Endovascular Grafts for Abdominal Aortic Aneurysms

Medical Policy

Section
Surgery

Original Policy Date
12:2013

Last Review Status/Date
Reviewed with literature search/12:2013

Issue
12:2013

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Description

Endovascular grafts are minimally invasive alternatives to open surgical repair for treatment of abdominal aortic aneurysms (AAAs). Open surgical repair of AAAs has high morbidity and mortality, and endovascular grafts have the potential to reduce the operative risk associated with AAA repair.

The conventional management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate of 4%, which may rise to 10% in symptomatic patients. Due to this high mortality rate, endovascular prostheses have been investigated as a minimally invasive, catheter-based alternative to open surgical excision of AAAs. These devices are deployed across the aneurysm such that the aneurysm is effectively “excluded” from the circulation, with subsequent restoration of normal blood flow.

There are several types of grafts currently under investigation—straight grafts, in which both ends are anchored to the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored to the infrarenal aorta, and the distal ends are anchored to the iliac arteries. Recently, fenestrated grafts have also been investigated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency through these critical arteries. In addition, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

In 1999, the U.S. Food and Drug Administration (FDA) approved two endovascular grafts for use in the abdominal aorta: the EBT Abdominal Aortic Endovascular Grafting System (Guidant Endovascular Technologies) and the AneuRx Prosthesis System (now called AneuRx AAAdvantage Stent Graft - Medtronic Vascular, Inc.). In the Guidant system, the endograft is placed in the aorta and expanded using balloon dilation. The graft is anchored to the vessel wall using sutureless hooks at its superior and inferior ends. The AneuRx system consists of a woven polyester interior surface with a self-expanding nitinol exoskeleton. The radial force of
the expanding stent embeds the exoskeleton into the aneurysm wall and thus constitutes the attachment mechanism. In April 2002, the FDA approved an additional Guidant device, the Ancure Aortoiliac System. The Ancure device consists of a woven polyester graft that is housed within a long flexible delivery tube (catheter) for use in patients whose anatomy is not suited for the use of the single tube or bifurcated endograft device. This version is identical to the earlier Guidant Endovascular Grafting System except that the aortoiliac Ancure grafts have suture loops on the superior and inferior attachment systems. Several other grafts have been subsequently approved, including the Gore Excluder (2002), the Zenith AAA Endovascular Graft (2003 – now called Zenith Flex AAA Endovascular Graft), the Endologix Powerlink (2004), and the Medtronic Talent Abdominal Stent Graft System (2008).

Grafts that extend across the visceral arteries are currently under development but are not FDA approved. For example, the Zenith Fenestrated AAA Endovascular Graft is currently under investigation as part of the FDA approval process.

**Policy**

The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) as a treatment of abdominal aortic aneurysms may be considered *medically necessary* as a treatment of abdominal aortic aneurysms in any of the following clinical situations:

- an aneurysmal diameter greater than 5.0 cm
- an aneurysmal diameter of 4–5.0 cm that has increased in size by 0.5 cm in the last 6 months
- an aneurysmal diameter that measures twice the size of the normal infrarenal aorta
- a ruptured abdominal aortic aneurysm (see Policy Guidelines).

The use of endoprostheses approved by the FDA as a treatment of abdominal aortic aneurysms is considered *investigational* for the following clinical situations:

- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery
- Treatment of aneurysms that do meet the recommended threshold for surgery in patients who are ineligible for open repair due to physical limitations or other factors

**Policy Guidelines**

For treatment of ruptured abdominal aortic aneurysm with endoprostheses, several factors must be considered including the following:
• The patient must be sufficiently stable to undergo detailed computed tomography (CT) examination for anatomic measurements,
• The aneurysm should be anatomically appropriate for endovascular repair, and
• Specialized personnel should be available.

To monitor for leaking of the graft after implantation, patients will typically undergo routine imaging with either computed tomography or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement is detected.

Coding

The overall procedure essentially involves 4 steps: establishment of vascular access, the introduction of catheters and guidewires into the arterial system, deployment of the endoprosthesis, and radiologic supervision.

1. The following CPT codes describe the establishment of vascular access; either the femoral or iliac arteries are used.

34812: Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision; unilateral
34820: Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision; unilateral

2. Introduction of catheters and guidewires

CPT code 36200 (introduction of catheter, aorta) may be used. Sometimes the renal arteries are catheterized to ensure that the renal arteries are not obstructed by the prosthesis. If this is the case, CPT code 36245 (selective catheter placement, arterial system, each first-order abdominal branch) may be used.

3. The following CPT codes describe the deployment of the prosthesis

34800: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using aorto-aortic tube prosthesis
34802: ;using modular bifurcated prosthesis (1 docking limb)
34803: ;using modular bifurcated prosthesis (2 docking limbs)
34804: ;using unibody bifurcated prosthesis
34805: ;using aorto-uniliac or aorta-unifemoral prosthesis
34825: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm; initial vessel
34826: ; each additional vessel

4. The following new CPT codes describe radiologic supervision
75952: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection, radiological supervision and interpretation

75953: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm, radiological supervision, and interpretation.

It is estimated that less than 5% of patients will be unsuccessfully treated with endovascular techniques to the extent that the patient must undergo urgent or emergent open surgical aneurysm repair. The following CPT codes have been introduced to describe this situation:

34830: Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis

34831: ; aorto-bi-iliac prosthesis

34832: ; aorto-bifemoral prosthesis

Category III Codes

There are also category III CPT codes that specifically identify the use of fenestrated grafts that allow extensions to be added into the visceral branches of the abdominal aorta. At the present time, these grafts are not FDA approved, and thus would be considered investigational according to this policy. The use of visceral extension prosthesis is reported separately from the use of the fenestrated graft since the number of visceral extensions may vary from 1 to 4, based on the aneurysm anatomy.

0078T: Endovascular repair of abdominal aortic aneurysm, pseudoaneurysm or dissection, abdominal aorta involving visceral vessels.

0079T: Placement of visceral extension prosthesis for endovascular repair of abdominal aortic aneurysm involving visceral vessels, each visceral branch.

Codes 0080T and 0081T describe the radiologic supervision of 0078T and 0079T, respectively.

Rationale

This policy was created in July 1998 and updated periodically with literature review. The most recent update with literature review covers the period from February 2011 through February 2012.

The main potential advantage of endovascular grafts for abdominal aortic aneurysm (AAA) is in offering a less invasive and risky approach to the repair of abdominal aneurysms. This approach has the potential to reduce the relatively high perioperative morbidity and mortality associated with open abdominal aortic aneurysm repair.

The use of endovascular grafts also has potential disadvantages. In particular, there are concerns regarding the durability of the anchoring system, aneurysm expansion, and other late complications related to the prosthetic graft. Aneurysm expansion may result from perivascular
leaks, aka endoleaks, which are a unique complication of endoprostheses. Perivascular leaks may result from an incompetent seal at one of the graft attachment sites, blood flow in aneurysm tributaries (these tributaries are ligated during open surgery), or perforation of graft fabric. (1-4)

This policy is also supported by a 2001 TEC Assessment. (5)

LITERATURE REVIEW

EVAR as an alternative to open repair for elective treatment of AAAs

A number of moderate to large-sized randomized, controlled trials (RCTs) have been completed comparing endovascular repair with open surgical repair, and these studies comprise the main body of literature on the comparative efficacy of the two procedures. (6-8) Early reports of outcomes from these trials demonstrated that the perioperative morbidity and mortality of an endovascular approach were improved compared to the control group of open surgical repair. (9, 10) These results were consistent with prior large observational studies. (11-13) However, the midterm results of these studies suggest that the short-term improvements are not associated with a long-term benefit compared to an open approach. These studies are reviewed below:

Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial.(7) The Dutch Randomized Endovascular Aneurysm Management (DREAM) trial enrolled 351 patients who were randomized to either endovascular or open repair. The incidence of aneurysm-related death (i.e., within 30 days) was 4.6% in the open repair group and 1.2% in the endovascular repair group. However, after 2 years, the cumulative survival rates were 89.6% for open repair and 89.7% for endovascular repair, due to a higher incidence of late death in the endovascular group. The authors suggest that an open approach may precipitate the mortality of frail patients who were most likely to die in the coming year and that the advantage of an endovascular approach may primarily be to delay death. Alternatively, the late mortality of endovascular repair may relate to its inferior ability to prevent rupture or prevent additional complications, compared to an open approach. If this is true, longer term follow-up is important to determine if the endovascular approach has an inferior outcome over the long term.

Longer term follow-up from this study was reported in 2010. (14) After 6 years of follow-up, the survival rates were similar between the EVAR and open repair groups (68.9% vs. 69.9%, respectively; 95% confidence interval [CI] for the difference: -0.8 to 10.8; p=0.97). Re-interventions were more common in the EVAR group. Freedom from reinterventions was 70.4% for EVAR compared to 81.9% for open repair (95% CI for difference: 2.0 to 21.0; p=0.03).

Endovascular Aneurysm Repair Versus Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR 1) Trial.(6) A larger trial, EVAR 1, enrolled 1,082 patients 60 years or older with abdominal aneurysms at least 5.5 cm in diameter and randomized them to either elective open or endovascular repair. Similar to the DREAM trial, endovascular repair was associated with an improvement in aneurysm-related survival (4.7% open vs. 1.7% at 30 days), but no advantage with respect to all-cause mortality and quality-of-life measures. For example, within 4 years of follow-up, endoscopic repair was associated with a complication rate of 41% compared to only 9% in the surgically treated group. Due to the higher incidence of late complications in those undergoing endovascular repairs, ongoing surveillance is required.
Longer term follow-up from this trial was reported by the EVAR Investigators in 2010. (15) This publication included a total of 1,252 patients with aneurysms 5.5 cm or larger randomized to EVAR or open repair. After 8 years of follow-up, there was no difference in survival between the groups (hazard ratio [HR]: 1.03; 95% CI: 0.86-1.23). This evidence suggests that the early survival advantage of EVAR is lost over time due to late endograft ruptures, some of which are fatal.

Another follow-up publication from the EVAR-1 trial focused on cardiovascular morbidity and mortality at 5 years post-treatment. (16) The EVAR group had a lower total cardiovascular event rate at all follow-up time points, but the difference over the course of the study did not reach statistical significance (HR: 0.83, 95% CI: 0.62-1.10). During the period of 6-24 months post-surgery, the EVAR group had a higher rate of cardiovascular events (HR: 1.44, 95% CI: 0.79-2.62), which attenuated the early benefit of EVAR and led to convergence of events between the two procedures. Cardiovascular mortality over the course of the trial was similar between the groups (HR: 1.06, 95% CI: 0.83-1.36).

ACE Trial. The ACE trial (17) compared EVAR to open surgical repair in patients who were low-to-moderate surgical risk. A total of 306 patients were randomized from 25 clinical centers in France. Inclusion criteria included a Society of Vascular Surgery comorbidity score of 0-2 and suitable anatomy for EVAR without high-risk features. There were 17 crossovers from open surgery to EVAR (11%) and 4 crossovers from EVAR to open surgery (3%). Median follow-up was 3 years.

Perioperative mortality was 1.3% for the EVAR group and 0.6% for the open surgery group (p=0.12). Survival at one year was 95.2% for EVAR and 96.5% for open surgery (p=0.24). At 3 years, survival remained similar at 86.3% for EVAR and 86.7% for open surgery. Major adverse cardiovascular events were present in 6.7% of EVAR patients compared to 4.0% of open surgery, a difference that was also not significant. Re-interventions were more common in the EVAR group compared to open surgery (16% vs. 2.7%, p<0.0001).

Endoleaks were identified on follow-up computed tomography (CT) scanning in 27% of EVAR patients (41/150). There were a total of 10 type I endoleaks; 5 were treated by endoluminal procedures, 2 were treated with open surgery, and 3 were treated by observation. There were a total of 31 type II endoleaks; 8 of these were treated with coil embolization and 23 were left untreated.

Systematic reviews. Agency for Healthcare Research and Quality (AHRQ) published an Evidence-based Practice Center report comparing endovascular and open surgical repair for abdominal aortic aneurysm. (18) Based primarily on the DREAM and EVAR studies discussed here, the report concludes that for aneurysms larger than 5.5 cm, endovascular intervention improves perioperative outcomes compared with open surgical repair, but it has not been shown to improve long-term survival or health status compared with open surgery. The U.K.’s National Institute for Health and Clinical Excellence (NICE) also updated their guidance following a 2005 systematic review of the safety and efficacy of elective endovascular repair. (19) The guidance states, “Current evidence on the efficacy and short-term safety of stent graft placement in abdominal aortic aneurysm appears adequate to support the use of this procedure.”

Nonrandomized studies. Endovascular grafts originally received FDA approval based on nonrandomized comparative studies that demonstrated potential improvements in outcomes. For the Guidant Endovascular Grafting System, (20) data were presented to the FDA on 88
control patients treated surgically; in the other groups, 118 received a straight endoprosthesis, and 162 received bifurcated grafts. Controls were patients who were not candidates for the endoprosthesis due to anatomic considerations, i.e., the vessels were too small for the catheter or the aneurysm extended too close to the renal arteries. The 30-day and long-term mortality were not significantly different among all 3 groups. The rate of significant complications (e.g., cardiac, respiratory, renal, gastrointestinal) in the endoprostheses groups was half that of the control group. Other immediate benefits experienced in the endoprosthesis group included shorter hospital stays, decreased operative blood loss, and opportunity to use regional anesthesia. Leaking around the graft was reported in about 25% of patients at 1 year, although only 10% showed aneurysm enlargement.

For the AneurRx Bifurcated Endovascular Endoprosthesis System, (21) data were presented on 53 patients treated surgically and 199 patients treated with an endoprosthesis. The control group consisted of candidates for aneurysm repair just prior to the introduction of the endoprosthesis. Therefore, the patient selection criteria for the 2 groups were the same. There was no difference in perioperative or late mortality between the groups. The risk of severe treatment-related adverse events was significantly lower in the endoprosthesis group. There were also decreases in anesthesia time, blood loss, earlier ambulation, and resumption of normal diet. The duration of time in the intensive care unit (ICU) decreased from 3.5 days in the surgical group to 0.9 days in the endoprosthesis group. Leaking around the graft was detected in about 25% of patients. Similar to the Guidant system, there was a lack of correlation with clinically significant complications.

A systematic review of nonrandomized studies that compared EVAR versus open surgery in elderly patients 80 years or older was published in 2011. (22) This analysis included observational studies of elderly patients who had undergone EVAR and compared results with observational studies of elderly patients undergoing open repair. Pooled analysis revealed that operative mortality was lower in the EVAR group (2.3%) compared to the open surgery group (8.6%), and that EVAR also had lower rates of postoperative cardiac, pulmonary and renal complications. Survival at 3 years was not different between patients undergoing EVAR and open repair (Risk ratio [RR]: 1.10, 95% CI: 0.77-1.57).

Conclusions. Evidence from several randomized controlled trials (RCTs) supports that EVAR is a reasonable alternative to open surgical repair for aneurysms greater than 5.5 cm, or that have high-risk features such as rapid growth. In unselected patients with AAAs appropriate for surgery, EVAR is associated with lower perioperative morbidity and mortality. However, EVAR is associated with a higher rate of longer-term complications, including endoleaks and the need for re-interventions. Longer-term mortality is similar between EVAR and open surgery at 5-8 years of follow-up. For patients who are low risk for open surgery, one RCT reports low perioperative morbidity and mortality for both EVAR and open surgery, with no difference between the 2 procedures. Thus, the advantage for EVAR in reduced perioperative morbidity and mortality may not be present for patients who are low-risk for surgery.

EVAR as an alternative to open repair for ruptured aneurysms

Emergency EVAR (eEVAR) for ruptured abdominal aortic aneurysms is being studied as a potential method to decrease the high mortality rate associated with open surgical repair. There are no randomized trials of EVAR versus open surgery for rupture AAAs. RCTs are difficult in this area due to the emergent or semi-emergent nature of treatment for ruptured aneurysms. As a result, the most relevant evidence on this question is from non-randomized, comparative
studies of EVAR versus open surgery. However, there is a high risk for selection bias in uncontrolled studies. Aneurysms that meet the anatomical criteria for EVAR tend to be smaller and less complex than aneurysms that do not meet criteria for EVAR, resulting in the highest risk patients being preferentially treated with open surgery.

Several nonrandomized comparative studies have been performed from hospital databases. Using a Nationwide Inpatient Sample, McPhee and colleagues found that rates of endovascular treatment of ruptured abdominal aortic aneurysms increased from 6% in 2001 to 19% in 2006. (23) They found that EVAR had a lower overall in-hospital mortality rate than open repair (32% vs. 41%, respectively) and that the effect was amplified when stratified by institutional volume. 

(24) Based on analysis of data from Medicare beneficiaries, Egorova and colleagues found that EVAR repair of ruptured abdominal aortic aneurysms had a protective effect (hazard ratio [HR]: 0.86, p=0.0061) on long-term survival controlling for comorbidities, demographics, and volume.

Another similar study was an analysis of hospital discharge databases for California, Florida, New Jersey, and New York. (25) Perioperative mortality rates were lower for patients treated with eEVAR compared to open surgical repair.

One comparative, nonrandomized study was identified that compared EVAR and open repair for ruptured aneurysms at one institution. Ten Bosch et al. (26) performed a retrospective comparison of 25 patients who underwent EVAR with 79 patients who underwent open repair. EVAR was performed if the EVAR-trained vascular surgeon was on call and the patient was suitable for EVAR; otherwise open repair was performed. Perioperative mortality was 4.0% in the EVAR group compared to 6.1% in the open repair group (p>0.99). At 30 days, mortality was lower for the EVAR group (20.0% vs. 45.5%, respectively; p=0.04), and this survival advantage was maintained at 6 months (28% vs. 54.5%, respectively; p=0.04). Median length of stay was also lower with EVAR (9.5 days vs. 17.0 days, respectively, p=0.03).

Another study retrospectively compared early postoperative outcomes in patients with ruptured AAAs who underwent EVAR or open repair in one hospital in the Netherlands. (27) There were a total of 56 patients treated over a 2-year period, 15 by EVAR and 41 by open surgery. Thirty-day mortality was 26% in the EVAR group compared to 46% in the open surgery group. The overall complication rate was not different between groups.

One study attempted to address the issue of selection bias by assessing the overall mortality rate in a unit where eEVAR has become the treatment of choice and comparing it with the overall mortality rate of historical controls treated with open surgical repair. (28) For a 2-year period between 2002 and 2004, patients received eEVAR unless they presented with shock or cardiac arrest during transportation to the hospital or if the CT scan indicated an unfavorable anatomic configuration of the aortic neck (short, conical, or wide). Fifty-one patients (17 eEVAR and 34 open repair) were treated during the study period; they were compared with a group of 41 patients treated in the previous 2-year period in the same unit and by the same vascular surgeons. The study found a decrease in length of stay in intensive care (5.5 vs. 0 days, respectively) and a trend toward a decrease in mortality (59% vs. 39%, respectively; p=0.065) with eEVAR. However, the study also found that patients who were considered too unstable for eEVAR had a 77% mortality rate, while those who were considered unsuitable for eEVAR due to unsuitable aortic neck anatomy had a 19% mortality rate. These results suggest that the favorable mortality rates found in uncontrolled eEVAR studies are due to selection bias.

A different approach to this problem was taken by an industry-sponsored study that enrolled 100 consecutive patients across 10 institutions to determine the percentage of patients for whom...
eEVAR was applicable and to compare mortality and morbidity between the 2 groups. (29) Open surgical repair was performed in 51 patients; in 80% of cases, this was due to a configuration of the neck that was unfavorable for endovascular repair. Patients with severe hemodynamic instability also received open surgical repair. This study found no difference between the 2 groups in either in-hospital (35% to 39%, respectively) or 3-month mortality (40% in the eEVAR group and 42% in the open repair group). Blood loss, time in intensive care, and the duration of mechanical ventilation were lower in patients treated by eEVAR than in those treated by open surgery. Identical mortality rates (53%) were also found in a pilot study with 32 patients randomized to eEVAR or open surgical repair by intention-to-treat analysis. (30) In addition, endovascular repair requires long-term monitoring and possible re-intervention due to endoleaks, graft migration, and aneurysm enlargement. Paraplegia resulting from spinal cord ischemia during eEVAR has also been reported. (31)

In a Cochrane Review, Dillon and colleagues concluded that while there are no randomized trials, data suggest that endovascular repair is feasible in selected patients with outcomes comparable to best conventional open surgical repair for ruptured abdominal aortic aneurysms. (32)

Conclusions. There are no randomized trials of EVAR for ruptured aneurysms, but a number of studies and systematic reviews have presented comparative data on use of EVAR for this purpose. The majority of these publications report that early mortality is substantially reduced with EVAR compared to open surgery. However, these trials do not adequately control for the possibility of selection bias as aneurysms that are not anatomically suitable for EVAR are more likely to be high risk. As a result, the internal validity of these analyses is not high. High-quality RCTs are difficult to perform in this area due to the emergency nature of ruptured aneurysms and the accompanying logistical concerns. For patients with ruptured abdominal aortic aneurysms to be candidates for endovascular repair, the lesions need to be suitable for the endovascular devices and patients need to be sufficiently stable to undergo CT evaluation.

EVAR compared to non-surgical treatment for smaller aneurysms that do not meet current size criteria for surgery or for patients who are ineligible for open surgery

There are a limited number of randomized trials that address patients with aneurysms that cannot be treated by open surgery. This includes patients who have smaller aneurysms that do not meet the size threshold for open surgery, and also patients who cannot undergo open surgery due to prohibitive operative risk.

Caesar Trial. The Caesar trial (33) compared the use of EVAR for small AAAs, which did not meet the current thresholds recommended for intervention, with active surveillance. The study enrolled 360 patients, 50-79-years-old, with aneurysms of 4.1-5.4 cm. Patients were randomized to early EVAR treatment or surveillance by ultrasound and/or CT. In the surveillance group, surgery was performed only after the AAA met current recommendations for intervention (≥5.5 cm, growth 1 cm/year, or symptomatic). If repair was indicated, EVAR was performed unless the anatomy of the AAA was unsuitable for EVAR, in which case open repair was performed. Patients were followed for a median of 32.4 months for the primary outcome of all-cause mortality.

The primary outcome occurred at a lower rate than anticipated, thus limiting the power to detect a difference. At final follow-up, there was no significant difference in the main endpoint. Kaplan-Meier estimates of all-cause mortality were 10.1% for the surveillance group compared with
14.5% for the EVAR group (HR: 0.76; 95% CI: 0.30-1.93). Aneurysm-related mortality, aneurysm rupture, and major morbidity rates were also similar between groups. For patients in the surveillance group, the Kaplan-Meier estimate of undergoing aneurysm repair was 59.7% at 36 months and 84.5% at 54 months.

A follow-up publication from the Caesar trial reported on quality-of-life (QOL) outcomes. (34) Patients were assessed with the SF-36 short-form at baseline, 6 months, 12 months, and yearly after that with a mean follow-up of 31.8 months. Following EVAR, QOL scores in the EVAR arm rose while those in the observation arm declined. At 6 months’ follow-up, QOL scores in the EVAR group were significantly higher than in the observation group, with significant differences found for overall score (mean difference 5.4, p=0.002), physical domain score (mean difference 3.8, p=0.02), and mental domain score (mean difference 6.0, p=0.001). Over longer periods of time, scores in both the EVAR and observation group declined, and the differences were not significantly different at time periods of one year or longer.

PIVOTAL Trial. The PIVOTAL (Positive Impact of Endovascular Options for Treating Aneurysms Early) trial (35) randomly assigned 728 patients with AAAs of 4-5 cm to early EVAR or ultrasound surveillance. Patients were followed for a mean 20 +/- 12 months for the primary outcomes of aneurysm rupture, aneurysm-related death, and overall mortality. At the final follow-up, overall mortality was the same in both groups at a rate of 4.1%. Aneurysm rupture or aneurysm-related death occurred at a low rate and was also the same between groups at a rate of 0.6%. The hazard ratio for the primary outcome measures was 0.99 (95% CI: 0.14-7.06).

EVAR 2 Trial.(8) The U.K. EVAR Investigators published an RCT of EVAR versus no treatment of AAAs 5.5 cm or larger, but in whom surgery was not an option due to prohibitive surgical risk or patient preference. This trial was the only trial that evaluated patients who were unsuitable for open surgery and compared endovascular repair to no surgical intervention. EVAR 2 randomized 338 patients to either endovascular repair or medical management. Endovascular repair had a considerable 30-day operative mortality and did not improve survival over no intervention. However, the results of this trial are limited, since 20% of patients assigned to medical management underwent elective aneurysm repair in violation of the protocol. In addition, endovascular repair was not performed until a median of 57 days after randomization; during this period, 9 aneurysms ruptured, contributing to the endovascular mortality calculation, biasing results against endovascular repair.

A follow-up publication for this trial reported on longer-term follow-up of 404 patients randomized to EVAR or no treatment. Perioperative mortality in the EVAR group was 7.3%. At the 8-year follow-up point, aneurysm-related mortality was lower in the EVAR group, but overall mortality did not differ (HR: 0.99; 95% CI: 0.78-1.27). There was a high rate of long-term complications in the EVAR group, with 48% of patients having a graft-related complication, and 27% of patients requiring reintervention for complications.

Accompanying editorials provided the following comments. (36, 37)

- While there has been no difference in overall survival in the EVAR 1 trial, only 24% of patients have reached 4-year follow-up, and further study is required. With an enrolment of 1,082 patients, EVAR 1 is powered to show a difference in overall mortality, while the smaller DREAM trial is not.

- Suitability for endovascular repair depends on anatomic factors. In EVAR 1 only 54% of patients were considered suitable candidates, but this ranged from 6% to 100% across
the participating institutions, indicating marked variability in the assessment of anatomic suitability.

- Given that the rate of interventions for endovascular repair increases over time, open repair may be recommended for those with longer life expectancies.

- The numbers of elective aneurysm repairs may grow, considering the recent recommendation of the United States Preventive Services Task Force (USPSTF) for screening for abdominal aortic aneurysms in men who have ever smoked. (38)

- It is estimated that approximately 300,000 aneurysms will be identified in this targeted screening population. Many of these aneurysms will measure less than 5.5 cm in diameter and thus will be managed with periodic imaging surveillance, but patients with larger aneurysms will be faced with choosing between open and endovascular repair. The U.S. Agency for Healthcare Research and Quality (AHRQ) has commissioned a technology assessment to compare endovascular and open repair in terms of effectiveness, cost, and quality of life.

Systematic reviews. Based solely on the EVAR 2 trial, the AHRQ report concluded that endovascular repair does not improve survival in patients who are medically unfit for open surgery. (18) As previously discussed, the EVAR 2 trial, and thus the AHRQ assessment, is compromised by the high proportion of patients who crossed over from nonoperative to endovascular repair, and by the number of patients who died in the interval between randomization and treatment with EVAR. Professional guidelines based on both randomized and nonrandomized trials suggest that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open operations. (39)

A Cochrane Review summarized the evidence on interventions for small aneurysms, 4.0-5.5 cm in size, either by open surgery or EVAR. (40) There were a total of 4 RCTs identified, including the 2 RCTs on EVAR included in this policy review (33, 35) and an additional 2 RCTs on open surgical repair. Combined analysis of the 2 EVAR trials revealed no difference in mortality at one year (odds ratio [OR]: 1.15, 95% CI: 0.59-2.25). There was also no survival benefit for the trials of open surgery, nor was there any benefit apparent when all 4 trials were combined.

Conclusions. The evidence does not indicate that EVAR improves outcomes for patients who are not suitable for open surgery, as judged by aneurysm size and or clinical factors that indicate prohibitive risk for open surgery. For small aneurysms, RCT evidence reports that morbidity and mortality outcomes from surveillance are as good as those from early intervention with EVAR. For patients who are prohibitive operative risk, one RCT reports that EVAR is associated with lower aneurysm mortality but no difference in overall mortality, and that there is a high rate of long-term complications and re-interventions with EVAR. This RCT evidence is limited by a high rate of crossovers, primarily from open surgery to EVAR, which may limit the ability to detect a difference between the 2 treatments.

Summary

Evidence from randomized, controlled trials comparing EVAR to open repair for elective treatment of aneurysms indicates that neither approach is clearly superior to the other. These trials report on longer term outcomes, greater than 5 years after surgery, and continue to show comparable survival for EVAR compared to open repair at these longer time points. The early advantage of EVAR is balanced out by the higher rate of long-term complications. One trial of patients who were of low-to-moderate surgical risk reported that the early benefit of EVAR was
not evident in this population, raising the question of whether the early benefits of EVAR extend to patients at lower risk for open surgery. Based on these data, EVAR may be considered medically necessary as an alternative to open surgery in patients who are candidates for both procedures.

For patients with ruptured AAAs, evidence from non-randomized, matched comparisons report that EVAR is associated with lower short-term morbidity and mortality. While these studies are prone to selection bias, since the highest risk aneurysms tend to be less suitable for EVAR due to anatomic considerations, RCTs are difficult in this area due to the emergent nature of the condition and logistical considerations. For these reasons, EVAR may be considered medically necessary for ruptured aneurysms.

At least 2 RCTs have evaluated EVAR versus no surgical intervention in patients who were not eligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials do not report superior outcomes with EVAR and thus do not support use of EVAR in these patients. As a result, EVAR is considered investigational for patients who are not candidates for open surgery due to aneurysm size or prohibitive surgical risk.

Clinical Practice Guidelines and Position Statements

Guidelines for the use of EVAR were developed jointly by the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, and the Canadian Interventional Radiology Association. (41) These guidelines state that:

- Indications for EVAR are currently the same as open repair
- Patient preference for EVAR versus open repair should be considered when appropriate
- Endovascular abdominal aortic aneurysm repair should be considered as having an intermediate to high cardiac risk that ranges from 3% to 7%
- There has been increasing use of EVAR for ruptured aneurysms. Achieving optimal EVAR results for ruptured AAA requires establishment of a treatment protocol involving the emergency department, the endovascular team, anesthesiology, and the operating room personnel
- Lifelong imaging surveillance of patients after EVAR is critical for
  - the detection and, if possible, the characterization of endoleaks;
  - evidence of expansion or shrinkage of the residual AAA sac through measurement of aneurysm size, volume calculation, and identification of substantial changes in aneurysm dimensions;
  - detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and
  - evaluation of the long-term performance of the endoprosthesis.

The Society for Vascular Surgery (SVS) published guidelines for the treatment of AAAs in 2009. (42) These guidelines indicate that either open surgery or EVAR is an option for patients with aneurysms that meet the current treatment threshold. These guidelines also contained the following statements and recommendations:
• EVAR is progressively replacing open surgery as the treatment of choice, and accounts for more than half of all elective AAA repairs in the U.S.

• Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible (level of recommendation: strong; quality of evidence: moderate).

• EVAR may be considered for high-risk patients unfit for surgical repair (level of recommendation: weak, quality of evidence: low).

**Medicare National Coverage**

None

**References:**


5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Endovascular Stent-Grafts for Abdominal Aortic Aneurysm Repair. TEC Assessment Program 2001; Volume 16, Tab 2.


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