema
  - Severe pulmonary dysfunction
  - Home O2 or Forced Expiratory Flow (FEF) 25-75 of < 20% predicted

- **Renal:**
  - Creatinine > 250 umol/L
  - Dialysis dependent

*** (ASA III or IV) or (SVS/ISCVS Category II or III) (see References – Hollier)**

II: Hostile Abdomen

III: Technical Challenges

- Inflammatory aneurysm
- Renal anomalies eg: horseshoe kidney
  renal allograft
- Anastomotic aneurysm

IV: Thoracic Aortic Pathology

- Aneurysm
- Dissection
- Penetrating thoracic ulcer
- trauma

London Health Sciences Centre Endovascular Aortic Repair Program

PATIENT SELECTION CRITERIA

"Patients with aortic pathology, known to be at higher risk for perioperative morbidity (e.g. paraplegia) and mortality with standard open surgical therapy, either because of the nature of the aortic pathology and/or patients' associated co-morbid conditions."

"Patients with an otherwise estimated life expectancy of at least 24 months."

A. Thoracic Aorta (irrespective of age and co-morbid conditions).

- traumatic rupture of thoracic aorta
- ruptured (symptomatic) thoracic aortic aneurysm/aortic ulcer.
- asymptomatic thoracic aortic aneurysm >6.0 cm in diameter.
- adjunct to treatment of thoracic aortic dissection (i.e. failure of medical therapy).
- recurrent thoracic aortic aneurysm (i.e. pseudoaneurysms, anastomotic

B. Abdominal Aorta and Iliac Arteries

- Ruptured (symptomatic) infrarenal aortic and/or iliac artery aneurysm. (Irrespective of age and co-morbid conditions).
- anastomotic or para-anastomotic aortic and/or iliac artery aneurysm following previous open surgical repair
- asymptomatic infrarenal aortic aneurysm > 5.5 cm in diameter (with high risk anatomical and/or physiological criteria).
- asymptomatic iliac artery aneurysm > 4.0 cm in diameter (with high risk anatomical and/or physiological criteria).

  "HIGH-RISK" Anatomical Criteria

  - "inflammatory" abdominal aortic aneurysm.
  - patient with "hostile abdomen" (i.e. numerous previous laparotomies, known retroperitoneal fibrosis, abdominal wall stomas).
  - special anatomical situations (e.g. horseshoe kidney, renal transplant graft).
  - aborted attempt at open surgical repair.
  - patient refuses to accept blood transfusion (e.g. Jehovah Witness).

“HIGH-RISK” Physiological Criteria

Endovascular repair to be considered in patients with any of the following high-risk co-morbid conditions (SVS/ISCVS Category II or III). J Vasc Surg 1992;15: 1046-1056.

Age >80 years

Cardiac

- stable angina or prior myocardial infarction, but moderate coronary lesions, or abnormal myocardial perfusion scan without major areas of reperfusion.
- Class II - III angina or significant myocardium at risk on basis of coronary angiography or myocardial perfusion scan with large areas of reperfusion.
- left ventricular ejection fraction (LVEF) <30%.
- recent congestive heart failure.
- recent myocardial infarction.
- moderate-to-severe aortic valvular stenosis.

Pulmonary

- chronic obstructive pulmonary disease (COPD), emphysema or previous pulmonary resection with moderate-to-severe pulmonary dysfunction (documented with pulmonary function studies).
- pulmonary dysfunction requiring home oxygen or with forced expiratory flow (FEF) of <20% predicted.

Renal

- serum creatinine >250 umol/L.
- dialysis dependent.

Such “high risk” patients are classified as ASA III, IV, or V.

American Society of Anaesthesiologists (ASA) grade:

III - severe systemic disease that limits activity but is not incapacitating.
IV - incapacitating systemic disease which is constantly life threatening.
V - moribund, not expected to survive 24 hours without surgery.

C. Anatomical Suitability (for infrarenal AAA)

1) Proximal Neck

a) 10 mm. in length.
b) 32 mm. in diameter.
c) infrarenal neck/AAA angulation 80 degrees.
d) free of circumferential aortic calcification and/or significant thrombus.

2) at least one common iliac artery must be patent and 6 mm. in diameter.

3) iliac artery angulation <90 degrees or <60 degrees in presence of severe calcification.

4) dispensable inferior mesenteric artery.

D. Exclusion Criteria

1. unsuitable anatomy.
2. serious systemic or groin infection.
3. anaphylactic reaction to contrast material (true anaphylaxis).
4. allergy to stainless steel or polyester.
5. serious (uncorrectable) coagulopathy.
6. unwillingness or inability to comply with follow-up surveillance protocol.
7. patient’s life expectancy estimated at <2 years.

Appendix II Literature Search Strategy

Appendix II Search Strategy

Database: Ovid MEDLINE(R) <1966 to November Week 1 2004>

Search Strategy:

1 exp aortic aneurysm/ (23889)

2 (aort$ or aneurysm).mp. (188326)

3 1 or 2 (188326)

4 aorta abdominal/ (14624)

5 abdominal aortic aneurysm/ (6431)

6 aaa.mp. (3492)

7 abdom$.mp. (152145)

8 4 or 5 or 6 or 7 (162211)

9 3 and 8 (27344)

10 blood vessel prosthesis/ (16545)

11 vascular surgical procedures/ or blood vessel prosthesis implantation/ (15834)

12 exp stents/ (19355)

13 endograft.mp. (434)

14 evar.mp. (131)

15 evr.mp. (90)

16 endovascular repair.mp. (837)

17 endoluminal.mp. (1854)

18 stent$.mp. (26131)

19 (ancure or vanguard or trivascular or aneurx or talent or challenger or quantum lp or lifepath or excluder or zenith or powerlink or anaconda).mp. (1422)

20 Prosthesis Failure/ (10860)

21 endoleak.mp. (544)

22 graft migration.mp. (105)

23 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 (65925)

24 9 and 23 (6524)

25 exp clinical trials/ (162302)

26 exp comparative study/ (1175521)

27 clinical trial$.mp. (184327)

28 compar$.mp. (2393239)

29 study.mp. (2135660)

30 registr$.mp. (48643)

31 (prosp$ or retrosp$).mp. (503656)

32 25 or 26 or 27 or 28 or 29 or 30 or 31 (4039859)

33 24 and 32 (2563)

34 limit 33 to yr=1990 - 2004 (2156)

35 limit 34 to english language (1805)

36 limit 35 to human (1570)

Appendix II Search Strategy

Database: EMBASE <1980 to 2004 Week 46>

Search Strategy:

---

1 exp aortic aneurysm/ (11920)

2 (aort$ or aneurysm).mp. (128173)

3 1 or 2 (128594)

4 aorta abdominal/ (3207)

5 abdominal aortic aneurysm/ (5978)

6 aaa.mp. (2868)

7 abdom$.mp. (132923)

8 4 or 5 or 6 or 7 (134069)

9 3 and 8 (15700)

10 exp blood vessel prosthesis/ (3329)

11 vascular surgery/ (9231)

12 endovascular surgery/ (3862)

13 aorta surgery/ or aorta graft/ or aorta prosthesis/ (4909)

14 stent/ (13744)

15 endograft.mp. (396)

16 evar.mp. (129)

17 evr.mp. (71)

18 endovascular repair.mp. (759)

19 endoluminal.mp. (1719)

20 stent$.mp. (23562)

21 (ancure or vanguard or trivascular or aneurx or talent or challenger or quantum lp or lifepath or excluder or zenith or powerlink or anaconda).mp. (1197)

22 exp Prosthesis Failure/ (7858)

23 endoleak.mp. (546)

24 graft migration.mp. (97)

25 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (49660)

26 9 and 25 (3866)

27 exp clinical trial/ (325036)

28 exp clinical study/ (2814568)

29 exp comparative study/ (200835)

30 clinical trial$.mp. (358343)

31 compar$.mp. (1482979)

32 study.mp. (1754214)

33 registr$.mp. (29514)

34 (prosp$ or retrosp$).mp. (316591)

35 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 (4496121)

36 26 and 35 (3219)

37 limit 36 to yr=1990-2005 (2677)

38 limit 37 to english language (2372)

39 limit 38 to human (2210)

Appendix II Search Strategy

Database: CINAHL - Cumulative Index to Nursing & Allied Health Literature <1982 to November Week 2 2004>

Search Strategy:

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1 exp aortic aneurysm/ (541)

2 (aort$ or aneurysm).mp. (2348)

3 1 or 2 (2348)

4 exp Aorta, Abdominal/ (32)

5 exp Aortic Aneurysm, Abdominal/ (266)

6 aaa.mp. (95)

7 abdom$.mp. (4539)

8 4 or 5 or 6 or 7 (4661)

9 3 and 8 (428)

10 exp Blood Vessel Prosthesis/ (50)

11 exp Vascular Surgery/ (2314)

12 exp Stents/ (835)

13 exp Grafts/ (1744)

14 evar.mp. (2)

15 evr.mp. (3)

16 endovascular repair.mp. (37)

17 endoluminal repair.mp. (2)

18 stent$.mp. (1011)

19 (ancure or vanguard or trivascular or aneurx or talent or challenger or quantum lp or lifepath or excluder or zenith or powerlink or anaconda).mp. (195)

20 exp Prosthesis Failure/ (182)

21 endoleak.mp. (12)

22 graft migration.mp. (2)

23 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 (4945)

24 9 and 23 (103)

25 exp Clinical Trials/ (26899)

26 exp Comparative Studies/ (25419)

27 clinical trial$.mp. (23463)

28 compar$.mp. (72119)

29 study.mp. (130503)

30 registr$.mp. (5128)

31 (prosp$ or retrosp$).mp. (53073)

32 25 or 26 or 27 or 28 or 29 or 30 or 31 (199410)

33 24 and 32 (31)

34 limit 33 to yr=1990 - 2005 (31)

35 limit 34 to english (31)

36 from 35 keep 1-31 (31)

Appendix II Search Strategy

Database: CDSR, ACP Journal Club, DARE, CCTR

Search Strategy:

---

1 exp aortic aneurysm/ (257)

2 (aort$ or aneurysm).mp. (3542)

3 1 or 2 (3542)

4 exp aorta abdominal/ (221)

5 exp abdominal aortic aneurysm/ (176)

6 aaa.mp. (120)

7 abdom$.mp. (8468)

8 4 or 5 or 6 or 7 (8497)

9 3 and 8 (654)

10 blood vessel prosthesis.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (374)

11 vascular surgery.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (426)

12 exp stent$/ (756)

13 exp grafts/ (5)

14 evar.mp. (4)

15 evr.mp. (7)

16 endovascular repair.mp. (16)

17 endoluminal repair.mp. (1)

18 stent$.mp. (1522)

19 (ancure or vanguard or trivascular or aneurx or talent or challenger or quantum lp or lifepath or excluder or zenith or powerlink or anaconda).mp. (45)

20 prosthesis failure.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (204)

21 endoleak.mp. (11)

22 graft migration.mp. (2)

23 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 (2427)

24 9 and 23 (138)

25 clincal trials.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (10)

26 comparative studies.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] (816)

27 clinical trials.mp. (43625)

28 compar$.mp. (205886)

29 study.mp. (249859)

30 registr$.mp. (1599)

31 (prosp$ or retrosp$).mp. (57549)

32 25 or 26 or 27 or 28 or 29 or 30 or 31 (304036)

33 24 and 32 (128)

34 limit 33 to yr=1990 - 2004 [Limit not valid in: DARE; records were retained] (106)

35 from 34 keep 1-106 (106)

Database: Health and Psychosocial Instruments <1985 to September 2004>

Search Strategy:

---

1 aortic aneurysm.mp. [mp=title, acronym, descriptors, abstract] (1)

2 (aort$ or aneurysm).mp. [mp=title, acronym, descriptors, abstract] (33)

3 1 or 2 (33)

4 abdominal aortic aneurysm.mp. [mp=title, acronym, descriptors, abstract] (1)

5 aaa.mp. (5)

6 abdom$.mp. (91)

7 4 or 5 or 6 (95)

8 3 and 7 (2)

9 from 8 keep 1-2 (2)

Relevant articles (0)

Appendix II Search Strategy

Table 44. Summary of references obtained from each database

Database(s)	Number of Citations
MEDLINE	1570
MEDLINE duplicate citations	32
MEDLINE final number of citations	1538
EMBASE	2210
EMBASE duplicate citations	5
EMBASE final number of citations	2205
CINAHL	31
CDSR, ACP Journal Club, DARE and CCTR	106
Health and Psychosocial Instruments	0
Total number of References	3919
Total number of Unique References	2980

Table 45. Identification of databases containing final citations

Database(s)	Subtotal	Cumulative
EMBASE only	1386	1386
MEDLINE only	691	2077
Cochrane only	34	2111
CINAHL only	14	2125
EMBASE, MEDLINE	769	2894
MEDLINE, Cochrane	33	2927
EMBASE, Cochrane	7	2934
MEDLINE, CINAHL	6	2940
EMBASE, CINAHL	2	2942
EMBASE, MEDLINE, Cochrane	29	2971
EMBASE, MEDLINE, CINAHL	9	2980

Appendix III Literature Screening & Data Abstraction Forms

EVAR Study Data Abstraction Form

Reviewer Initials: _____ RefMan no: _____
Study Rating: + / 0 / - Date: _____
Citation: _____

Inclusion criteria for Literature Review:

Study examined Abdominal Aortic Aneurysm (AAA)	Yes	No
Study examined non-ruptured AAA	Yes	No
Mean AAA size > 5 cm	Yes	No
Publication date is 1991 onwards	Yes	No

Study Information:

First Author: _____ Country: _____
Year of Publication: _____ Randomization: _____
Study Time: _____
Duration of outcomes: Perioperative (Yes/No). Long-term follow-up: __ months.
Study Type: RCT, Case Control, Observational, Lit. Review, Other _____
Prospective or Retrospective: _____

EVAR suitability in OSR group	Yes	No
Risk Level: High / Low / Unspecified		
Kaplan Meier Estimates	Yes	No

Study Objectives:

_____

_____

_____

	Study Arm	
Characteristics	**EVAR**	**OSR**
# of patients		
% Males		
Mean age		
Mean AAA size ± s.d.		
Median AAA size (range)		
SVS risk levels		
ASA risk levels		
Risk Factors (# patients)		
Tobacco use		

Hypertension		
Diabetes		
Hyperlipidemia		
Cardiac disease		
Cerebral vascular disease		
Pulmonary disease		
Peripheral vascular disease		
Renal problems		
Strokes		
Procedural information		
Length of procedure (hrs)		
Mean blood loss (ml)		
Time in ICU (days)		
Length of hospital stay (days)		
Recovery Time (days)		
Devices Used		
Outcomes		
Deaths < 30 days		
Deaths > 30 days		
Endoleaks (< 30 days)		
Type 1 (distal attachment)		
Type 1 (proximal attachment)		
Type 1 (unspecified)		
Type 2 (retrograde flow to branches)		
Type 3 (graft degeneration)		
Type 4 (porosity)		
Endoleaks (> 30 days)		
Type 1 (distal attachment)		
Type 1 (proximal attachment)		
Type 1 (unspecified)		
Type 2 (retrograde flow to branches)		
Type 3 (graft degeneration)		
Type 4 (porosity)		
Secondary Procedures (< 30 days)		
Amputation		
Endograft extension/cuff		
Conversion to open repair		
Eendograft/artery stent		

Endograft/artery PTCA		
AAA embolization		
Artery bypass		
Femofemoral endograft		
Aortoiliac endografting		
Total graft removal		
Rupture		
Amputation		
Endograft extension/cuff		
Conversion to open repair		
Endograft/artery stent		
Secondary Procedures (> 30 days)		
Amputation		
Endograft extension/cuff		
Conversion to open repair		
Eendograft/artery stent		
Endograft/artery PTCA		
AAA embolization		
Artery bypass		
Femofemoral endograft		
Aortoiliac endografting		
Total graft removal		
Rupture		
Amputation		
Endograft extension/cuff		
Conversion to open repair		
Endograft/artery stent		
Cardiac Complications (< 30 days)		
Cardiac (MI)		
Cardiac (CHF)		
Cardiac (arryth)		
Cardiac (angina)		
Cardiac - unspecified/other		
Cardiac - major		
Cardiac - moderate		
Cardiac Complications (> 30 days)		
Cardiac (MI)		
Cardiac (CHF)		
Cardiac (arryth)		
Cardiac (angina)		
Cardiac - unspecified/other		

Cardiac - major		
Cardiac - moderate		
Pulmonary Complications (< 30 days)		
Pulmonary (failure)		
Pulmonary (edema)		
Pulmonary (pneumonia)		
Pulmonary (pneumothorax)		
Pulmonary (embolism)		
Pulmonary - unspecified		
Pulmonary - major (if not specified)		
Pulmonary - moderate (if not specified)		
Pulmonary Complications (> 30 days)		
Pulmonary (failure)		
Pulmonary (edema)		
Pulmonary (pneumonia)		
Pulmonary (pneumothorax)		
Pulmonary (embolism)		
Pulmonary - unspecified		
Pulmonary - major (if not specified)		
Pulmonary - moderate (if not specified)		
Renal Complications (< 30 days)		
Renal (permanent failure)		
Renal (temp failure)		
Renal - unspecified		
Renal - major		
Renal - moderate		
Renal Complications (> 30 days)		
Renal (permanent failure)		
Renal (temp failure)		
Renal - unspecified		
Renal - major		
Renal - moderate		
Neural Complications (< 30 days)		
Stroke		
TIA		
Bowel/colon ischemia		
Limb ischemia		
Other ischemia		

Neural Complications (> 30 days)		
Stroke		
TIA		
Bowel/colon ischemia		
Limb ischemia		
Other ischemia		
Other Graft Problems (< 30 days)		
Graft obstruction		
Graft infection		
Graft kinks or folds		
Graft migration		
Graft thrombosis		
Arterial or graft obstruction		
Other Graft Problems (> 30 days)		
Graft obstruction		
Graft infection		
Graft kinks or folds		
Graft migration		
Graft thrombosis		
Arterial or graft obstruction		
Surgical Complications (< 30 days)		
Hemorrhage - major		
Hemorrhage - moderate		
Thromboembolism - major		
Thromboembolism - moderate		
Groin hemotoma / seroma / lymphocoele - minor		
Obstruction of main renal artery		
Iatrogenic perforation - severe		
Surgical Complications (> 30 days)		
Hemorrhage - major		
Hemorrhage - moderate		
Thromboembolism - major		
Thromboembolism - moderate		
Groin hemotoma / seroma / lymphocoele - minor		
Obstruction of main renal artery		
Iatrogenic perforation - severe		

Surgical Complications (< 30 days)		
Groin/wound infection		
Peudoaneurysm - abdominal		
Pseudoaneurysm - groin		
Aortenteric fistula		
Groin - major problem		
Wound - major problem (hernia,etc)		
Iatrogenic perforation - severe		
Surgical Complications (> 30 days)		
Groin/wound infection		
Peudoaneurysm - abdominal		
Pseudoaneurysm - groin		
Aortenteric fistula		
Groin - major problem		
Wound - major problem (hernia,etc)		
Iatrogenic perforation - severe		
Other		
Dehiscence		
Parapalegia (Tefera)		
Prolonged ileus		
Delerium tremors		
Sciatic nerve palsy		
Erectile/orgasmic function		

EVAR Full Text Screening
Identification of Unique Patient Populations

Refman #: _____
Author: _____
Publication Year: _____

Time period of patient enrollment: _____ to _____

In what country(ies) was the study conducted
(also specify States/Provinces if provided)

Is this study a single centre report or from multiple centres?

Single Multiple

If from a single centre please provide the name of the centre.

Centre name: _____

Is this study a subanalysis of a multiple centre trial?

Yes No Can't Tell

What was (were) the primary device(s) used in the study?

Comparing this study to the other trials, is this study a unique or primary publication of patient data.

Yes No Can't tell

If No, then is this study the most recent publication from the centre with greatest sample size.

Yes No Can't tell

Reviewed by (initials): _____ Date: _____

Appendix IV Articles Included in Systematic Review

Comparative Clinical Studies (n = 96) including studies with duplicate patient information (listed alphabetically)

Aho P-S, Niemi T, Lindgren L, Lepantalo M. Endovascular vs open AAA repair: Similar effects on renal proximal tubular function. Scandinavian Journal of Surgery: SJS 2004; 93(1):52-56.

Akkersdijk GJM, Prinssen M, Blankensteijn JD. The impact of endovascular treatment on in-hospital mortality following non-ruptured AAA repair over a decade: A population based study of 16,446 patients. European Journal of Vascular & Endovascular Surgery 2004; 28(1):41-46.

Allen BT, Hovsepian DM, Reilly JM, Rubin BG, Malden E, Keller CA et al. Endovascular stent grafts for aneurysmal and occlusive vascular disease. American Journal of Surgery 1998; 176(6):574-580.

Anderson PL, Arons RR, Moskowitz AJ, Gelijns A, Magnell C, Faries PL et al. A statewide experience with endovascular abdominal aortic aneurysm repair: Rapid diffusion with excellent early results. Journal of Vascular Surgery 2004; 39(1):10-19.

Angle N, Dorafshar AH, Moore WS, ones-Baldrich WJ, Gelabert HA, Ahn SS et al. Open versus endovascular repair of abdominal aortic aneurysms: What does each really cost? Annals of Vascular Surgery 2004; 18(5):612-618.

Aquino RV, Jones MA, Zullo TG, Missig-Carroll N, Makaroun MS. Quality of life assessment in patients undergoing endovascular or conventional AAA repair. Journal of Endovascular Therapy 2001; 8[5]: -528.

Arko FR, Lee WA, Hill BB, Olcott C, Dalman RL, Harris Jr EJ et al. Aneurysm-related death: Primary endpoint analysis for comparison of open and endovascular repair. Journal of Vascular Surgery 2002; 36(2):297-304.

Arko FR, Hill BB, Olcott C. Endovascular repair reduces early and late morbidity compared to open surgery for abdominal aortic aneurysm. Journal of Endovascular Therapy 2002; 9(6):711-718.

Arko FR, Hill BB, Reeves TR, Olcott IC, Harris Jr EJ, Fogarty TJ et al. Early and late functional outcome assessments following endovascular and open aneurysm repair. Journal of Endovascular Therapy 2003; 10(1):2-9.

Ballard JL, Abou-Zamzam AM, Teruya TH, Bianchi C, Petersen FF, Quinones W et al. Quality of life before and after endovascular and retroperitoneal abdominal aortic aneurysm repair. Journal of Vascular Surgery 2004; 39(4):797-803.

Baxendale BR, Baker DM, Hutchinson A, Chuter TA, Wenham PW, Hopkinson BR. Haemodynamic and metabolic response to endovascular repair of infra-renal aortic aneurysms. British Journal of Anaesthesia 1996; 77[5]: 581-585.

Becquemin J-P, Bourriez A, d'Audiffret A, Zubilewicz T, Kobeiter H, Allaire E et al. Mid-term results of endovascular versus open repair for abdominal aortic aneurysm in patients anatomically suitable for endovascular repair. European Journal of Vascular & Endovascular Surgery 2000; 19(6):656-661.

Beebe HG, Cronenwett JL, Katzen BT, Brewster DC, Green RM. Results of an aortic endograft trial: Impact of device failure beyond 12 months. Journal of Vascular Surgery 2001; 33: S55-S64.

Berman SS.Gentile AT.Berens ES.Haskell. Institutional economic losses associated with AAA repair are independent of technique. Journal of Endovascular Therapy 2002; 9(3):282-288.

Bertrand M, Godet G, Koskas F, Cluzel P, Fleron M-H, Kieffer E et al. Endovascular treatment of abdominal aortic aneurysms: Is there a benefit regarding postoperative outcome? European Journal of Anaesthesiology 2001; 18(4):245-250.

Birch SE, Stary DR, Scott AR. Cost of endovascular versus open surgical repair of abdominal aortic aneurysms. Australian & New Zealand Journal of Surgery 2000; 70(9):660-666.

Bolke E, Jehle PM, Storck M, Braun C, Schams S, Steinbach G et al. Endovascular stent-graft placement versus conventional open surgery in infrarenal aortic aneurysm: A prospective study on acute phase response and clinical outcome. Clinica Chimica Acta 2001; 314(1-2):203-207.

Bosch JL, Lester JS, McMahon PM, Beinfeld MT, Halpern EF, Kaufman JA et al. Hospital costs for elective endovascular and surgical repairs of infrarenal abdominal aortic aneurysms. Radiology 2001; 220(2):492-497.

Boyle JR, Thompson JP, Thompson MM, Sayers RD, Smith G, Bell PRF. Improved respiratory function and analgesia control after endovascular AAA repair. Journal of Endovascular Surgery 1997; 4(1):62-65.

Boyle JR, Thompson MM, Sayers RD, Nasim A, Healey P, Bell PRF. Changes in referral practice, workload, and operative mortality after establishment of an endovascular abdominal aortic aneurysm program. Journal of Endovascular Surgery 1998; 5(3):201-205.

Boyle JR, Goodall S, Thompson JP, Bell PRF, Thompson MM. Endovascular AAA repair attenuates the inflammatory and renal responses associated with conventional surgery. Journal of Endovascular Therapy 2000; 7(5):359-371.

Bracale G, Porcellini M, Spinetti F, Cecere D, Bracale UM, Del Guercio L et al. Standard open surgical repair versus endovascular repair of anastomotic abdominal aortic aneurysms. Giornale Italiano di Chirurgia Vascolare 2003; 10(3):223-237.

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Appendix IV Articles Included in Systematic Review

Table 46. Comparative clinical studies reviewed and identification of unique publication of patient data.

Author	Year	Study Location	Randomized	Enrollment Start	Enrollment Finish	Outcome	EVAR (n)	OSR (n)	Unique	Primary Study/Exclusion Rationale
Cuypers PWM	2001	Netherlands	Yes	Sep 1996	Oct 1999	Mortality/Morbidity	57	19	Unique	
Lottman PEM	2004	Netherlands	Yes	Sep 1996	Oct 1999	QOL	57	19	no	Cuypers PWM 2001
Cuypers PWM	2001	Netherlands	No	May 1996	Aug 1998	Cardiac response	49	71	no	Cuypers PWM 2001
Greenberg RK	2004	United States	Yes	Jan 2000	Jul 2001	Mortality/Morbidity	200	80	Unique	
Greenhalgh RM	2004	United Kingdom	Yes	Sep 1999	Dec 2003	Mortality/Morbidity	543	539	Unique	
Prinssen M	2004	Netherlands, Belgium	Yes	Nov 2000	Dec 2003	Mortality/Morbidity	171	174	Unique	
Prinssen M	2004	Netherlands, Belgium	Yes	Nov 1999	Aug 2002	QOL	77	76	no	Prinssen M 2004
Aho P	2004	Finland	No	na	na	Renal function	15	9	Unique	
Akkersdijk GJM	2004	Netherlands	No	Jan 1990	Dec 2000	Mortality/Morbidity	857	15589	Unique	
Allen BT	1998	United States	No	Mar 1996	Feb 1998	Mortality/Morbidity	34	9	Unique	
Bracale G	2003	Italy	No	Jan 1994	Dec 2001	anastomotic aneurysms	13	8	no	Anastomotic aneurysms only
Makaroun MS	2002	United States	No	Dec 1995	Feb 1998	Mortality/Morbidity	242	111	Ancure	Ancure
Moore WS	2001	United States	No	Apr 1996	Dec 1998	Mortality/Morbidity	542	111	Ancure	Ancure
Aquino RV	2001	United States	No	Dec 1997	Apr 1999	QOL	25	26	Ancure	Ancure
Quinones-Baldrich	1999	United States	No	Feb 1993	Aug 1997	Cost	61	64	Ancure	Ancure
Moore WS	1999	United States	No	Jan 1992	Dec 1998	Mortality/Morbidity	100	100	Ancure	Ancure
Brewster DC	1998	United States	No	Jan 1994	May 1997	Mortality/Morbidity	28	28	Ancure	Ancure
Makaroun M	1998	United States	No	Feb 1996	Jan 1998	Mortality/Morbidity	50	69	Ancure	Ancure
Anderson PL	2004	United States	No	Jan 2000	Dec 2002	Mortality/Morbidity	871	783	Unique	
Angle N	2004	United States	No	Jul 2000	Sep 2001	Cost	55	64	Unique	

Author	Year	Study Location	Randomized	Enrollment Start	Enrollment Finish	Outcome	EVAR (n)	OSR (n)	Unique	Primary Study/Exclusion Rationale
Arko FR	2003	United States	No	Oct 1996	Jul 2000	Mortality	153	141	Unique	
Arko FR	2002	United States	No	Jul 1993	Jun 2000	Mortality/Morbidity	177	264	no	Arko FR 2003
Hill BB	2002	United States	No	Aug 1995	Nov 1998	Mortality/Morbidity	79	70	no	Arko FR 2003
Arko FR	2002	United States	No	Jan 1996	May 2000	Mortality/Morbidity	200	297	no	Arko FR 2003
Zarins CK	2000	United States	No	Nov 1996	Feb 2000	Mortality/Morbidity	149	268	no	Arko FR 2003
Ballard JL	2004	United States	No	Oct 2000	May 2003	QOL	22	107	Unique	
Baxendale BR	1996	United Kingdom	No	na	na	Metabolic repsonses	10	10	Unique	
Becquemin J	2000	France	No	Jan 1995	Mar 1999	Mortality/Morbidity	73	107	Unique	
Beebe HG	2001	United States	No	Aug 1997	Sep 1998	Mortality/Morbidity	268	98	Unique	
Berman SS	2002	United States	No	Aug 1999	Aug 2000	Cost	9	11	Unique	
Bertrand M	2001	France	No	Jan 1997	Jun 2000	Mortality/Morbidity	193	193	Unique	
Birch SE	2000	Australia	No	Jun 1996	Oct 1999	Cost	31	31	Unique	
Cao	2004	Italy	No	Jan 1997	Dec 2003	Mortality/Morbidity	534	585	Unique	
Carpenter JP	2002	United States	No	Oct 1998	Dec 2000	Long term outcomes	174	163	Unique	
Ceelen W	1999	Belgium	No	na	na	Cost	9	20	Unique	
Clair DG	2000	United States	No	Jan 1998	Oct 1998	Cost	45	90	Unique	
Cohnert TU	2000	Germany	No	Apr 1996	Jul 1998	Mortality/Morbidity	37	37	Unique	
Criado FJ	2003	United States	No	Mar 1999	Sep 2000	Mortality/Morbidity	240	126	Unique	
de Virgilio C	1999	United States	No	Jul 1995	Jul 1998	Cardiac response	83	63	Unique	
Decker D	2003	Germany	No	na	na	Surgical response	16	16	Unique	
Dias NV	2003	Sweden	No	May 1998	Dec 2001	Mortality/Morbidity	117	11	Unique	
Dryjski M	2003	United States	No	Jan 2000	Dec 2000	Cost	73	57	Unique	
Du Toit DF	1998	South Africa	No	na	na	Acute phase response	12	10	Unique	
Elkouri S	2004	United States	No	Dec 1999	Dec 2001	Mortality/Morbidity	94	261	Unique	

Author	Year	Study Location	Randomized	Enrollment Start	Enrollment Finish	Outcome	EVAR (n)	OSR (n)	Unique	Primary Study/Exclusion Rationale
Forbes TL	2002	Canada	No	Jan 1988	Dec 1989	Cost	7	31	Unique	
Galle C	2000	Belgium	No	na	na	Inflammatory response	7	5	Unique	
Garcia-Madrid C	2004	Spain	No	Mar 1997	Aug 2000	Mortality/Morbidity	53	30	Unique	
Gawenda M	2003	Germany	No	Jan 1985	Dec 2002	Anastomotic aneurysms	10	16	Unique	
Hansman MF	2003	United States	No	Nov 1999	Jan 2002	Mortality/Morbidity	50	50	Unique	
Jordan WD	2003	United States	No	Jan 2000	Jun 2002	Mortality/Morbidity	129	58	Unique	
Junnarkar S	2003	Ireland	No	na	na	Renal function	7	8	Unique	
Kahn RA	1999	United States	No	Apr 1995	Mar 1997	Hemodynamic response	17	72	Unique	
Lee WA	2004	United States	No	Jan 2001	Dec 2001	Mortality/Morbidity	2565	4607	Unique	
Lifeline Registry	2002	United States, Canada	No	na	na	Mortality/Morbidity	1646	111	Unique	
Ligush JJ	2002	United States	No	Dec 1999	Jun 2001	Identification of predictive medical risks	33	66	Unique	
Malina M	2000	Sweden	No	May 1997	Mar 1998	QOL	21	21	Unique	
Metzsch C	2001	Sweden	No	na	na	Metabolic repsonses	8	8	no	Malina M 2000
Syk I	1998	Sweden	No	na	na	Bowel ischemia	23	14	no	Malina M 2000
Syk I	1999	Sweden	No	na	na	Immune response	26	16	no	Malina M 2000 – No info on time
Swartbol P	1996	Sweden	No	na	na	Inflammatory response	7	7	no	Malina M 2000 – No info on time
Matsumura JS	2003	United States	No	na	na	Mortality/Morbidity	235	99	Unique	
Kibbe MR	2003	United States	No	na	na	Mortality/Morbidity long term data	235	99	Unique	
May J	2001	Australia	No	May 1995	Dec 1998	Life table estimates	148	135	Unique	
May J	1998	Australia	No	May 1992	May 1996	Mortality/Morbidity	108	195	no	May J 2001
White GH	1996	Australia	No	May 1992	Nov 1994	Mortality/Morbidity	28	27	no	May J 1998

Author	Year	Study Location	Randomized	Enrollment Start	Enrollment Finish	Outcome	EVAR (n)	OSR (n)	Unique	Primary Study/Exclusion Rationale
Bosch JL	2001	United States	No	Jan 1997	Sep 1999	Cost	182	274	no	Multiple Clinical Trials
Sicard GA	2001	United States	No	Jan 1997	Oct 2000	Mortality/Morbidity	260	210	no	Multiple Clinical Trials
Xenos ES	2003	United States	No	Jan 1999	Jul 2002	Erectile function	40	31	no	No Clinical Data Available
Jones MA	2002	United States	No	na	na	Effects of early discharge	25	26	no	No Clinical Data Available
Odegard A	2000	Norway	No	na	na	Inflammatory response	10	10	Unique	
Patel AP	2003	United States	No	Jan 1996	Dec 2001	Mortality/Morbidity	16	35	Unique	
Rowlands TE	2001	United Kingdom	No	na	na	Inflammatory response	16	16	Unique	
Sangiorgi G	2001	Italy	No	Aug 1999	Oct 2000	Abdominal wall matrix proteins	30	15	Unique	
Scharrer-Pamler R	1999	Germany	No	Oct 1996	Aug 1997	Mortality/Morbidity	31	29	Unique	
Bolke E	2001	Germany	No	Jan 1996	Dec 2000	Acute phase response	20	20	no	Scharrer-Pamler R 1999
Seiwert AJ	1999	United States	No	Mar 1997	Apr 1998	Mortality/Morbidity/Cost	16	16	Unique	
Teufelsbauer H	2002	Austria	No	Jan 1995	Dec 2000	Propensity score analysis	206	248	Unique	
Kozon A	1998	Austria	Yes	Mar 1995	Apr 1996	Nursing dependancy	25	25	no	Teufelsbauer H 2002
Holzenbein T	1997	Austria	No	Feb 1995	Mar 1996	Cost	22	22	no	Teufelsbauer H 2002
Ting ACW	2003	Hong Kong	No	Jul 1999	Sep 2001	Mortality/Morbidity	27	25	Unique	
Treharne GD	1999	United Kingdom	No	Dec 1994	Nov 1997	Mortality/Morbidity	49	104	Unique	
Lloyd AJ	2000	United Kingdom	No	na	na	QOL	34	48	no	Treharne GD 1999
Thompson JP	1999	United Kingdom	No	na	na	Respiratory function	11	9	no	Treharne GD 1999
Boyle JR	1998	United Kingdom	No	Jan 1994	Dec 1996	Mortality	41	101	no	Treharne GD 1999

Author	Year	Study Location	Randomized	Enrollment Start	Enrollment Finish	Outcome	EVAR (n)	OSR (n)	Unique	Primary Study/Exclusion Rationale
Boyle JR	1997	United Kingdom	No	na	na	Respiratory function	12	10	no	Treharne GD 1999
Boyle JR	2000	United Kingdom	No	na	na	Inflammatory response	23	20	no	Treharne GD 1999 Possible
Turnipseed W	2003	United States	No	Jan 1999	Dec 2002	Mortality/Morbidity/Cost	70	96	Unique	
Tefera G	2004	United States	No	Jan 2000	Dec 2002	Mortality/Morbidity	61	23	no	Turnipseed W 2003
Van Sambeek MRHM	2002	The Netherlands	No	Jan 2001	Jul 2001	Feasibility	6	6	Unique	
Watson DR	2004	United States	No	Jun 2001	Mar 2003	Cost	69	118	Unique	
Wijnen MHWA	2001	The Netherlands	No	na	na	Renal response	15	22	Unique	
Zarins CK	1999	United States	No	May 1996	Nov 1997	Mortality/Morbidity	190	60	Unique	
Salartash K	2001	United States	No	na	na	Tissue stress response	10	9	no	Zarins CK 1999
Sternbergh III, WC	2000	United States	No	May 1996	Nov 1997	Cost	131	49	no	Zarins CK 1999
Zeebregts CJ	2004	Netherlands	No	Apr 1998	Jan 2003	Early and late outcomes	93	82	Unique	
Davies MJ	2002								Unique	Not available at time of interim analysis

Appendix V Characteristics of Studies and Patients

Comparative Clinical Studies (n = 59) including studies with unique patient information (listed alphabetically)

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Appendix V Characteristics of Studies and Patients

Table 47. Characteristics of unique comparative clinical trials included in analysis

Author	Year	Study Location	Rmd.	EVAR (n)	OSR (n)	EVAR recruitment	OSR recruitment	EVAR Anatomically Suitable	Surgical Risk Category	EVAR Device	EVAR Long-term follow-up (months)	OSR Long-term follow-up (months)
Greenberg RK	2004	United States	Yes	200	80	prospective	prospective	no		Zenith	12	12
Greenhalgh RM	2004	United Kingdom	Yes	543	539	prospective	prospective	suitable	low	Mixed		
Prinssen M	2004	Netherlands, Belgium	Yes	171	174	prospective	prospective	suitable	low	Mixed		
Cuypers PWM	2001	Netherlands	Yes	57	19	prospective	prospective	suitable	low	Mixed		
Aho P	2004	Finland	No	15	9	prospective	prospective	no		Mixed		
Akkersdijk GJM	2004	Netherlands	No	857	15589	retrospective	retrospective	no		AneuRx		
Anderson PL	2004	United States	No	871	783	retrospective	retrospective	no		na		
Angle N	2004	United States	No	55	64	retrospective	retrospective	no		Mixed		
Ballard JL	2004	United States	No	22	107	prospective	prospective			na	12	12
Cao	2004	Italy	No	534	585	prospective	prospective	no		Mixed	33	35
Elkouri S	2004	United States	No	94	261	retrospective	retrospective	no		Mixed	12	12
Garcia-Madrid C	2004	Spain	No	53	30	retrospective	retrospective	suitable		Mixed	36	36
Lee WA	2004	United States	No	2565	4607	retrospective	retrospective	no		na		
Watson DR	2004	United States	No	69	118	prospective	prospective	no		Mixed		
Zeebregts CJ	2004	Netherlands	No	93	82	prospective	prospective	no		Mixed	19.2	42.7
Arko FR	2003	United States	No	153	141	prospective	prospective	no		AneuRx	6	6
Criado FJ	2003	United States	No	240	126	prospective	prospective	no	low	Talent	13	10.5
Decker D	2003	Germany	No	16	16	prospective	retrospective	no		Vanguard		
Dias NV	2003	Sweden	No	117	11	prospective	retrospective	suitable		Zenith	21	43

Author	Year	Study Location	Rmd.	EVAR (n)	OSR (n)	EVAR recruitment	OSR recruitment	EVAR Anatomically Suitable	Surgical Risk Category	EVAR Device	EVAR Long-term follow-up (months)	OSR Long-term follow-up (months)
Dryjski M	2003	United States	No	73	57	retrospective	retrospective	no		Mixed		
Gawenda M	2003	Germany	No	10	16	retrospective	retrospective	suitable		na		
Hansman MF	2003	United States	No	50	50	prospective	retrospective	no		Mixed	12	12
Jordan WD	2003	United States	No	129	58	retrospective	retrospective	no	low	Mixed		
Junnarkar S	2003	Ireland	No	7	8	prospective	prospective	no		Mixed		
Kibbe MR	2003	United States	No	235	99	prospective	prospective	no		Excluder	24	24
Matsumura JS	2003	United States	No	235	99	prospective	prospective	no	high/low	Excluder	24	12
Patel AP	2003	United States	No	16	35	retrospective	retrospective	no	high	Mixed		
Ting ACW	2003	Hong Kong	No	27	25	prospective	prospective	no		Mixed	12	12
Turnipseed W	2003	United States	No	70	96	prospective	prospective	no		na		
Berman SS	2002	United States	No	9	11	prospective	prospective	no		Mixed		
Carpenter JP	2002	United States	No	174	163	retrospective	retrospective	no	high	Mixed	10.6	12.3
Forbes TL	2002	Canada	No	7	31	retrospective	retrospective	suitable		Vanguard		
Lifeline Registry	2002	United States, Canada	No	1646	111	retrospective	retrospective	no		na	12	12
Ligush JJ	2002	United States	No	33	66	retrospective	retrospective	no		AneuRx		
Teufelsbauer H	2002	Austria	No	206	248	retrospective	retrospective	no		Mixed	30	30
Van Sambeek MRHM	2002	Netherlands	No	6	6	prospective	prospective	no		Mixed		
Beebe HG	2001	United States	No	268	98	prospective	prospective	no		Vanguard	24	24
Bertrand M	2001	France	No	193	193	prospective	prospective	no		custom		
May J	2001	Australia	No	148	135	prospective	retrospective	no	high/low	Mixed	24	24
Rowlands TE	2001	United Kingdom	No	16	16	prospective	prospective	no		Mixed		
Sangiorgi G	2001	Italy	No	30	15	prospective	prospective	no		Mixed		

Author	Year	Study Location	Rmd.	EVAR (n)	OSR (n)	EVAR recruitment	OSR recruitment	EVAR Anatomically Suitable	Surgical Risk Category	EVAR Device	EVAR Long-term follow-up (months)	OSR Long-term follow-up (months)
Wijnen MHWA	2001	Netherlands	No	15	22	prospective	prospective	no		Mixed		
Becquemin J	2000	France	No	73	107	prospective	prospective	suitable	high/low	Mixed	12	12
Birch SE	2000	Australia	No	31	31	retrospective	retrospective	no		Mixed	12	12.5
Clair DG	2000	United States	No	45	90	prospective	prospective	no		AneuRx		
Cohnert TU	2000	Germany	No	37	37	prospective	retrospective	no		Mixed	12	12
Galle C	2000	Belgium	No	7	5	prospective	prospective	no		Corvita		
Malina M	2000	Sweden	No	21	21	prospective	prospective	no		Mixed	3	3
Odegard A	2000	Norway	No	10	10	prospective	prospective	no		Vanguard		
Ceelen W	1999	Belgium	No	9	20	retrospective	retrospective	no		Vanguard		
de Virgilio C	1999	United States	No	83	63	prospective	retrospective	no		na		
Kahn RA	1999	United States	No	17	72	retrospective	retrospective	na		na		
Scharrer-Pamler R	1999	Germany	No	31	29	prospective	prospective	no		Mixed		
Seiwert AJ	1999	United States	No	16	16	retrospective	retrospective	no		Mixed		
Treharne GD	1999	United Kingdom	No	49	104	prospective	prospective	no		Mixed		
Zarins CK	1999	United States	No	190	60	prospective	prospective	no		AneuRx		
Allen BT	1998	United States	No	34	9	prospective	prospective	no		Ancure	6	6
Du Toit DF	1998	South Africa	No	12	10	prospective	prospective	no	high	AneuRx		
Baxendale BR	1996	United Kingdom	No	10	10	prospective	prospective	no		Chuter		

Appendix VI Patient Baseline Clinical Characteristics

Appendix VI Patient Baseline Clinical Characteristics

Table 48. Patient Demographics and Aneurysm Size

Author	Year	EVAR (n)	OSR (n)	EVAR (% males)	OSR (% males)	EVAR age (mean)	OSR age (mean)	EVAR AA (cm) mean ± sd	EVAR AA Median (min - max)	OSR AA (cm) mean ± sd	OSR AA Median (min - max)
Greenberg RK	2004	200	80	93.5	88.75	71	69				
Greenhalgh RM	2004	543	539	91	91	74.2	74	6.5 ± 0.9		6.5 ± 1.0	
Prinssen M	2004	171	174	93	90.2	70.7	69.5	6.06 ± 0.90	5.8	6.00 ± 0.85	5.8
Cuypers PWM	2001	57	19	95	84	69	68	5.6	(5.2 - 8.4)	5.2	(4.0 - 6.1)
Aho P	2004	15	9	86.7	77.8	75	70	6.6 ± 0.6		5.8 ± 0.8	
Akkersdijk GJM	2004	857	15589								
Anderson PL	2004	871	783								
Angle N	2004	55	64			75.9	74.6	5.50 ± 0.98		6.1 ± 1.1	
Ballard JL	2004	22	107	20	81	77	72				
Cao	2004	534	585	94	90	73	72	5.20 ± 0.74		5.60 ± 0.89	
Elkouri S	2004	94	261						5.7		5.7
Garcia-Madrid C	2004	53	30	96.2	93.3	73	70	6.2		6.4	
Lee WA	2004	2565	4607	84.4	78.1	73.4	71.9				
Watson DR	2004	69	118	89.8	83.8	72.3	70.4	5.3	(4.9 - 7.5)		(4.6 - 9.7)
Zeebregts CJ	2004	93	82	93.5	90.2	70.9	69.1	6.02 ± 1.13		6.35 ± 1.28	
Arko FR	2003	153	141	83	86	74.2	73.8	5.76 ± 0.94	(4 - 8.7)	6.24 ± 0.18	(4.0 - 11.5)
Criado FJ	2003	240	126	90	80	75.5	70	5.67 ± 0.96	(4 - 10)		
Decker D	2003	16	16			67	62.8	5.2	(5 - 6.3)	5.1	(4.1 - 7.0)
Dias NV	2003	117	11	84	91	73	65	5.9	(5.3 - 6.6)	5.2	(4.8 - 6.2)
Dryjski M	2003	73	57	83	74	72.4	71.8				
Gawenda M	2003	10	16	90	87.5	52.5	57				

Author	Year	EVAR (n)	OSR (n)	EVAR (% males)	OSR (% males)	EVAR age (mean)	OSR age (mean)	EVAR AA (cm) mean ± sd	EVAR AA Median (min - max)	OSR AA (cm) mean ± sd	OSR AA Median (min - max)
Hansman MF	2003	50	50	84	76	72.5	72.1	5.5 ± 0.9		6.2 ± 1.3	
Jordan WD	2003	129	58	92.4	92.4	71	71	5.5	(3 - 12)		(3 - 12)
Junnarkar S	2003	7	8	85.7	75	74	72.5	6.2	(5.8 - 6.5)	6.6	(5.7 - 7.8)
Kibbe MR	2003	235	99	87	74	73	70.1	5.560 ± 0.061		5.860 ± 0.109	
Matsumura JS	2003	235	99	87	74	73	70.1	5.56 ± 0.06		5.86 ± 0.11	
Patel AP	2003	16	35	93.7	68.6	83.5	83				
Ting ACW	2003	27	25	88.9	76	74	73	6.3 ± 0.9	(4.7 - 8.2)	6.6 ± 1.4	(5 - 10)
Turnipseed W	2003	70	96	92.9	75	73	70	5.9		5.8	
Berman SS	2002	9	11			77.9	69.6				
Carpenter JP	2002	174	163	91.4	76.1	77.3	74				
Forbes TL	2002	7	31			70.8	71.7	6.1		6.2	
Lifeline Registry	2002	1646	111	88.6	76.6	73.1	71.1	5.57		5.51	
Ligush JJ	2002	33	66	88	88	71.9	69.7	5.4 ± 0.6		5.8 ± 1.2	
Teufelsbauer H	2002	206	248	89.8	91.5	73.4	70.6				
Van Sambeek MRHM	2002	6	6					6.3	(4.8 - 8.4)	8	(4.5 - 8.2)
Beebe HG	2001	268	98					5.4	(4 - 11.5)	5.7	(4.0 - 11.5)
Bertrand M	2001	193	193	94	90.6	72	70				
May J	2001	148	135	92.5	83	72	69				
Rowlands TE	2001	16	16	87.5	68.8			6.3		5.8	
Sangiorgi G	2001	30	15	80	80	66	65				
Wijnen MHWA	2001	15	22	86.7	90.9	69	70	5.4	(5 - 8.4)		(4.5 - 8.0)
Becquemin J	2000	73	107	90	93	70	69	5.00 ± 0.55		5.05 ± 1.10	
Birch SE	2000	31	31	87	81	73	72	5.70 ± 1.23		6.15 ± 1.29	
Clair DG	2000	45	90	86.6	83	75.5	71.1				

Author	Year	EVAR (n)	OSR (n)	EVAR (% males)	OSR (% males)	EVAR age (mean)	OSR age (mean)	EVAR AA (cm) mean ± sd	EVAR AA Median (min - max)	OSR AA (cm) mean ± sd	OSR AA Median (min - max)
Cohnert TU	2000	37	37	97	97	67.9	68.2	5.670 ± 0.074		6.02 ± 1.14	
Galle C	2000	7	5	100	100	73	66.2	5.637 ± 0.387		5.640 ± 0.595	
Malina M	2000	21	21	81	76	74	74				
Odegard A	2000	10	10	80	70	73	69	5.8	(5.3 - 6.3)	5.7	(5.3 - 6.7)
Ceelen W	1999	9	20			68	71		5.4		6.5
de Virgilio C	1999	83	63	84	91	73	65				
Kahn RA	1999	17	72	82	78	74	73				
Scharrer-Pamler R	1999	31	29	94	83	66.1	69.7	5.2		6.5	
Seiwert AJ	1999	16	16	56	81	7.2	7.3	5.1 ± 0.3		5.9 ± 0.4	
Treharne GD	1999	49	104	85.7	82.7	68	72	5.7	(4.7 - 7.6)	5.9	(4.9 - 9.8)
Zarins CK	1999	190	60	90	85	73	69	5.60 ± 0.90	(3.3 - 9)	5.6 ± 1.1	(3.5 - 10.0)
Allen BT	1998	34	9	93.3	56	71.8	71.8	5.23		4.99	
Du Toit DF	1998	12	10	72.5				5.5	(4.6 - 6.2)	6.63	
Baxendale BR	1996	10	10	90	90	68.5	72.9				

Appendix VI Patient Baseline Clinical Characteristics

Table 49. Comparison of patient baseline comorbidities in EVAR and OSR groups

Author	Year		n	Smoking	Cardiac	HTN	HLD	CVD	Stroke	PVD	Pulmonary	Diabetes	Renal
Greenberg RK	2004	EVAR	200	40 (20.0)		127 (63.5)		19 (9.5)		31 (15.5)	9 (4.5)	24 (12.0)	0 (0.0)
		OSR	80	28 (35.0)		65 (81.3)		13 (16.3)		19 (23.8)	14 (17.5)	12 (15.0)	0 (0.0)
Greenhalgh RM	2004	EVAR	543	115 (21.2)	234 (43.1)		177 (32.6)					49 (9.0)	
		OSR	539	117 (21.7)	229 (42.5)	181 (33.6)	181 (33.6)					62 (11.5)	
Prinssen M	2004	EVAR	171	111 (64.9)	70 (40.9)	99 (57.9)	80 (46.8)				47 (27.5)	17 (9.9)	13 (7.6)
		OSR	174	94 (54.0)	81 (46.6)	94 (54.0)	93 (53.4)				30.972 (17.8)	17 (9.8)	13 (7.5)
Cuypers PWM	2001	EVAR	57	26 (45.6)	25 (43.9)	31 (54.4)					17 (29.8)	8 (14.0)	
		OSR	19	5 (26.3)	10 (52.6)	12 (63.2)					4 (21.1)	4 (21.1)	
Aho P	2004	EVAR	15										
		OSR	9										
Akkersdijk GJM	2004	EVAR	857										
		OSR	15589										
Anderson PL	2004	EVAR	871	74 (8.5)	209 (24.0)	481 (55.2)	169 (19.4)			33 (3.8)	225 (25.8)	95 (10.9)	
		OSR	783	56 (7.2)	135 (17.2)	338 (43.2)	101 (12.9)			23 (2.9)	202 (25.8)	53 (6.8)	
Angle N	2004	EVAR	55		30 (54.5)	28 (50.9)			1 (1.8)		8 (14.5)	9 (16.4)	
		OSR	64		45 (70.3)	52 (81.3)			9 (14.1)		15 (23.4)	12 (18.8)	
Ballard JL	2004	EVAR	22	14 (63.6)	18 (81.8)	14 (63.6)	13 (59.1)				8 (36.4)	8 (36.4)	2 (9.1)
		OSR	107	78 (72.9)	85 (79.4)	87 (81.3)	61 (57.0)				57 (53.3)	20 (18.7)	19 (17.8)

Cao	2004	EVAR	534		248 (46.4)	355 (66.5)	248 (46.4)	76 (14.2)			298 (55.8)	49 (9.2)	61 (11.4)
		OSR	585		216 (36.9)	385 (65.8)	177 (30.3)	60 (10.3)			224 (38.3)	40 (6.8)	57 (9.7)
Elkouri S	2004	EVAR	94										
		OSR	261										
Garcia-Madrid C	2004	EVAR	53	46 (86.8)	36 (67.9)	45 (84.9)	29 (54.7)				42 (79.2)	12 (22.6)	13 (24.5)
		OSR	30	18 (60.0)	16 (53.3)	18 (60.0)	11 (36.7)				15 (50.0)	2 (6.7)	15 (50.0)
Lee WA	2004	EVAR	2565		506 (19.7)	1463 (57.0)		17 (0.7)		282 (11.0)	645 (25.1)	284 (11.1)	87 (3.4)
		OSR	4607		652 (14.2)	2436 (52.9)		19 (0.4)		576 (12.5)	1321 (28.7)	492 (10.7)	312 (6.8)
Watson DR	2004	EVAR	69	15 (21.7)	35 (50.7)	48 (69.6)	30 (43.5)			21 (30.4)	22 (31.9)	2 (2.9)	7 (10.1)
		OSR	118	25 (21.2)	59 (50.0)	81 (68.6)	48 (40.7)			20 (16.9)	38 (32.2)	3 (2.5)	6 (5.1)
Zeebregts CJ	2004	EVAR	93										
		OSR	82										
Arko FR	2003	EVAR	153		120 (78.4)	86 (56.2)					81 (52.9)	55 (35.9)	9 (5.9)
		OSR	141		107 (75.9)	86 (61.0)					66 (46.8)	41 (29.1)	13 (9.2)
Criado FJ	2003	EVAR	240	178 (74.2)	91 (37.9)	168 (70.0)			34 (14.2)	46 (19.2)		29 (12.1)	34 (14.2)
		OSR	126	103 (81.7)	32 (25.4)	95 (75.4)			16 (12.7)	24 (19.0)		9 (7.1)	10 (7.9)
Decker D	2003	EVAR	16										
		OSR	16										
Dias NV	2003	EVAR	117		54 (46.2)	68 (58.1)					30 (25.6)	8 (6.8)	8 (6.8)
		OSR	11		5 (45.5)	6 (54.5)					0 (0.0)	1 (9.1)	0 (0.0)

Dryjski M	2003	EVAR	73	15 (20.5)	43 (58.9)	49 (67.1)				18 (24.7)	22 (30.1)	8 (11.0)	
		OSR	57	8 (14.0)	34 (59.6)	29 (50.9)		3 (5.3)		8 (14.0)	9 (15.8)	3 (5.3)	
Gawenda M	2003	EVAR	10	4 (40.0)	4 (40.0)	7 (70.0)					3 (30.0)	0 (0.0)	1 (10.0)
		OSR	16	5 (31.3)	5 (31.3)	8 (50.0)		0 (0.0)			5 (31.3)	1 (6.3)	1 (6.3)
Hansman MF	2003	EVAR	50	27 (54.0)	24 (48.0)	30 (60.0)		9 (18.0)			11 (22.0)	11 (22.0)	
		OSR	50	31 (62.0)	27 (54.0)	44 (88.0)		12 (24.0)			13 (26.0)	11 (22.0)	
Jordan WD	2003	EVAR	129										
		OSR	58										
Junnarkar S	2003	EVAR	7										
		OSR	8										
Kibbe MR	2003	EVAR	235				116 (49.4)						
		OSR	99				38 (38.4)						
Matsumura JS	2003	EVAR	235				116 (49.4)						
		OSR	99				38 (38.4)						
Patel AP	2003	EVAR	16	12 (75.0)	6 (37.5)	14 (87.5)						2 (12.5)	
		OSR	35	34 (97.1)	18 (51.4)	31 (88.6)						1 (2.9)	
Ting ACW	2003	EVAR	27		12 (44.4)	17 (63.0)					5 (18.5)	0 (0.0)	8 (29.6)
		OSR	25		8 (32.0)	19 (76.0)					3 (12.0)	6 (24.0)	8 (32.0)
Turnipseed W	2003	EVAR	70		52 (74.3)	46 (65.7)					49 (70.0)	14 (20.0)	
		OSR	96		48 (50.0)	69 (71.9)					38 (39.6)	9 (9.4)	
Berman SS	2002	EVAR	9		4 (44.4)						6 (66.7)		
		OSR	11		5 (45.5)						7 (63.6)		

Carpenter JP	2002	EVAR	174		81 (46.6)	113 (64.9)					35 (20.1)		26 (14.9)
		OSR	163		47 (28.8)	108 (66.3)					33 (20.2)		20 (12.3)
Forbes TL	2002	EVAR	7										
		OSR	31										
Lifeline Registry	2002	EVAR	1646			1051 (63.9)					483 (29.3)	188 (11.4)	65 (3.9)
		OSR	111			79 (71.2)					33 (29.7)	11 (9.9)	5 (4.5)
Ligush JJ	2002	EVAR	33	29 (87.9)	18 (54.5)	25 (75.8)	18 (54.5)	6 (18.2)		4 (12.1)	23 (69.7)	8 (24.2)	8 (24.2)
		OSR	66	58 (87.9)	44 (66.7)	51 (77.3)	36 (54.5)	8 (12.1)		10 (15.2)	24 (36.4)	12 (18.2)	12 (18.2)
Teufelsbauer H	2002	EVAR	206	172 (83.5)	160 (77.7)	175 (85.0)		21 (10.2)			67 (32.5)	40 (19.4)	34 (16.5)
		OSR	248	155 (62.5)	114 (46.0)	128 (51.6)		32 (12.9)			34 (13.7)	22 (8.9)	27 (10.9)
Van Sambeek MRHM	2002	EVAR	6										
		OSR	6										
Beebe HG	2001	EVAR	268	230 (85.8)	88 (32.8)	153 (57.1)					82 (30.6)		
		OSR	98	95 (96.9)	38 (38.8)	63 (64.3)					33 (33.7)		
Bertrand M	2001	EVAR	193		83 (43.0)	112 (58.0)					81 (42.0)	10 (5.2)	35 (18.1)
		OSR	193		81 (42.0)	125 (64.8)					69 (35.8)	6 (3.1)	46 (23.8)
May J	2001	EVAR	148	27 (18.2)	83 (56.1)	52 (35.1)					10 (6.8)	10 (6.8)	12 (8.1)
		OSR	135	31 (23.0)	69 (51.1)	45 (33.3)						11 (8.1)	5 (3.7)
Rowlands TE	2001	EVAR	16										
		OSR	16										

Sangiorgi G	2001	EVAR	30	3 (10.0)	4 (13.3)	13 (43.3)	4 (13.3)				12 (40.0)	4 (13.3)	4 (13.3)
		OSR	15	3 (20.0)	5 (33.3)	9 (60.0)	3 (20.0)				6 (40.0)	2 (13.3)	1 (6.7)
Wijnen MHWA	2001	EVAR	15										
		OSR	22										
Becquemin J	2000	EVAR	73	25 (34.2)	41 (56.2)	39 (53.4)	22 (30.1)				18 (24.7)	8 (11.0)	8 (11.0)
		OSR	107	39 (36.4)	46 (43.0)	55 (51.4)	22 (20.6)				24 (22.4)	11 (10.3)	14 (13.1)
Birch SE	2000	EVAR	31		21 (67.7)	15 (48.4)	9 (29.0)	2 (6.5)		7 (22.6)		1 (3.2)	2 (6.5)
		OSR	31		17 (54.8)	17 (54.8)	11 (35.5)	2 (6.5)		6 (19.4)		3 (9.7)	2 (6.5)
Clair DG	2000	EVAR	45		30 (66.7)						19 (42.2)		
		OSR	90		52 (57.8)						29 (32.2)		
Cohnert TU	2000	EVAR	37		25 (67.6)	26 (70.3)	4 (10.8)		2 (5.4)			2 (5.4)	2 (5.4)
		OSR	37		23 (62.2)	22 (59.5)	7 (18.9)		3 (8.1)			1 (2.7)	2 (5.4)
Galle C	2000	EVAR	7	5 (71.4)	2 (28.6)	3 (42.9)	4 (57.1)	1 (14.3)			5 (71.4)	0 (0.0)	0 (0.0)
		OSR	5	5 (100.0)	1 (20.0)	2 (40.0)	3 (60.0)	0 (0.0)			5 (100.0)	0 (0.0)	0 (0.0)
Malina M	2000	EVAR	21		10 (47.6)	5 (23.8)					4 (19.0)		
		OSR	21		9 (42.9)	11 (52.4)					5 (23.8)		
Odegard A	2000	EVAR	10										
		OSR	10										
Ceelen W	1999	EVAR	9		1 (11.1)						3 (33.3)		
		OSR	20										
de Virgilio C	1999	EVAR	83									11 (13.3)	
		OSR	63									8 (12.7)	

Kahn RA	1999	EVAR	17		13 (76.5)	7 (41.2)		2 (11.8)			4 (23.5)	1 (5.9)	
		OSR	72		33 (45.8)	34 (47.2)		4 (5.6)			9 (12.5)	3 (4.2)	
Scharrer-Pamler R	1999	EVAR	31										
		OSR	29										
Seiwert AJ	1999	EVAR	16	11 (68.8)	4 (25.0)	6 (37.5)						0 (0.0)	
		OSR	16	13 (81.3)	5 (31.3)	12 (75.0)						1 (6.3)	
Treharne GD	1999	EVAR	49	18 (36.7)	8 (16.3)	15 (30.6)		2 (4.1)				1 (2.0)	
		OSR	104	49 (47.1)	24 (23.1)	44 (42.3)		5 (4.8)				3 (2.9)	
Zarins CK	1999	EVAR	190	162 (85.3)	160 (84.2)	131 (68.9)			36 (18.9)	34 (17.9)		13 (6.8)	8 (4.2)
		OSR	60	20 (33.3)	52 (86.7)	36 (60.0)			9 (15.0)	15 (25.0)		6 (10.0)	
Allen BT	1998	EVAR	34	11 (32.4)	25 (73.5)	19 (55.9)		5 (14.7)			7 (20.6)	3 (8.8)	1 (2.9)
		OSR	9	8 (88.9)	3 (33.3)	5 (55.6)		0 (0.0)			4 (44.4)	0 (0.0)	
Du Toit DF	1998	EVAR	12										
		OSR	10										
Baxendale BR	1996	EVAR	10		4 (40.0)	2 (20.0)					0 (0.0)		1 (10.0)
		OSR	10		3 (30.0)	1 (10.0)					0 (0.0)		

Appendix VI Patient Baseline Clinical Characteristics

Table 50. Surgical risk assessment from studies using American Society of Anesthesiologist (ASA) rating

Author	Year	Risk		Sample (n)	EVAR Suitability	ASA I n (%)	ASA II n (%)	ASA III n (%)	ASA IV n (%)
Prinssen M	2004	low	EVAR	171		37 (21.6)	119 (69.6)	14 (8.2)	1 (0.6)
			OSR	174	suitable	44 (25.3)	106 (60.9)	24 (13.8)	0 (0.0)
Cuypers PWM	2001	low	EVAR	57			34 (59.6)	23 (40.4)	
			OSR	19	suitable		15 (78.9)	4 (21.1)	
Aho P	2004		EVAR	15		0 (0.0)	1 (6.7)	11 (73.3)	3 (20.0)
			OSR	9	no	0 (0.0)	0 (0.0)	9 (100.0)	0 (0.0)
Cao	2004		EVAR	534					87 (16.3)
			OSR	585	no				36 (6.2)
Garcia-Madrid C	2004		EVAR	53				48 (90.6)	
			OSR	30	suitable			27 (90.0)	
Watson DR	2004		EVAR	69				52 (75.4)	14 (20.3)
			OSR	118	no			88 (74.6)	24 (20.3)
Dias NV	2003		EVAR	117		0 (0.0)	9 (7.7)	89 (76.1)	19 (16.2)
			OSR	11	suitable	2 (18.2)	6 (54.5)	3 (27.3)	0 (0.0)
Gawenda M	2003		EVAR	10		0 (0.0)	2 (20.0)	7 (70.0)	1 (10.0)
			OSR	16	suitable	1 (6.3)	3 (18.8)	12 (75.0)	0 (0.0)

Author	Year	Risk		Sample (n)	EVAR Suitability	ASA I n (%)	ASA II n (%)	ASA III n (%)	ASA IV n (%)
Junnarkar S	2003		EVAR	7		0 (0.0)	2 (28.6)	4 (57.1)	1 (14.3)
			OSR	8	no	0 (0.0)	6 (75.0)	2 (25.0)	0 (0.0)
Ligush JJ	2002		EVAR	33		0 (0.0)	4 (12.1)	23 (69.7)	6 (18.2)
			OSR	66	no	0 (0.0)	4 (6.1)	48 (72.7)	14 (21.2)
Teufelsbauer H	2002		EVAR	206				111 (53.9)	85 (41.3)
			OSR	248	no			134 (54.0)	26 (10.5)
May J	2001	high/low	EVAR	148					
			OSR	135	no			19 (14.1)	
Birch SE	2000		EVAR	31		1 (3.2)	10 (32.3)	14 (45.2)	6 (19.4)
			OSR	31	no	1 (3.2)	11 (35.5)	14 (45.2)	5 (16.1)
Kahn RA	1999		EVAR	17		0 (0.0)	1 (5.9)	4 (23.5)	12 (70.6)
			OSR	72	na	0 (0.0)	2 (2.8)	53 (73.6)	17 (23.6)
Scharrer-Pamler R	1999		EVAR	31		0 (0.0)	6 (19.4)	25 (80.6)	0 (0.0)
			OSR	29	no	1 (3.4)	3 (10.3)	21 (72.4)	4 (13.8)
Zarins CK	1999		EVAR	190				124 (65.3)	49 (25.8)
			OSR	60	no			39 (65.0)	10 (16.7)
Du Toit DF	1998	high	EVAR	12		0 (0.0)		5 (41.7)	
			OSR	10	no		4 (40.0)		

Appendix VII Short-term Clinical Outcome & Safety Data

Appendix VII Short-term Clinical Outcome & Safety Data

Table 51. Perioperative and surgical outcomes and resource utilization

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
Greenberg RK	2004	EVAR	200	2.55	299	0.4	2.6		40 (20.0)	22 (11.0)	13 (6.5)
		OSR	80	3.98	1676	3.4	8.8		34 (42.5)	25 (31.3)	21 (26.3)
Greenhalgh RM	2004	EVAR	543	3.00			7		52 (9.6)	29 (5.3)	23 (4.2)
		OSR	539	3.33			12		30 (5.6)	16 (3.0)	14 (2.6)
Prinssen M	2004	EVAR	171	2.25	394	0.67	6		29 (17.0)	35 (20.5)	26 (15.2)
		OSR	174	2.52	1654	3.00	13		33 (19.0)	24 (13.8)	65 (37.4)
Cuypers PWM	2001	EVAR	57	3		0.8	5		36 (63.2)		
		OSR	19			0.9	11		25 (131.6)		
Aho P	2004	EVAR	15		810						
		OSR	9		2210						
Akkersdijk GJM	2004	EVAR	857								
		OSR	15589								
Anderson PL	2004	EVAR	871								
		OSR	783								
Angle N	2004	EVAR	55	3.8	511	0.09	1.96			5 (9.1)	3 (5.5)
		OSR	64	3.77	700	3.5	7.3			4 (6.3)	12 (18.8)
Ballard JL	2004	EVAR	22				1.9				
		OSR	107				4.4				
Cao	2004	EVAR	534	2	200		2		49 (9.2)	27 (5.1)	27 (5.1)

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
		OSR	585	3	1400		6		109 (18.6)	58 (9.9)	41 (7.0)
Elkouri S	2004	EVAR	94								
		OSR	261								
Garcia-Madrid C	2004	EVAR	53	2.08	300	0.08	2				
		OSR	30	3	3100	0.71	6				
Lee WA	2004	EVAR	2565				3.6		456 (17.8)		77 (3.0)
		OSR	4607				8.8		1317 (28.6)		320 (6.9)
Watson DR	2004	EVAR	69	2.67	379		1.94				
		OSR	118	4.28	1930		9.38				
Zeebregts CJ	2004	EVAR	93	2.45	355	0.3	9.2		30 (32.3)	17 (18.3)	13 (14.0)
		OSR	82	3.58	3476	6.6	19.2		56 (68.3)	24 (29.3)	32 (39.0)
Arko FR	2003	EVAR	153				2.8	32.1			
		OSR	141				8.3	99.3			
Criado FJ	2003	EVAR	240	2.87	345.5	0.6	4.6		65 (27.1)		
		OSR	126	3.7	1541.6	2.3	8.7		112 (88.9)		
Decker D	2003	EVAR	16								
		OSR	16								
Dias NV	2003	EVAR	117						19 (16.2)	8 (6.8)	9 (7.7)
		OSR	11						2 (18.2)	3 (27.3)	1 (9.1)
Dryjski M	2003	EVAR	73	4.18		0.4	2.9			8 (11.0)	3 (4.1)
		OSR	57	5.195		5	12.6				5 (8.8)
Gawenda M	2003	EVAR	10	1.67	300	0.75	11				
		OSR	16	3.58	1000	1	22				
Hansman MF	2003	EVAR	50	2.82	451	0	2.3		10 (20.0)	3 (6.0)	7 (14.0)

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
		OSR	50	3.12	783	1.2	5.9		12 (24.0)	5 (10.0)	7 (14.0)
Jordan WD	2003	EVAR	129				2.5		9 (7.0)		
		OSR	58				8.6		14 (24.1)		
Junnarkar S	2003	EVAR	7	2.00	500						
		OSR	8	2.225	1997						
Kibbe MR	2003	EVAR	235	2.40	310	6	2	42			
		OSR	99	3.27	1590	2.79	9.8	92			
Matsumura JS	2003	EVAR	235	2.4	310	0.25	2	42	70 (29.8)		
		OSR	99	3.3	1590	2.8	9.8	92	146 (147.5)		
Patel AP	2003	EVAR	16		225	0	2		4 (25.0)	3 (18.8)	3 (18.8)
		OSR	35		2100	3	12		24 (68.6)	7 (20.0)	52 (148.6)
Ting ACW	2003	EVAR	27	4.15	600	1	9				
		OSR	25	3.43	1074	3	13				
Turnipseed W	2003	EVAR	70						19 (27.1)	5 (7.1)	28 (40.0)
		OSR	96						17 (17.7)	3 (3.1)	15 (15.6)
Berman SS	2002	EVAR	9				1.9				
		OSR	11				8.4				
Carpenter JP	2002	EVAR	174								
		OSR	163								
Forbes TL	2002	EVAR	7				5.6				
		OSR	31				10.7				
Lifeline Registry	2002	EVAR	1646								

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
		OSR	111								
Ligush JJ	2002	EVAR	33	2.95		0.2	2.1		10 (30.3)	8 (24.2)	4 (12.1)
		OSR	66	4.62		3.2	10.7		13 (19.7)	6 (9.1)	15 (22.7)
Teufelsbauer H	2002	EVAR	206								
		OSR	248								
Van Sambeek MRHM	2002	EVAR	6	3.22	125	0.33	7.5				
		OSR	6	3.38	3400	2.58	15.5				
Beebe HG	2001	EVAR	268			0.34	3.6				
		OSR	98			1.3	9				
Bertrand M	2001	EVAR	193	2.5	650	0.9			67 (34.7)		
		OSR	193	3.1	1800	1.1	14		155 (80.3)		
May J	2001	EVAR	148						45 (30.4)		
		OSR	135						35 (25.9)	9 (6.7)	26 (19.3)
Rowlands TE	2001	EVAR	16	3.15	340		7				
		OSR	16	2.82	780		9				
Sangiorgi G	2001	EVAR	30								
		OSR	15								
Wijnen MHWA	2001	EVAR	15								
		OSR	22								
Becquemin J	2000	EVAR	73	2.48	96		7		12 (16.4)	1 (1.4)	11 (15.1)
		OSR	107	2.22	985		13		30 (28.0)	2 (1.9)	28 (26.2)
Birch SE	2000	EVAR	31	3.4	545	0.07	6		15 (48.4)	14 (45.2)	8 (25.8)

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
		OSR	31	3.73	1735	2.9	13.4		26 (83.9)	11 (35.5)	22 (71.0)
Clair DG	2000	EVAR	45	2.76		0.06	3.2		1 (2.2)	1 (2.2)	0 (0.0)
		OSR	90	4.75		2.97	9.7		6 (6.7)	1 (1.1)	4 (4.4)
Cohnert TU	2000	EVAR	37	3.88		1.5	10		7 (18.9)	7 (18.9)	0 (0.0)
		OSR	37	3.3		1.4	10.4		4 (10.8)	4 (10.8)	0 (0.0)
Galle C	2000	EVAR	7	1.87	21						
		OSR	5	2.97	1700						
Malina M	2000	EVAR	21	2.7	500	1.5	5				
		OSR	21	3.3	2400	2	8				
Odegard A	2000	EVAR	10	2.92			6				
		OSR	10	3.58			12				
Ceelen W	1999	EVAR	9	1.5		5					
		OSR	20	2.1			11				
de Virgilio C	1999	EVAR	83				5.7				5 (6.0)
		OSR	63				15				3 (4.8)
Kahn RA	1999	EVAR	17								
		OSR	72								
Scharrer-Pamler R	1999	EVAR	31			1.49		5.7			
		OSR	29			3.22		8.1			
Seiwert AJ	1999	EVAR	16	3.67	400	1	2.6				
		OSR	16	4.6	1800	2.9	6.6				
Treharne GD	1999	EVAR	49								
		OSR	104								
Zarins CK	1999	EVAR	190	3	641	0.9	3.4	2.9	40 (21.1)		

Author	Year		Sample (n)	OR time (hrs)	Blood Loss (mL)	ICU LOS (days)	Hospital LOS (days)	Recovery Time (days)	Total Perioperative Complications n (%)	Local/Vascular Perioperative Complications n (%)	Systemic Perioperative Complications n (%)
		OSR	60	3.6	1596	2.5	9.4	9.1	18 (30.0)	10 (16.7)	8 (13.3)
Allen BT	1998	EVAR	34	3.1	458		3.09		3 (8.8)	1 (2.9)	2 (5.9)
		OSR	9	2.94	983.3		6.1			1 (11.1)	1 (11.1)
Du Toit DF	1998	EVAR	12	1.91	245		1.43	3			
		OSR	10	3.65			12.8				
Baxendale BR	1996	EVAR	10	2.38	515						
		OSR	10	2.24	1403						

Appendix VIII Consent Form

Evaluation of the Endovascular Repair Program for Aortic Aneurysm (EVAR) at LHSC

LETTER OF INFORMATION

You are being invited to participate in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and ask us if there is anything that is not clear or if you would like more information.

Purpose:

Across Ontario, vascular surgeons perform hundreds of abdominal aortic aneurysm surgery annually. An aneurysm is a dilatation or swelling on your aorta (the largest blood vessel in your body). Many are repaired using the usual open surgical technique (through the abdomen). In the past few years a new technique known as an endovascular stent graft has been used. In this type of repair there is no incision in the abdomen; the graft is introduced via the femoral artery to exclude the aneurysm. This procedure is very expensive and is limited to higher risk patients. However, we have limited information about the cost, quality of life and outcomes of the endovascular surgery that we provide to our patients. Such information would be useful to vascular surgeons to help guide their efforts to improve the quality of care for their patients. The purpose of this study is to compare the cost effectiveness, quality of life and outcomes of the endovascular stent graft repair with the open surgical repair of abdominal aortic aneurysms.

Why have I been chosen?

You have been chosen to participate in this study because you are scheduled to undergo an abdominal aortic aneurysm repair at the London Health Sciences Centre. Approximately 250 patients will be studied at this centre.

What will I be asked to do if I agree to participate?

We are asking for your permission to allow your surgeon to provide information about your surgery to the co-coordinating centre (McMaster University). Information collected will include: age, OHIP number, medical history, date of surgery, type of surgery, pre-operation level of care (e.g. home or nursing home), general health, information about your procedure and treatments used to prevent complications. We will also collect information from your charts or on the telephone about your progress after the surgery for the next two years. You will be asked to complete quality of life questionnaires before your surgery and every three months for the next two years after your surgery. These can be done over the telephone and take approximately fifteen minutes to complete. There are no known risks to participating in this study.

Do I have to take part?

Your participation in this study is strictly voluntary. You may refuse to participate, refuse to answer questions or withdraw at any time with no effect on your surgery or future care. If you decide to take part you will sign a consent form and be given a copy of this information sheet and the consent form.

Will my taking part in the study be kept confidential?

All your information in this study is strictly confidential. No identifying information such as your name or address will be included in any reports. No one outside the research team will have access to any identifiable information and all identifiable information will be kept securely.

How will my information be used?

The research team at the London Health Sciences Centre and McMaster University will prepare reports for the Ministry of Health and Long Term Care of Ontario. This information may help surgeons and hospitals to make better decisions about the care of abdominal aortic aneurysm surgical patients.

We will also use the information provided to assist Ministry of Health and Long Term Care of Ontario in the decision making process for future funding for endovascular abdominal aortic aneurysm vascular surgical procedures across Ontario.

Questions or Concerns:

If you have any questions or concerns about the conduct of the conduct of the study or your rights as a research subject you may contact Dr. J. Gilbert, VP Research & Development at the London Health Sciences Centre at 519-667-6649.
If you have any questions or concerns about the study please contact Dr. Guy DeRose at 519-667-6644 or the study nurse Teresa Novick at 519-685-8300 ext 75926.

You will be given a copy of this letter of information and a signed and dated copy of the consent.

Consent

“Evaluation of the Endovascular Repair Program for Aortic Aneurysm (EVAR) at LHSC”

I have read this Letter of Information and agree to participate in the above study. All questions have been answered to my satisfaction.

_____	_____
Patient signature	Date

_____	_____
Signature of Person obtaining Informed Consent	Date

AAA STUDY

Interviewer Version

Patient #

BASELINE EMPLOYMENT, PRESCRIPTION COVERAGE AND MEDICATION USE

EMPLOYMENT STATUS

Which of the following best describes your current employment status or main activity?

[Interviewer: Read list and tick one box only]

- ☐ Working at a full time job (1)
- ☐ Working at a part time job (2)
- ☐ Temporary sick leave or long term disability (3)

→ What is your current occupation: _____

- ☐ Looking for work/between jobs (4)
- ☐ Going to school (5)
- ☐ Homemaking (6)
- ☐ Retired (7)
- ☐ Other, specify (8) _____

COVERAGE FOR PRESCRIPTION MEDICATIONS

Which of the following best describes your coverage for prescription medications?

[Interviewer: Read list and tick one box only]

- ☐ I have no insurance coverage for prescription medicines
- ☐ I have coverage under the provincial government drug plan
- ☐ I have coverage under an employer drug plan
- ☐ I have coverage under a private insurance drug plan

Which of the following best describes what **YOU** pay for prescriprion medications?

[Interviewer: tick one box only]

- ☐ I pay nothing at all
- ☐ I pay a fixed amount per prescription → If so, how much per prescription? $ _____
- ☐ I pay a fixed amount per year → If so, how much per year? $ _____
- ☐ I pay a fixed percentage per prescription → If so, what percent per prescription? _____ %

Patient #

AAA STUDY

Interviewer Version

PRESCRIPTION MEDICATIONS

Can you tell me what prescription medications you are currently taking?

	Drug Name and Strength (e.g., Metropolol 50 mg)	Route (e.g., pill, tablet, injection)	Number per day
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

OVER-THE-COUNTER MEDICATIONS

Over the past month have you taken any over-the-counter or off-the-shelf medications (i.e., non-prescription) as a result of your aneurysm**?**

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s) and strength of these medications and approximately how many pills/tablets they have taken during the past month]**

	Name and strength of over-the-counter medication (e.g., ASA 325mg)	**Approximate number of pills during the past month**
1.		
2.		
3.		
4.		
5.		
6		
7.		
8.		
9.		
10.		

AAA STUDY

Telephone Assistance Card

STUDY INFORMATION SHEET

Every 3 months we will be contacting you by telephone to collect information on your use of medications, doctor visits, and other health care services. This card lists the type of information we will be collecting. We do not expect that there will be a lot of information for you to report back to us, however, you may find it useful to record this information on a calendar or in the date book.

1) Emergency room visits
- How many visits
- Hospital and reason

2) Hospital admissions
- Admission and discharge dates
- Surgeries (if any)
- Reason
- Hospital
- Where you were discharged to

3) Family doctor visits
- How many visits

4) Specialist visits
- Type of specialist (Examples: vascular surgeon, cardiologist)
- How many visits
- Where you visited them (hospital clinic, private office)

5) Visits to outpatient clinics
- Type of clinic (Examples: vascular clinic)
- How many visits

6) Tests, procedures and surgery
- Type of test or procedure (Examples: blood test, x-ray, angiogram, ECG, open surgical repair, endovascular repair)
- How many tests

7) Prescription medications
- Changes to prescription mediations (drug name, strength and number of times taken per day). For example: Metoprolol 50mg, twice per day.

8) Over-the-counter medications
- Drug name and strength (Examples: aspirin 325mg)
- How many taken over the past month

9) Visits to other health care professionals or use of other health care services
- Type of professional or service (Examples: physiotherapist, dietician, home care, meals-on-wheels)
- How many visits or times used

10) Time off from paid employment
- Number of days lost from paid employment because of your health
- Number of days lost from paid employment for another person because of your health

11) Assistance form others
- Type of activities other persons have helped you with because of your health
- Number of hours of assistance in past month

AAA Study – Medical Patients	*Interviewer version*	**Which assessment does this form correspond to: 3-month**

SECTION A: EMERGENCY ROOM VISITS AND HOSPITALIZATIONS

Q1 **Since your clinic visit on** | mmm | ddd | yyyy | have you visited an emergency room for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q1b How many times? _____.**

[Interviewer: For each emergency room visit, ask the patient the reason for the visit and the hospital name]

VISIT #1 Reason: _____
Hospital: _____

VISIT #2 Reason: _____
Hospital: _____

VISIT #3 Reason: _____
Hospital: _____

Q2. **Since your clinic visit on** | mmm | ddd | yyyy | have you been admitted to a hospital overnight, (including overnight emergency room visits) for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q2b How many times? _____.**

[Interviewer: For each hospitalization, ask the patient the admission and discharge dates, the number of days in an ICU/CCU, the reason for the hospitalization, major surgeries/procedures performed, the name of the hospital and to where they were discharged]

ADMISSION #1:
Admission date: | mm | dd | yy |
Discharge date: | mm | dd | yy | Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #2:
Admission date: | mm | dd | yy |
Discharge date: | mm | dd | yy | Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #3
Admission date: | mm | dd | yy |
Discharge date: | mm | dd | yy | Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

SECTION B: FAMILY DOCTOR VISITS

Q3 **Since your clinic visit on** | mmm | ddd | yyyy | how many times have you seen your family doctor for any reason?

# of visits: _____

Q4 How many of these family doctor visits do you feel are related to your **aneurysm**?

# of visits: _____

SECTION C: SPECIALIST VISITS AND OUTPATIENT CLINICS

Q5 **Since your clinic visit on** | mmm | ddd | yyyy | have you visited a specialist for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of specialist(s), the number of visits to each, the location(s) of the visits and how many of these visits were related to their aneurysm]**

Specialist	Tick if yes	# of visits	Location of visit (tick one)		How many related to your aneurysm?
			Private Office	Hospital Clinic	
Vascular surgeon	☐ →	_____ →	☐	☐	_____
Urologist	☐ →	_____ →	☐	☐	_____
Cardiologist	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____

Q6 **Since your clinic visit on** | mmm | ddd | yyyy | have you visited any other clinics for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of clinic(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Type of clinic	Tick if yes	# of Visits	How many related to your aneurysm?
Walk-in clinic	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____

SECTION D: TESTS, PROCEDURES AND SURGERIES

Q7 **Since your clinic visit on** | mmm | ddd | yyyy | have you had any tests, procedures or surgeries for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of test(s) or procedure(s), the number of each and how many of each test/procedure was related to their aneurysm]**

Test or procedure	Tick if yes	# of tests	How many related to your aneurysm?
CBC or other blood test	☐ →		
CT Scan	☐ →		
MRI	☐ →		
X-ray	☐ →		
Angiogram (arteriogram)	☐ →		
Electrocardiogram (ECG)	☐ →		
Electroencephalography (EEG)	☐ →		
Pulmonary function test	☐ →		
Urinalysis	☐ →		
Percutaneous treatment	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION E: PRESCRIPTION MEDICATIONS

Q8 **Since your clinic visit on** | mmm | ddd | yyyy | have you had any changes to the prescription medications you were taking?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s), strength and route of these medications and how many pills/tablets they take per day]**

	Drug Name and Strength (e.g., Metropolol 50 mg)	Route (e.g., pill, tablet, injection)	Number per day
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

SECTION F: OVER-THE-COUNTER MEDICATIONS

Q9 **Over the past month** have you taken any over-the-counter or off-the-shelf medications (i.e., non-prescription) as a result of your aneurysm**?**

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s) and strength of these medications and approximately how many pills/tablets they have taken during the past month]**

	Name and strength of over-the-counter medication (e.g., ASA 325mg)	**Approximate number of pills during the past month**
1.		
2.		
3.		
4.		
5.		
6		
7.		
8.		

SECTION G: OTHER HEALTH CARE PROFESSIONALS / SERVICES

Q10 **Since your clinic visit on** | mmm | ddd | yyyy | have you seen any other health professionals or used any of the following services for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of professional(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Professional	Tick if yes	# of visits	How many related to your aneurysm?
Physiotherapist	☐ →		
Occupational Therapist	☐ →		
Chiropractor	☐ →		
Speech Pathologist	☐ →		
Home care or community nurse visit (e.g., V.O.N)	☐ →		
Social Worker	☐ →		
Dietician	☐ →		
Meals-on-wheels	☐ →		
Transportation service (e.g. DARTS)	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION H: EMPLOYMENT STATUS AND TIME-OFF-WORK FROM PAID EMPLOYMENT

[Interviewer: Have the patient's previous employment status ready]

Q11a **At your clinic visit on** | mmm | ddd | yyyy | you told us you were:

_____ **[Interviewer: read off previous employment status]**

Has there been a change to your employment status or main activity since then?

☐ No ☐ Yes → **[Interviewer: If yes, ask Q11b]**

↓

[Interviewer: If no and previous status was (1), (2) or (3), ask Q11d
If no and previous status was (4) – (8), ask Q12]

Q11b Which of the following best describes your **current employment status or main activity?**

[Interviewer: Read list and tick one box only]

☐ Working at a full time job (1)
☐ Working at a part time job (2)
☐ Temporary sick leave or long term disability (3)

→ Q11c What is your current occupation: _____

_____

☐ Looking for work/between jobs (4)
☐ Going to school (5)
☐ Homemaking (6)
☐ Retired (7)
☐ Other, specify (8) _____

→ **SKIP TO Q12**

Q11d **Since your clinic visit on** | mmm | ddd | yyyy | how many days of **paid employment*** did you take off as a result of your health (including hospitalizations, doctor visits, treatment and rehabilitation)?
[Interviewer: ask the patient to add up partial days (e.g., 3½ or 3.5)]

_____ days off from **paid employment*** by patient

Q12 **Since your clinic visit on** | mmm | ddd | yyyy | how many days of **paid employment*** did another person (e.g., relative, friend, other caregiver) take off as a result of your health (including assistance related to personal care, treatment, and rehabilitation)? **[Interviewer: Ask the patient to add up partial days (3 ½ or 3.5)].**

_____ days off from **paid employment*** by another person

* in these calculations make sure the patient excludes homemaking and volunteer activities

SECTION I: ASSISTANCE FROM OTHERS

Q13 **During the past month** have you needed assistance from a friend or relative for health care, personal care, shopping, household activities, or transportation because of your health?

☐ No ☐ Yes

↓

[Interviewer: If yes, ask the patient about the type(s) of activities, approximately how many hours of assistance they received in the past month, and the relationship of the person to the patient]

Activity	Tick if yes	# Hours of assistance in past month	Relationship of person to you (i.e., friend, spouse, son, daughter)
Health care activities			
Taking medications	☐		
Exercises / rehabilitation	☐		
Other _____	☐		
Personal care activities			
Dressing / undressing	☐		
Bathing / showering	☐		
Going to the bathroom	☐		
Personal appearance (hair, make-up, shaving)	☐		
Other: _____	☐		
Shopping or household activities			
Shopping (groceries, household items, clothes..)	☐		
Meal preparation / eating / clean-up	☐		
Housework	☐		
Finances / managing money	☐		
Other: _____	☐		
Transportation			
Doctor appointments, shopping, other	☐		

AAA Study – Medical Patients	*Interviewer version*	Which assessment does this form correspond to: ○ 6 month ○ 9 month ○ 12 month

SECTION A: EMERGENCY ROOM VISITS AND HOSPITALIZATIONS

Q1 **Since the last time we contacted you on** [mmm] [ddd] [yyyy] have you visited an emergency room for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q1b How many times? _____.**

[Interviewer: For each emergency room visit, ask the patient the reason for the visit and the hospital name]

VISIT #1 Reason: _____
Hospital: _____

VISIT #2 Reason: _____
Hospital: _____

VISIT #3 Reason: _____
Hospital: _____

Q2. **Since the last time we contacted you on** [mmm] [ddd] [yyyy] have you been admitted to a hospital overnight, (including overnight emergency room visits) for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q2b How many times? _____.**

[Interviewer: For each hospitalization, ask the patient the admission and discharge dates, the number of days in an ICU/CCU, the reason for the hospitalization, major surgeries/procedures performed, the name of the hospital and to where they were discharged]

ADMISSION #1:
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #2:
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #3
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

SECTION B: FAMILY DOCTOR VISITS

Q3 **Since the last time we contacted you on** | mmm | ddd | yyyy | how many times have you seen your family doctor for any reason?

# of visits: _____

Q4 How many of these family doctor visits do you feel are related to your **aneurysm**?

# of visits: _____

SECTION C: SPECIALIST VISITS AND OUTPATIENT CLINICS

Q5 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you visited a specialist for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of specialist(s), the number of visits to each, the location(s) of the visits and how many of these visits were related to their aneurysm]**

Specialist	Tick if yes	# of visits	Location of visit (tick one)		How many related to your aneurysm?
			Private Office	Hospital Clinic	
Vascular surgeon	☐ →	_____ →	☐	☐	_____
Urologist	☐ →	_____ →	☐	☐	_____
Cardiologist	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____

Q6 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you visited any other clinics for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of clinic(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Type of clinic	Tick if yes	# of Visits	How many related to your aneurysm?
Walk-in clinic	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____

SECTION D: TESTS, PROCEDURES AND SURGERIES

Q7 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you had any tests, procedures or surgeries for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of test(s) or procedure(s), the number of each and how many of each test/procedure was related to their aneurysm]**

Test or procedure	Tick if yes		# of tests	How many related to your aneurysm?
CBC or other blood test	☐	→		
CT Scan	☐	→		
MRI	☐	→		
X-ray	☐	→		
Angiogram (arteriogram)	☐	→		
Electrocardiogram (ECG)	☐	→		
Electroencephalography (EEG)	☐	→		
Pulmonary function test	☐	→		
Urinalysis	☐	→		
Percutaneous treatment	☐	→		
Other	☐	→		
Other _____	☐	→		
Other _____	☐	→		
Other _____	☐	→		
Other _____	☐	→		
Other _____	☐	→		
Other _____	☐	→		

SECTION E: PRESCRIPTION MEDICATIONS

Q8 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you had any changes to the prescription medications you were taking?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s), strength and route of these medications and how many pills/tablets they take per day]**

	Drug Name and Strength (e.g., Metropolol 50 mg)	Route (e.g., pill, tablet, injection)	Number per day
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

SECTION F: OVER-THE-COUNTER MEDICATIONS

Q9 **Over the past month** have you taken any over-the-counter or off-the-shelf medications (i.e., non-prescription) as a result of your aneurysm**?**

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s) and strength of these medications and approximately how many pills/tablets they have taken during the past month]**

	Name and strength of over-the-counter medication (e.g., ASA 325mg)	**Approximate number of pills during the past month**
1.		
2.		
3.		
4.		
5.		
6		
7.		
8.		

SECTION G: OTHER HEALTH CARE PROFESSIONALS / SERVICES

Q10 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you seen any other health professionals or used any of the following services for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of professional(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Professional	Tick if yes	# of visits	How many related to your aneurysm?
Physiotherapist	☐ →		
Occupational Therapist	☐ →		
Chiropractor	☐ →		
Speech Pathologist	☐ →		
Home care or community nurse visit (e.g., V.O.N)	☐ →		
Social Worker	☐ →		
Dietician	☐ →		
Meals-on-wheels	☐ →		
Transportation service (e.g. DARTS)	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION H: EMPLOYMENT STATUS AND TIME-OFF-WORK FROM PAID EMPLOYMENT

[Interviewer: Have the patient's previous employment status ready]

Q11a **The last time we contacted you on** | mmm | ddd | yyyy | you told us you were:

_____ **[Interviewer: read off previous employment status]**

Has there been a change to your employment status or main activity since then?

☐ No ☐ Yes → **[Interviewer: If yes, ask Q11b]**

↓

[Interviewer: If no and previous status was (1), (2) or (3), ask Q11d
If no and previous status was (4) – (8), ask Q12]

Q11b Which of the following best describes your current employment status or main activity?

[Interviewer: Read list and tick one box only]

☐ Working at a full time job (1)
☐ Working at a part time job (2)
☐ Temporary sick leave or long term disability (3)

→ Q11c What is your current occupation: _____

☐ Looking for work/between jobs (4)
☐ Going to school (5)
☐ Homemaking (6)
☐ Retired (7)
☐ Other, specify (8) _____

→ **SKIP TO Q12**

Q11d **Since the last time we contacted you on** | mmm | ddd | yyyy | how many days of **paid employment*** did you take off as a result of your health (including hospitalizations, doctor visits, treatment and rehabilitation)?
[Interviewer: ask the patient to add up partial days (e.g., 3½ or 3.5)]

_____ days off from **paid employment*** by patient

Q12 **Since the last time we contacted you on** | mmm | ddd | yyyy | how many days of **paid employment*** did another person (e.g., relative, friend, other caregiver) take off as a result of your health (including assistance related to personal care, treatment, and rehabilitation)? **[Interviewer: Ask the patient to add up partial days (3 ½ or 3.5)].**

_____ days off from **paid employment*** by another person

* in these calculations make sure the patient excludes homemaking and volunteer activities

SECTION I: ASSISTANCE FROM OTHERS

Q13 **During the past month** have you needed assistance from a friend or relative for health care, personal care, shopping, household activities, or transportation because of your health?

☐ No ☐ Yes

↓

[Interviewer: If yes, ask the patient about the type(s) of activities, approximately how many hours of assistance they received in the past month, and the relationship of the person to the patient]

Activity	Tick if yes	# Hours of assistance in past month	Relationship of person to you (i.e., friend, spouse, son, daughter)
Health care activities			
Taking medications	☐		
Exercises / rehabilitation	☐		
Other _____	☐		
Personal care activities			
Dressing / undressing	☐		
Bathing / showering	☐		
Going to the bathroom	☐		
Personal appearance (hair, make-up, shaving)	☐		
Other: _____	☐		
Shopping or household activities			
Shopping (groceries, household items, clothes..)	☐		
Meal preparation / eating / clean-up	☐		
Housework	☐		
Finances / managing money	☐		
Other: _____	☐		
Transportation			
Doctor appointments, shopping, other	☐		

AAA Study – Surgical Patients	*Interviewer version*	**Which assessment does this form correspond to:** ○ **30 day post surgery**

SECTION A: EMERGENCY ROOM VISITS AND HOSPITALIZATIONS

Q1 **Since being discharged for surgery on** [mmm | ddd | yyyy] have you visited an emergency room for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q1b How many times? _____.**

[Interviewer: For each emergency room visit, ask the patient the reason for the visit and the hospital name]

VISIT #1 Reason: _____
Hospital: _____

VISIT #2 Reason: _____
Hospital: _____

VISIT #3 Reason: _____
Hospital: _____

Q2. **Since being discharged for surgery on** [mmm | ddd | yyyy] have you been admitted to a hospital overnight, (including overnight emergency room visits) for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q2b How many times? _____.**

[Interviewer: For each hospitalization, ask the patient the admission and discharge dates, the number of days in an ICU/CCU, the reason for the hospitalization, major surgeries/procedures performed, the name of the hospital and to where they were discharged]

ADMISSION #1:
Admission date: [mm | dd | yy]
Discharge date: [mm | dd | yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #2:
Admission date: [mm | dd | yy]
Discharge date: [mm | dd | yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #3
Admission date: [mm | dd | yy]
Discharge date: [mm | dd | yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

SECTION B: FAMILY DOCTOR VISITS

Q3 **Since being discharged for surgery on** mmm | ddd | yyyy how many times have you seen your family doctor for any reason?

# of visits: _____

Q4 How many of these family doctor visits do you feel are related to your **aneurysm**?

# of visits: _____

SECTION C: SPECIALIST VISITS AND OUTPATIENT CLINICS

Q5 **Since being discharged for surgery on** mmm | ddd | yyyy have you visited a specialist for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of specialist(s), the number of visits to each, the location(s) of the visits and how many of these visits were related to their aneurysm]**

Specialist	Tick if yes	# of visits	Location of visit (tick one)		How many related to your aneurysm?
			Private Office	Hospital Clinic	
Vascular surgeon	☐ →	_____ →	☐	☐	_____
Urologist	☐ →	_____ →	☐	☐	_____
Cardiologist	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____

Q6 **Since being discharged for surgery on** mmm | ddd | yyyy have you visited any other clinics for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of clinic(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Type of clinic	Tick if yes	# of Visits	How many related to your aneurysm?
Walk-in clinic	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____

SECTION D: TESTS, PROCEDURES AND SURGERIES

Q7 **Since being discharged for surgery on** | mmm | ddd | yyyy | have you had any tests, procedures or surgeries for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of test(s) or procedure(s), the number of each and how many of each test/procedure was related to their aneurysm]**

Test or procedure	Tick if yes	# of tests	How many related to your aneurysm?
CBC or other blood test	☐ →		
CT Scan	☐ →		
MRI	☐ →		
X-ray	☐ →		
Angiogram (arteriogram)	☐ →		
Electrocardiogram (ECG)	☐ →		
Electroencephalography (EEG)	☐ →		
Pulmonary function test	☐ →		
Urinalysis	☐ →		
Percutaneous treatment	☐ →		
Other	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION E: PRESCRIPTION MEDICATIONS

Q8 **Since being discharged for surgery on** | mmm | ddd | yyyy | have you had any changes to the prescription medications you were taking?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s), strength and route of these medications and how many pills/tablets they take per day]**

	Drug Name and Strength (e.g., Metropolol 50 mg)	Route (e.g., pill, tablet, injection)	Number per day
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

SECTION F: OVER-THE-COUNTER MEDICATIONS

Q9 **Over the past month** have you taken any over-the-counter or off-the-shelf medications (i.e., non-prescription) as a result of your aneurysm**?**

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s) and strength of these medications and approximately how many pills/tablets they have taken during the past month]**

	Name and strength of over-the-counter medication (e.g., ASA 325mg)	**Approximate number of pills during the past month**
1.		
2.		
3.		
4.		
5.		
6		
7.		
8.		

SECTION G: OTHER HEALTH CARE PROFESSIONALS / SERVICES

Q10 **Since being discharged for surgery on** | mmm | ddd | yyyy | have you seen any other health professionals or used any of the following services for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of professional(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Professional	Tick if yes	# of visits	How many related to your aneurysm?
Physiotherapist	☐ →		
Occupational Therapist	☐ →		
Chiropractor	☐ →		
Speech Pathologist	☐ →		
Home care or community nurse visit (e.g., V.O.N)	☐ →		
Social Worker	☐ →		
Dietician	☐ →		
Meals-on-wheels	☐ →		
Transportation service (e.g. DARTS)	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION H: EMPLOYMENT STATUS AND TIME-OFF-WORK FROM PAID EMPLOYMENT

[Interviewer: Have the patient's previous employment status ready]

Q11a **Before your surgery on** | mmm | ddd | yyyy | you told us you were:

_____ **[Interviewer: read off previous employment status]**

Has there been a change to your employment status or main activity since then?

☐ No ☐ Yes → **[Interviewer: If yes, ask Q11b]**

↓

[Interviewer: If no and previous status was (1), (2) or (3), ask Q11d
If no and previous status was (4) – (8), ask Q12]

Q11b Which of the following best describes your current employment status or main activity?

[Interviewer: Read list and tick one box only]

☐ Working at a full time job (1)
☐ Working at a part time job (2)
☐ Temporary sick leave or long term disability (3)

→ Q11c What is your current occupation: _____

☐ Looking for work/between jobs (4)
☐ Going to school (5)
☐ Homemaking (6)
☐ Retired (7)
☐ Other, specify (8) _____

→ **SKIP TO Q12**

Q11d **Since being discharged for surgery on** | mmm | ddd | yyyy | how many days of **paid employment*** did you take off as a result of your health (including hospitalizations, doctor visits, treatment and rehabilitation)?
[Interviewer: ask the patient to add up partial days (e.g., 3½ or 3.5)]

_____ days off from **paid employment*** by patient

Q12 **Since being discharged for surgery on** | mmm | ddd | yyyy | how many days of **paid employment*** did another person (e.g., relative, friend, other caregiver) take off as a result of your health (including assistance related to personal care, treatment, and rehabilitation)? **[Interviewer: Ask the patient to add up partial days (3 ½ or 3.5)].**

_____ days off from **paid employment*** by another person

* in these calculations make sure the patient excludes homemaking and volunteer activities

SECTION I: ASSISTANCE FROM OTHERS

Q13 **During the past month** have you needed assistance from a friend or relative for health care, personal care, shopping, household activities, or transportation because of your health?

☐ No ☐ Yes

↓

[Interviewer: If yes, ask the patient about the type(s) of activities, approximately how many hours of assistance they received in the past month, and the relationship of the person to the patient]

Activity	Tick if yes	# Hours of assistance in past month	Relationship of person to you (i.e., friend, spouse, son, daughter)
Health care activities			
Taking medications	☐		
Exercises / rehabilitation	☐		
Other _____	☐		
Personal care activities			
Dressing / undressing	☐		
Bathing / showering	☐		
Going to the bathroom	☐		
Personal appearance (hair, make-up, shaving)	☐		
Other: _____	☐		
Shopping or household activities			
Shopping (groceries, household items, clothes..)	☐		
Meal preparation / eating / clean-up	☐		
Housework	☐		
Finances / managing money	☐		
Other: _____	☐		
Transportation			
Doctor appointments, shopping, other	☐		

AAA Study - Surgical Patients	*Interviewer version*	**Which assessment does this form correspond to:** ○ **3 month** ○ **6 month** ○ **9 month** ○ **12 month**

SECTION A: EMERGENCY ROOM VISITS AND HOSPITALIZATIONS

Q1 **Since the last time we contacted you on** [mmm] [ddd] [yyyy] have you visited an emergency room for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q1b How many times?** _____.

[Interviewer: For each emergency room visit, ask the patient the reason for the visit and the hospital name]

VISIT #1 Reason: _____
Hospital: _____

VISIT #2 Reason: _____
Hospital: _____

VISIT #3 Reason: _____
Hospital: _____

Q2. **Since the last time we contacted you on** [mmm] [ddd] [yyyy] have you been admitted to a hospital overnight, (including overnight emergency room visits) for any reason?

☐ **No** ☐ **Yes** **If yes** → **Q2b How many times?** _____.

[Interviewer: For each hospitalization, ask the patient the admission and discharge dates, the number of days in an ICU/CCU, the reason for the hospitalization, major surgeries/procedures performed, the name of the hospital and to where they were discharged]

ADMISSION #1:
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #2:
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

ADMISSION #3
Admission date: [mm] [dd] [yy]
Discharge date: [mm] [dd] [yy] Days in ICU/CCU: _____
Major surgery/procedure (if any): _____
Reason: _____
Hospital: _____
Discharged to: _____

SECTION B: FAMILY DOCTOR VISITS

Q3 **Since the last time we contacted you on** mmm | ddd | yyyy how many times have you seen your family doctor for any reason?

# of visits: _____

Q4 How many of these family doctor visits do you feel are related to your **aneurysm**?

# of visits: _____

SECTION C: SPECIALIST VISITS AND OUTPATIENT CLINICS

Q5 **Since the last time we contacted you on** mmm | ddd | yyyy have you visited a specialist for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of specialist(s), the number of visits to each, the location(s) of the visits and how many of these visits were related to their aneurysm]**

Specialist	Tick if yes	# of visits	Location of visit (tick one)		How many related to your aneurysm?
			Private Office	Hospital Clinic	
Vascular surgeon	☐ →	_____ →	☐	☐	_____
Urologist	☐ →	_____ →	☐	☐	_____
Cardiologist	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____
Other _____	☐ →	_____ →	☐	☐	_____

Q6 **Since the last time we contacted you on** mmm | ddd | yyyy have you visited any other clinics for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of clinic(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Type of clinic	Tick if yes	# of Visits	How many related to your aneurysm?
Walk-in clinic	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____
Other: _____	☐ →	_____	_____

SECTION D: TESTS, PROCEDURES AND SURGERIES

Q7 **Since the last time we contacted you on** [mmm] [ddd] [yyyy] have you had any tests, procedures or surgeries for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of test(s) or procedure(s), the number of each and how many of each test/procedure was related to their aneurysm]**

Test or procedure	Tick if yes	# of tests	How many related to your aneurysm?
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CT Scan	☐ →		
MRI	☐ →		
X-ray	☐ →		
Angiogram (arteriogram)	☐ →		
Electrocardiogram (ECG)	☐ →		
Electroencephalography (EEG)	☐ →		
Pulmonary function test	☐ →		
Urinalysis	☐ →		
Percutaneous treatment	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION E: PRESCRIPTION MEDICATIONS

Q8 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you had any changes to the prescription medications you were taking?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s), strength and route of these medications and how many pills/tablets they take per day]**

	Drug Name and Strength (e.g., Metropolol 50 mg)	Route (e.g., pill, tablet, injection)	Number per day
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

SECTION F: OVER-THE-COUNTER MEDICATIONS

Q9 **Over the past month** have you taken any over-the-counter or off-the-shelf medications (i.e., non-prescription) as a result of your aneurysm**?**

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient the name(s) and strength of these medications and approximately how many pills/tablets they have taken during the past month]**

	Name and strength of over-the-counter medication (e.g., ASA 325mg)	**Approximate number of pills during the past month**
1.		
2.		
3.		
4.		
5.		
6		
7.		
8.		

SECTION G: OTHER HEALTH CARE PROFESSIONALS / SERVICES

Q10 **Since the last time we contacted you on** | mmm | ddd | yyyy | have you seen any other health professionals or used any of the following services for any reason?

☐ No ☐ Yes → **[Interviewer: If yes, ask the patient about the type(s) of professional(s), the number of visits to each and how many of these visits were related to their aneurysm]**

Professional	Tick if yes	# of visits	How many related to your aneurysm?
Physiotherapist	☐ →		
Occupational Therapist	☐ →		
Chiropractor	☐ →		
Speech Pathologist	☐ →		
Home care or community nurse visit (e.g., V.O.N)	☐ →		
Social Worker	☐ →		
Dietician	☐ →		
Meals-on-wheels	☐ →		
Transportation service (e.g. DARTS)	☐ →		
Other _____	☐ →		
Other _____	☐ →		

SECTION H: EMPLOYMENT STATUS AND TIME-OFF-WORK FROM PAID EMPLOYMENT

[Interviewer: Have the patient's previous employment status ready]

Q11a **The last time we contacted you on** | mmm | ddd | yyyy | you told us you were:

_____ **[Interviewer: read off previous employment status]**

Has there been a change to your employment status or main activity since then?

☐ No ☐ Yes → **[Interviewer: If yes, ask Q11b]**

↓

[Interviewer: If no and previous status was (1), (2) or (3), ask Q11d
If no and previous status was (4) – (8), ask Q12]

Q11b Which of the following best describes your current employment status or main activity?

[Interviewer: Read list and tick one box only]

☐ Working at a full time job (1)
☐ Working at a part time job (2)
☐ Temporary sick leave or long term disability (3)

→ Q11c What is your current occupation: _____

☐ Looking for work/between jobs (4)
☐ Going to school (5)
☐ Homemaking (6)
☐ Retired (7)
☐ Other, specify (8) _____

→ **SKIP TO Q12**

Q11d **Since the last time we contacted you on** | mmm | ddd | yyyy | how many days of **paid employment*** did you take off as a result of your health (including hospitalizations, doctor visits, treatment and rehabilitation)? **[Interviewer: ask the patient to add up partial days (e.g., 3½ or 3.5)]**

_____ days off from **paid employment*** by patient

Q12 **Since the last time we contacted you on** | mmm | ddd | yyyy | how many days of **paid employment*** did another person (e.g., relative, friend, other caregiver) take off as a result of your health (including assistance related to personal care, treatment, and rehabilitation)? **[Interviewer: Ask the patient to add up partial days (3 ½ or 3.5)].**

_____ days off from **paid employment*** by another person

* in these calculations make sure the patient excludes homemaking and volunteer activities

SECTION I: ASSISTANCE FROM OTHERS

Q13 **During the past month** have you needed assistance from a friend or relative for health care, personal care, shopping, household activities, or transportation because of your health?

☐ No ☐ Yes

↓

[Interviewer: If yes, ask the patient about the type(s) of activities, approximately how many hours of assistance they received in the past month, and the relationship of the person to the patient]

Activity	Tick if yes	# Hours of assistance in past month	Relationship of person to you (i.e., friend, spouse, son, daughter)
Health care activities			
Taking medications	☐		
Exercises / rehabilitation	☐		
Other _____	☐		
Personal care activities			
Dressing / undressing	☐		
Bathing / showering	☐		
Going to the bathroom	☐		
Personal appearance (hair, make-up, shaving)	☐		
Other: _____	☐		
Shopping or household activities			
Shopping (groceries, household items, clothes..)	☐		
Meal preparation / eating / clean-up	☐		
Housework	☐		
Finances / managing money	☐		
Other: _____	☐		
Transportation			
Doctor appointments, shopping, other	☐		

EQ - 5D

Health Questionnaire

(Canadian English version)

By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

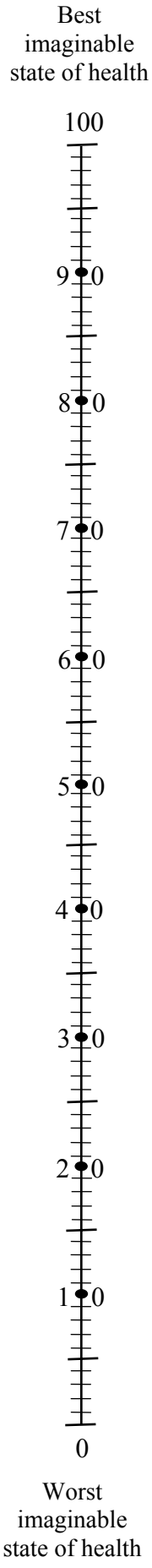
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today



All replies are anonymous. It will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness?

	Yes	No
yourself	❑	❑
in your family	❑	❑
when caring for others	❑	❑

PLACE A CHECK IN THE APPROPRIATE BOXES

2. What is your age in years ? ☐

3. Are you:

Male	Female
❑	❑

PLACE A CHECK IN THE APPROPRIATE BOX

4. Are you:

a current smoker	❑
an ex-smoker	❑
never smoked	❑

PLACE A CHECK IN THE APPROPRIATE BOX

5. Do you now, or did you ever, work in health or social services?

Yes	No
❑	❑

PLACE A CHECK IN THE APPROPRIATE BOX

If so, in what capacity? .....

6. Which of the following best describes your main activity?

employed or self employed	❑
retired	❑
housework	❑
student	❑
seeking work	❑
other (please specify)	❑ .....

PLACE A CHECK IN THE APPROPRIATE BOX

7. Did your education continue after the age of 16?

Yes	No
❑	❑

PLACE A CHECK IN THE APPROPRIATE BOX

8. Do you have a University degree or equivalent professional qualification?

Yes	No
❑	❑

PLACE A CHECK IN THE APPROPRIATE BOX

9. If you know your postal code, would you please write it here ☐

RAND 36-Item Health Survey 1.0 Questionnaire Items

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?
(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?
(Circle One Number on Each Line)

	Yes	No

13. Cut down the amount of time you spent on work or other activities	1	2
14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(Circle One Number on Each Line)

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
(Circle One Number)
Not at all 1
Slightly 2
Moderately 3
Quite a bit 4
Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?
(Circle One Number)
None 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe 6
22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?
(Circle One Number)
Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.
How much of the time during the **past 4 weeks** . . .
(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?
(Circle One Number)
All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
None of the time 5

How TRUE or FALSE is each of the following statements for you.
(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False

33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

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