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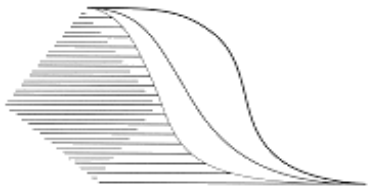

ENDOVASCULAR GRAFT TREATMENT OF INFRARENAL AORTIC ANEURYSMS

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Endovascular graft treatment of infrarenal aortic aneurysms

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Introduction to the Series

The Joint Heath Technology Assessment Series reports on projects initiated by the British Columbia Office of Health Technology Assessment (BCOHTA) and evidence-based medicine programs in BC. These programs are dedicated to producing unbiased, systematic reviews of clinical efficacy and effectiveness evidence for health care providers, administrators, policy makers, and the general public, and currently include:

- Therapeutics Initiative (TI), Department of Pharmacology and Therapeutics, Faculty of Medicine, University of BC, Vancouver
- Technology Assessment Committee, Capital Health Region, Victoria
- Drug Benefit Committee, Pharmacare, and ad hoc Health Technology Assessment Committees, the Ministry of Health and Ministry Responsible for Seniors, Victoria
- Technology Assessment Committee, Workers' Compensation Board of BC, Richmond
- Population Testing Programs, Boundary Health Unit, South Fraser Health Unit, Surrey
- BC Research Institute for Child and Family Health, BC Women's and Children's Hospital, Vancouver
- Public Health Nursing, Boundary Health Unit, South Fraser Health Region, Surrey
- Centre for Clinical Epidemiology and Evaluation, Vancouver Hospital and Health Sciences Centre, Vancouver

Topics reflect initiative and institutional needs. Priority is given to topics with significant impact on patient health and health care costs, and with issues in more than one context. The goal is to teach systematic review and critical appraisal skills and coordinate efforts among geographically separate and institutionally diverse contexts.

Two different types of evidence-based medicine problems are addressed:

1. uncertainty regarding new technology
2. discrepancy between evidence and practice for established technology.

The Joint HTA Series will produce scientifically valid systematic reviews that key individuals in each receptor site support. The key individuals are needed to present and defend the systematic review conclusions during ongoing committee debates. This step is essential to connect health policy, including funding decisions, to the available efficacy and effectiveness evidence.

1.0 Introduction

Endovascular graft (EVG) treatment whereby a graft is inserted through the femoral artery to repair infrarenal abdominal aortic aneurysm (AAA) has potential advantages for patients and the health care system. Patients may avoid the significant morbidity and mortality associated with current major abdominal surgery techniques utilized in the treatment of AAA. The health care system may benefit from saving operating room resources and reduced hospital utilization because this procedure requires less intra-operative and post-operative time.

Cardiovascular surgeons at the Vancouver Hospital and Health Sciences Centre and in Victoria have requested funding for this procedure. The Vancouver Hospital request asked the Acute and Continuing Care Division of the BC Ministry of Health to fund EVG placement in patients with AAA that have a high incidence of fatal rupture, who are considered too frail for open abdominal resection and have no other treatment option. The BC Ministry of Health agreed, on compassionate grounds, to fund 18 EVGs (not includind out of province cases) in inoperable patients with life-threatening aneurysms.

The cardiovascular surgeons and radiologists working in the Capital Health Region in Victoria, in contrast to the initial request to the BC Ministry of Health, asked for a more general application of EVGs beyond otherwise inoperable patients. The doctors in the Capital Health Region proposed EVGs as a substitute for open abdominal resection for patients considered suitable for this procedure.

2.0 Clinical background

Abdominal aortic aneurysm (AAA), along with coronary and cerebral artery occlusion, is one of the more severe features of arteriosclerotic vascular disease.[1] AAAs are the most frequent form of aneurysm. AAAs are most often located between the ostiums of the renal arteries and the aortic bifurcation. Most AAAs occur in men during the 6th or 7th decades.[2,3] The most common symptom is back pain, although two-thirds of AAAs remain asymptomatic. AAA rupture is frequently the cause of death.[4] Intra-operative mortality increases dramatically if rupture has occurred pre-operatively.[5] Patients at greatest risk of rupture also have the greatest operative risk due to extensive co-morbidity.[6]

Symptomatic and large (>5cm) AAAs have been successfully treated, since the early 1950s with resection of the affected aortic segment and replacement with a synthetic prosthesis.[7] Operative morbidity and mortality rates (3-7% or higher, depending on patient selection and surgical expertise) while generally declining, vary markedly among treatment centres, depending greatly on patient inclusion and exclusion criteria.[5p.807]
The treatment of AAAs smaller than 4-5cm remains controversial. Proponents of surgical repair argue that early treatment avoids the increased morbidity and mortality due to AAA enlargement and patient demise. Critics argue that surgical risk outweighs the risk of AAA rupture because little is known about whether the smaller AAAs will continue to enlarge or will ultimately need resection.

3.0 Technology background

Endovascular repair of AAAs reflects developments in both endovascular prostheses and imaging technology.

Endovascular prostheses consist of two elements:

1) a self-expanding or balloon-expandable stent, made from stainless steel or other alloys (i.e. Nitinol, a nickel titanium alloy). The stent portion is designed to maintain patency of the affected vessel and to keep the graft in place. The self-expanding stents retain their arterial location using radial force while the balloon-expandable stents usually use some form of fixation pins or hooks
2) a variety of woven and knitted fabrics (i.e. Dacron) grafts. Each fabric varies in important properties such as degree of tissue incorporation, elasticity, stability, and size.

EVGs have several technical requirements as summarized in a recent review article by Green *et al*:

> An endoprosthesis must adhere securely to the atherosclerotic aortic cuff. Any movement could compromise the renal or iliac artery orifices or result in a para-prosthetic leak. The prosthesis must also be secured distally in the aortic or iliac artery wall.[8p.102]

Basic science studies have not reported on the long term interaction between blood, graft, stent and vessel wall.[8p.106]

These fabric/stent EVG combinations are loaded into delivery systems of relatively small diameter. The more recent delivery system involves a wire introducer over which the graft is inserted and positioned.

The EVGs and their delivery systems have evolved rapidly from initial straight graphs to bifurcated grafts, inserted using bilateral femoral access. The advantages of a bifurcated graft are that it "allows the common channel to be very short, reduces the need for precise measurements of aneurysm length, and ensures adequate fixation of the distal components."[8p.103]

The addition of bifurcated grafts provides an important technical advantage over straight grafts because the two distal arms, which fit within the iliac arteries, help to secure the graft both proximally and distally. The second arm of the graft is placed by obtaining access through the contra-lateral iliac artery. Most case series, some of which are reported below, state that bifurcated grafts have increased the percentage of operable patients, particularly patients with a short proximal aortic cuff. Bifurcated grafts are the predominant technology under evaluation.

Along with rapid changes in graft technology have been equally rapid changes in imaging technology. Digital fluroscopic technology is needed not only to assess the size and shape

of the AAA prior to surgery, but also in the operating room to monitor placement of the prosthesis, and to assess patency and leakage.

Anatomical information is gathered on each aneurysm using aortography:

> The length and diameter of each cuff, the length of the aneurysm, the tortuosity, size, and morphology of the iliac arteries, the location of the renal arteries and the significance of the inferior mesenteric artery must be determined in every case. This will require specialized imaging with three-dimensional reconstructions or either computed tomography or magnetic resonance imaging data and aortography.[8p.102]

Cooperation is essential between radiologists and cardiovascular surgeons during the EVG placement procedures.

No straight or bifurcated EVGs have received approval by the US Food and Drug Administration (FDA). Therefore, EVGs used to date at the Vancouver Hospital do not reflect regulatory approval in the US. A consultant at the Canadian Health Protection Branch (HPB) recently explained that the EVGs used in Vancouver represent virtually all of the EVGs use to repair AAA in Canada to date.

The US FDA has approved Phase I and II studies[9] of one EVG, known as the "Talent graft" manufactured in the US.[10] This EVG graft and delivery system, which is used in Vancouver, has been described in detail[11,12] and received regulatory approval for commercial release by Europeon authorities.

A Phase II trial comparing EVG with conventional repair is described by Moore *et al*:

> During the Phase II portion of the study, a total of 15 centers will randomly allocate patients with abdominal aortic aneurysms, suitable for EGS [EVG] implantation, to either conventional operation or endovascular graft repair. The objective of the Phase II portion of the study will be to compare the 12 month morbidity, mortality, and cost between the experimental and control groups.[10p.338]

Some early results of the Phase II trial are reported from one centre.[13]

4.0 Assessment of clinical research

4.1 Standards of evidence

The individuals appraising the evidence at CHR, BC Ministry of Health, CCEE and BCOHTA all agree on the following standards of evidence for assessment of EVGs:

1) The burden of proof of patient benefit rests with the proponents of the EVG treatment.

2) EVG treatment can only be considered in the context of institutions with operating rooms with state-of-the-art imaging technology.

3) The effectiveness of EVG treatment of AAA should be scientifically proven where feasible in a randomized control trial. The necessary duration of patient assessment remains controversial. One group of authors recommends a minimum two-year assessment period,[14] while other authors recommend a minimum five-year period.[15] The latter authors argue that a five-year period is necessary to determine the relative rate of aneurysm rupture. The two-year period seems reasonable at this early stage of technology development.

4) The circumstances in which evidence from a study other than a randomized control trial may be acceptable is in the case of surgically inoperable patients with large aneurysms known to have a high incidence of rupture. In these instances alternative study designs may be useful to compare the new technique with a historical control group or some other comparison group.

5) Case series, while important to establish feasibility and safety, do not provide efficacy and effectiveness evidence.

4.2 Methods

Search strategy

The National Institute of Health, MEDLINE and European EMBASE databases, were searched from 1980 to present using the keywords: abdominal aortic aneurysm, endovascular, endograft, stent, endoluminal, transfemoral, endoprosthesis. The Current Contents database was searched to December 1997. The Cochrane Library was searched from 1993 to 1997.

The reference lists from retrieved articles were scanned to identify additional trials. No data was obtained directly from device manufacturers.

A fugitive literature search was conducted to identify the published and unpublished scientific literature that does not appear in peer-reviewed journals or that is not indexed in the more widely used commercially available databases. A comprehensive search was also

performed on all health technology assessment publication lists to verify the existence of similar reports.

Inclusion/exclusion criteria
The primary search was for randomized controlled trials comparing EVG with open abdominal repair. Because randomized controlled trials have not been conducted, clinical evidence obtained from non-randomized study designs was included if it met the following criteria:

- prospective
- reasonable number of patients
- explicit process for patient selection and assessment, and
- technology similar to what is being considered in BC

Review articles were also included to establish background understanding of EVG technology. In addition, selected articles that present the epidemiology and natural history of AAA were included.

This review excluded literature reporting on the relative merits of various pre and post operative imaging technologies.

Search findings
No published randomized or non-randomized, contolled trials have compared EVG with open abdominal resection of AAA.

One published case series by White *et al* (1996)[15] compared patients treated with endovascular grafts with historical controls.

Reports from three prospective case series are appraised below. White *et al*[15] is included because it compares EVG with an, albeit historical, control group. Moore *et al*[16] is chosen because it is the report from the Phase I trial sanctioned by the FDA, the most relevant regulatory body to Canada, and it uses the EVG technology currently in use in BC. Blum *et al*[17] was chosen because, although the trial uses a different form of EVG technology than that currently approved by the FDA for clinical trials in the US, it does use the EVG technology promoted for purchase in the Capital Health Region. The third study also is one of the largest and has one of the longest post operative patient assessments to date.

Several case series without historical controls have been published throughout the world.*

The following articles were retrieved, but not appraised:

Australia[15,18,19]
USA[11,12,13,16]
Germany and Austria[17]
United Kingdom[20]
France[14]
Netherlands[21]

Multinational case series are also reported.[20,22] Individual patient case histories are also common, particularly describing adverse events.[23]

Critical appraisal

The three case series[15,16,17] were critically appraised by four different assessers at the BC Ministry of Health, the Capital Health Region, the Centre for Clinical Epidemiology and Evaluation, and BCOHTA by using the methodology of Schechter and Leblanc.[24]

1) White *et al* (1996)[15]

White *et al* compared 27 patients receiving straight and bifurcated endovascular grafts to 28 matched historical controls. The authors did not consider the study as definitive. Rather, they compared the two populations in order to judge whether a randomized trial was ethical and feasible.

Population

Patient selection, although described as sequential, is extremely problematic. The authors eliminated patients from both groups considered unsuitable for open surgical resection or EVG repair, respectively. The primary analysis also excluded the six EVG patients who required immediate conversion to open repair. Excluding these patients, as the authors note, biases results in favour of the EVG population.

Design

The study was designed to compare immediate surgical and post surgical complications, safety, and resource utilization. The duration of patient assessment was not stated, but seems very short. For example, it does not include mortality rates at 30 days.

Device

Three graft systems were used: the EVT Endograft (8 patients; 7 straight, 1 bifurcated), the White-Yu endoluminal graft system (19 patients; 14 straight, 4 bifurcated), the Chuter bifurcated graft (1 patient).

* Note: the majority of case series were not retrieved.

Study findings
A strength of the report is that it includes details on individual patients, both operative and immediate post-operative complications:

mortality rate	EVG = 0	Open = 1
vascular complications	EVG = 25%	Open = 15%
systemic complications	EVG = 29%	Open = 37%

mean duration of operation	EVG = Open
incidence of remote/systemic complications	EVG = Open
length of hospital stay	EVG = Open
blood loss	EVG < Open

Key appraisal issues
Bias is likely due to open selection of historical controls. The study did not report on patient outcome after hospital discharge. No analysis of different EVG systems was conducted.

Study conclusion
RCT is needed and seems feasible.

Appraisal conclusion
The comparison is invalidated by patient selection bias and limited outcome measures. The trial provides no information on which version of a particular graft technology to use in the subsequent trial.

2) Moore *et al* (1996)[16]

The authors describe this as a feasibility, Phase I trial of straight tube grafts. The FDA established the necessary study design features and dictated which technology could be used. Partial reports of the same study population were published earlier.[11,12,13]
Note: multiple publications based on the same patient population are common.

Population
A total of 46 patients, in 13 US centres were considered suitable for an EVG procedure. In particular, all patients met the most limiting inclusion criteria which is that they all had an infrarenal AAA with at least 2 cm superior and inferior cuffs of non-aneurysmal vessel. Most patients with AAA were excluded. As the study reports:

> Although screening statistics were not a requirement of the study, one study centre did maintain these data; they reported that it was necessary to screen 69 patients to identify the 10 who subsequently received tube graft repair. The most common cause of rejection was the lack of a distal neck.[17p.551]

A study from the UK similarly found that only 5 of 44 patients were suitable for straight tube grafting.[20]

Design
The study was a prospective case series designed to provide descriptive details of patient selection, surgical technique, safety, resource utilization (13 centres were used, some insertion, only 1 device).

Device
The EVT graft consists of a self-expanding stent with metallic hook fixation devices that are seated using a moveable balloon catheter; Dacron fabric. The initial device, called EGS I, malfunctioned causing a halt in the trial until an EGS II device was developed. The problem is described as a metallic attachment system failure.

Primary end points
A 30-day mortality data was reported on the entire cohort. The mean follow-up was 14 months.

Study findings
39/46 attempts were successful; conversion to open abdominal resection was not required. Conversions to open abdominal resection were immediate (n=6) and after 4 days (n=1). The following complications were reported in the successful cases:

- myocardial infarction = 1
- iliofemoral artery injury = 8
- minor thromoboembolism = 2
- superficial cellulitis = 6
- lymphatic lead = 1
- postoperative fever = 9

In addition, 17/39 patients showed leaks on contrast-enhanced CT scans. Of these, 8/17 had persistent leaks, 5/17 underwent repeat percutaneous transluminal balloon angioplasty (successful in 1 patient). 1 needed open repair and 6 continued to leak without subsequent need of interventions.

Key appraisal issues
The patients were carefully selected as suitable candidates for straight tube graft insertion. This likely explains the relatively high (85%) initial success rate. The carefully selected patients from this series cannot be compared with patients considered suitable for either straight or bifurcated EVGs. A much higher percentage of patients with AAA are suitable for repair with bifurcated EVGs.

Appraisal conclusion
This study only provides information to the research community and committees considering whether or not, and how to conduct, Phase II trials of this technology. No efficacy conclusion can be drawn form this study.

3) Blum *et al* (1997)[17]

Blum *et al* report the largest case series published to date involving both straight and bifurcated EVGs. The authors, similar to Moore *et al*[17] discussed above, describe their research as a feasibility study.

Population
154/331 patients with infrarenal AAA (47%) were treated with straight (21/154) and bifurcated grafts (133/154) at three centres in Germany and Austria. Patients were classified into one of five categories determined by anatomical features of the AAA.

Category A: suitable aortic length for straight EVG
Categories B and C: suitable for bifurcated graft
Categories D and E: unsuitable, need open repair.

Design
The study was designed as a Phase I trial to provide descriptive details of patient selection, surgical technique, safety, and resource utilization. Angiography and CT scans were conducted at discharge, 3, 6, 12 and 24 months.

Device
The graft is "a self expanding endoprosthesis composed of a nitinol frame annealed into a tubular zigzag configuration by a 7.0 polypropylene thread and covered with a 0.1mm woven-polyester fabric."[18p.15]

Primary end points
Primary technical success: "the complete exclusion of the abdominal aortic aneurysm from the circulation, with the restoration of normal blood flow." [18p.15]

Study findings
Primary technical success was achieved in 134/154 (87%) of patients.

Category A, straight graphs = 18/21 (87%)
- 2 patients: proximal
- 1 patient: distal leak and dislodgment

Categories B and C, bifurcated graphs = 116/133 (87%)
- 3 patients: converted to surgical repair
- 1 patient: ruptured iliac artery with delivery device
- 2 patients: insertion device could not be advanced
- 8 patients: tears in polyester fabric required additional stents

Early complications

Minor complications included insertion site damage and biochemical changes
Major complications were rupture of iliac artery = 1, embolic graft occlusion requiring amputation of the foot = 1, and acute hepatic failure and death = 1.

Late complications
Category A, straight graphs: 3 patients required subsequent graphs due to leaks.
Categories B and C, bifurcated graphs: no migration, 11 leaks. No open procedures were required.

Appraisal conclusion
Further research is warranted and Phase II trials seem feasible.

5.0 Discussion

The initial clinical experience described by Parodi *et al*[25] and current EVG use in BC provide EVG on a compassionate basis to patients with contra-indications to conventional open abdominal resection. While much less commonly reported, other authors[22] continue to describe some success with EVG use in these highest risk patients. This review, however, concerns the much broader application of EVG technology as a potential substitute to open surgical repair.

In the continuum from experimental to state-of-the art, EVG treatment of AAA as a substitute for open abdominal resection remains at what the US National Institutes of Health call the "investigational" stage.[26] The investigational stage is defined as the place on the continuum where: "There is insufficient evidence to determine the safety of effectiveness of the technology. Use of the technology in patient populations should be confined largely to research protocols."[25p.19]

The investigation stage fits within a set of ordinal categories:

- **Inception:** virtually untested
- **Innovation:** preliminary testing
- **Investigation:** as above
- **Promising:** appropriate for some indications
- **Established:** adequately evaluated
- **Guidelines:** standard care

EVG remains in the investigation stage for several reasons:

1) EVG technology is in a rapid state of evolution. The technology used for repairs varies within studies, between studies, and even changes during studies.

2) Case series describe a wide range of procedural problems including the difficulties of obtaining access through small or tortuous iliac arteries, obtaining accurate measurements of the aneurysm and adjacent arteries, and securing the EVGs both proximally and distally. The attachment problems are particularly marked for patients

with a relatively short normal aortic cuff proximal to the aneurysm (but distal to the renal artery bifurcation).

3) EVG remains investigational because, while feasible in a few carefully selected individuals, the safety, effectiveness, and durability of any EVG system is not yet proven in randomized controlled trials. Most significantly, EVGs have not been shown to have medium and long term reduction in deaths from AAA rupture. The follow-up for EVG is relative short averaging 14 months in the study by Moore *et al*[16] and 13 months in the study by Blum *et al*.[17] Follow-up for conventional studies often exceeds 10 years.[7]

4) Clinical trial methodology, particularly outcome measures, have not become standardized. This may change with adoption of the recommendations of recent consensus conferences.[27,28] These conferences recommended standardized methods for anatomical classification of AAAs, a definition of procedural success, and a procedure for clinical assessment, as well as necessary data collection forms. Other authors[29] have called for more complete reporting of late as well as early EVG complications.

6.0 Conclusions

1) Decisions regarding public funding of EVG technology as a replacement for open abdominal resection of AAA must await technology maturity and clinical trial results regarding specific EVG technology.

2) The current practice of offering EVG on a compassionate basis to patients with contra-indications to conventional open abdominal resection should continue under study conditions. All patients should be offered a chance to enroll in a research study that is designed to measure the effectiveness of this procedure in this specific group of patients.

3) Literature review for further evidence on the effectiveness, indications, and cost benefit of EVG should occur in conjunction with the various stakeholders in this new therapy.

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