# Aneurysm-related death: Primary endpoint analysis for comparison of open and endovascular repair

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***Purpose:*** **The purpose of this study was to utilize an objective endpoint analysis of aneurysm treatment, which is based on the primary objective of aneurysm repair, and to apply it to a consecutive series of patients undergoing open and endovascular repair.**

***Method:*** **Aneurysm-related death was defined as any death that occurred within 30 days of primary aneurysm treatment (open or endovascular), within 30 days of a secondary aneurysm or graft-related treatment, or any death related to the aneurysm or graft at any time following treatment. We reviewed 417 consecutive patients undergoing elective infrarenal aortic aneurysm repair: 243 patients with open repair and 174 patients with endovascular repair.**

***Results:*** **There was no difference between the groups (open vs endovascular) with regard to mean age ± standard deviation (73 ± 8 years vs 74 ± 8 years) or aneurysm size (64 ± 2 mm vs 58 ± 10 mm) ($P$ = not significant [NS]). The 30-day mortality for the primary procedure after open repair was 3.7% (9/243) and after endovascular repair was 0.6% (1/174, $P < .05$). The 30-day mortality for secondary procedures after open repair was 14% (6/41) compared to 0% after endovascular repair ($P < .05$). The aneurysm-related death rate was 4.1% (10/243) after open surgery and 0.6% (1/174) after endovascular repair ($P < .05$). Mean follow-up was 5 months longer following open repair ($P < .05$). Secondary procedures were performed in 41 patients following open surgery and 27 patients following endovascular repair ($P$ = NS). Secondary procedures following open repair were performed for anastomotic aneurysms (n = 18), graft infection (n = 6), aortoenteric fistula (n = 5), anastomotic hemorrhage (n = 4), lower extremity amputation (n = 4), graft thrombosis (n = 3), and distal revascularization (n = 1). Secondary procedures following endovascular repair consisted of proximal extender cuffs (n = 11), distal extender cuffs (n = 11), limb thrombosis (n = 3), and surgical conversion (n = 2). The magnitude of secondary procedures following open repair was greater with longer operative time 292 ± 89 minutes vs 129 ± 33 minutes ($P < .0001$), longer length of stay 13 ± 10 days vs 2 ± 2 days ($P < .0001$) and greater blood loss 3382 ± 4278 mL vs 851 ± 114 mL ($P < .0001$).**

***Conclusions:*** **The aneurysm-related death rate combines early and late deaths and should be used as the primary outcome measure to objectively compare the results of open and endovascular repair in the treatment of infrarenal abdominal aortic aneurysms. In our experience, endovascular aneurysm repair reduced the overall aneurysm-related death rate when compared to open repair. Secondary procedures are required after both open and endovascular repair. However, the magnitude, morbidity, and mortality of secondary procedures are reduced significantly with endovascular repair. (J Vasc Surg 2002;36:297-304.)**

The natural history of aortic aneurysms is to enlarge and rupture. Death was the inevitable consequence of aneurysm rupture until 50 years ago when Charles Dubost first treated an aortic aneurysm with an aortic homograft thus preventing rupture.[1] Since that time, direct open surgical repair has been perfected and accepted as the standard of care. However, the procedure can cause death in 2% to 7% of patients with significant morbidity and disability.[2-4] Outcome analysis of open aneurysm repair has been primarily focused on operative mortality rates with risk-benefit analysis of surviving the operation versus the risk of aneurysm rupture. It is commonly assumed that following open surgical repair the patient is no longer at risk for aneurysm-related death. However, secondary procedures to treat recurrent aneurysms, pseudoaneurysms, graft thrombosis, graft infection, and aortoduodenal fistula can cause death but are not included in the primary endpoint analysis.

Parodi et al[5] introduced endovascular aneurysm repair 10 years ago as a less invasive treatment. Controlled clinical trials have consistently shown a significant reduction in morbidity with endovascular repair.[6-9] However, there is uncertainty regarding the long-term outcome of endovascular repair. In 1999, the U.S Food and Drug Administration (FDA) approved two endoluminal devices with a requirement of 5-year surveillance of the aneurysm and endovascular device. Surveillance of endovascular patients has now been extended to life-long because of reports of aneurysm ruptures and deaths.[10-12] Similar close follow-up

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strategies have not been applied to open surgical repair, despite the fact that there are a number of reports of deaths caused by aneurysm rupture and graft failure.[13-16] Thus, neither of the currently available methods of treating aneurysms is entirely effective in preventing aneurysm death.

The purpose of this study is to propose an endpoint for objective analysis in comparing open and endovascular aneurysm repair. We defined *aneurysm-related death* as any death that occurred within 30 days of primary aneurysm treatment, within 30 days of a secondary aneurysm or graft-related treatment, or any death related to the aneurysm or graft at any time following treatment. This endpoint analysis can be used for both open and endovascular treatment. We applied this primary endpoint analysis to 417 consecutive patients undergoing primary infrarenal aneurysm repair at a single institution. We also reviewed all secondary procedures performed following open and endovascular repair.

## PATIENTS AND METHODS

**Patients.** We reviewed all patients with infrarenal aortic aneurysms treated from July 1993 through June 2000 at Stanford University Medical Center. Fifty-nine patients with ruptured abdominal aortic aneurysms were excluded from further analysis. Primary nonruptured infrarenal aortic aneurysm repair was performed in 417 patients, including 243 open surgical repairs (58%) and 174 endovascular repairs (42%). Twenty-one patients had previously undergone open aneurysm repair elsewhere and presented with a recurrent aneurysm or graft complication requiring open surgical repair. Three patients had previously undergone endovascular aneurysm repair elsewhere and required a secondary endovascular procedure. Thus, a total of 264 patients underwent open aortic aneurysm repair and 177 patients underwent endovascular repair. From 1993 to 1996, only open aneurysm repair was available to patients. Beginning in 1996, endovascular repair using the AneuRx stent graft (Medtronic AVE, Santa Rosa, Calif) became available through the U.S. AneuRx multicenter clinical trial. After FDA market approval in 1999, patients were treated with use of the commercial device.

The treating surgeon determined the selection of open or endovascular repair. All treated patients were prospectively entered into a vascular registry. Patients considered for endovascular repair were presented to a panel of vascular surgeons who reviewed the aneurysm morphology on the basis of cross-sectional imaging with or without aortography and determined whether endovascular repair was appropriate. Criteria for endovascular repair required a proximal aortic neck length of ≥10 mm and aortic neck diameter of ≤26 mm.

**Technique of primary open repair.** Surgical technique was based on surgeon preference with 55%(135/243) of patients undergoing transperitoneal repair and 45% (108/243) retroperitoneal repair. All patients received synthetic grafts. Dacron grafts were utilized in 239 (98%) and polytetrafluoroethylene in four (2%). The most common open vascular reconstruction was a bifurcated aortoiliac graft in 121 (50%), aortic tube graft 78 (32%), and aortobifemoral bypass graft 44 (18%). All patients had infrarenal aneurysms and these were repaired using an infrarenal cross-clamp.

**Technique of primary endovascular repair.** The AneuRx bifurcated stent graft was utilized for all endovascular repairs; this procedure was performed under general anesthesia in 167 (96%) patients and epidural anesthesia in seven patients (4%). Bilateral transverse groin incisions were used to expose both common femoral arteries in 168 (97%) patients, with retroperitoneal exposure for external or common iliac artery access in six patients (3%). The first 23 endovascular patients received the early prototype stiff bifurcation stent graft and the following 151 patients received the flexible segmented bifurcation stent graft.

**Monitoring and surveillance.** Patients who received endovascular grafts were scheduled for routine follow-up with abdominal roentgenograms, duplex scanning, and/or computed tomographic or magnetic resonance angiography at 1, 6, and 12 months and then yearly thereafter. Surveillance following open aneurysm repair consisted of scheduled routine clinical follow-up at 1, 6, and 12 months and then yearly thereafter. Computed tomographic angiography, duplex scanning, and catheter angiography imaging was performed in patients who underwent open surgery as clinically indicated.

**Primary procedure.** The primary procedure was defined as the first treatment procedure used to exclude the abdominal aortic aneurysm and was either open or endovascular repair in each patient.

**Primary procedure–related mortality.** Primary procedure–related mortality was defined as death within 30 days of the primary procedure or death within the same hospitalization if it occurred after 30 days. The primary procedure–related mortality for this report will include only those patients who had their primary repair at Stanford University Medical Center.

**Secondary procedure.** A secondary procedure was defined as any surgical procedure following the primary procedure that was directly related to the aneurysm, the vascular graft, or the endoluminal device. Procedures were classified as transabdominal, transfemoral, or peripheral. We excluded seven secondary procedures performed on seven patients (six open surgery and one endovascular) that were the result of treatment-related morbidity but unrelated to the aneurysm or graft. These included two balloon angioplasties and stenting of coronary lesions, one following an endovascular and one following an open repair; two tracheostomies following open repair; two dialysis access catheters following open repair; and one cardiac pacemaker placed following open repair.

We also excluded all nonsurgical interventions related to the graft or aneurysm. These included 12 diagnostic arteriograms, one balloon angioplasty and stenting of a femoral limb, and one esophagogastroduodenoscopy in 13 patients following open surgery. We also excluded 10 diagnostic arteriograms, six coil embolizations, and one throm-

**Table I.** Preoperative patient characteristics

| *Characteristic* | *Open (n = 243)* | *Endovascular (n = 174)* | P *value* |
|---|---|---|---|
| Coronary artery disease | 184 (76) | 137 (79) | NS |
| Hypertension | 136 (56) | 106 (61) | NS |
| COPD | 114 (47) | 92 (53) | NS |
| Diabetes mellitus | 75 (31) | 62 (36) | NS |
| Chronic renal failure | 14 (6) | 12 (7) | NS |

Data are n (%) of patients and include only those patients who had their primary procedure performed at Stanford University.
*COPD*, chronic obstructive pulmonary disease.

bin injection of the aneurysm sac in 16 patients following endovascular repair.

**Secondary procedure–related mortality.** Secondary procedure–related mortality was defined as death within 30 days of the secondary procedure or death within the same hospitalization if it occurred after 30 days.

**Aneurysm-related death.** Aneurysm-related death was defined as primary procedure–related mortality plus secondary procedure–related mortality plus any death related to the aortic graft or aneurysm rupture at any time during follow-up.

**Statistical Analyses.** Results are reported as the mean ± standard deviation. Comparisons between groups were performed using the Student *t* test, Fisher exact test, and Wilcoxon rank-sum test as appropriate. Rates of survival free of secondary procedures and freedom from aneurysm-related death were estimated by the Kaplan-Meier method.

## RESULTS

There was no statistically significant difference between the open and endovascular patients who had their primary procedure at Stanford with regard to age 73.4 ± 7.8 years (range, 50-93 years) and 73.5 ± 8.1 years (range, 45-96 years) or gender, 83% and 86% were male, respectively ($P$ = not significant [NS]). The mean aneurysm size was 63.7 ± 1.5 mm (range, 40-115 mm) for open repair and 57.6 ± 9.4 mm (range, 40-87 mm) for endovascular repair ($P$ = NS). Patient demographics are shown in Table I. Mean length of follow-up was 16.6 ± 12.8 months (range, 1-69 months) for open surgery and 11.8 ± 9.5 months (range, 1-48 months) for endovascular repair ($P < .05$).

**Primary procedure mortality.** The 30-day primary procedure mortality for all patients who had their primary aneurysm procedure at Stanford was 2.4% (10/417). The 30-day primary procedure mortality for open surgery was 3.7% (9/243) and for endovascular repair was 0.6% (1/174) ($P < .05$). The cause of death following open surgery was cardiac arrest in three patients, respiratory failure in three patients, multiple-system organ failure in two patients, and stroke in one patient. The cause of the single death following primary endovascular aneurysm repair was myocardial infarction that occurred 3 weeks after hospital discharge following uneventful endovascular repair (Table II).

**Secondary procedure mortality.** The 30-day secondary procedure mortality following open surgery was 14%(6/41) and for endovascular repair was zero of 27 (0%) ($P < .05$%). Of the 41 open secondary procedures, 20 patients had their primary procedure performed at Stanford and 21 patients had their primary procedure elsewhere. Among the 20 patients who had their primary procedure at Stanford, there was one (5%) death. Among the 21 patients whose primary procedure was elsewhere, there were 5 (24%) deaths following the secondary open aneurysm repair. The causes of death after the primary and secondary procedure are listed in Table II. The causes of death following secondary procedures in open surgery were multiple-system organ failure in three patients, cardiac arrest in two patients, and respiratory failure in one patient.

**Aneurysm-related death.** The aneurysm-related death rate following open aortic aneurysm repair was 4.1%and included nine deaths following the primary procedure and one death following a secondary procedure among 243 patients treated at Stanford. Aneurysm-related death rate following endovascular repair was significantly lower at 0.6%, with a single death among 174 patients undergoing primary and secondary procedures at Stanford ($P < .05$) (Table III). Kaplan-Meier estimates for freedom from aneurysm-related death at 3 years was 94% for open repair and 99% for endovascular repair ($P = .056$) (Fig 1) in patients who had their primary and secondary procedures at Stanford. The aneurysm-related death rate is 5.7% (15/264) following open surgery and 0.5% (1/177) ($P < .05$) if all outside patients and their secondary procedures are included.

**Primary procedure morbidity.** The primary procedure morbidity rate for the entire group of patients repaired at Stanford was 10.5% (44/417). There was no difference in morbidity rate following the primary procedure for open 11% (27/243) or endovascular repair 10% (17/174). The morbidities following the primary and secondary procedure are listed in Table IV.

**Secondary procedure morbidity.** The procedure morbidity rate following secondary procedures was 17%(7/41) in the open group and 7% (2/27) following endovascular ($P$ = NS). However, the secondary procedure morbidity following endovascular repair consisted of local wound complications, whereas the secondary procedure morbidity following open repair was comprised of systemic complications (cardiac, respiratory, and renal) (Table IV).

**Secondary procedures.** There was no difference in the incidence of secondary procedures following open, 8.2% (20/243), or endovascular repair, 13.7% (24/174) ($P$ = NS), in patients who had their primary procedure at Stanford University. Furthermore, there was no difference in the incidence of secondary procedures between open, 15.5% (41/264), and endovascular repair, 15.2% (27/177), when those patients who had their primary procedure elsewhere were included. Kaplan-Meier estimates for freedom from secondary procedures at 1 and 3 years following

**Table II.** Procedure-related mortality following open and endovascular aneurysm repair*

| | *Open* | *Endovascular* | P *value* |
|---|---|---|---|
| Primary procedure | 3.7% (9/243) | 0.6% (1/174) | <.05 |
| Cardiac | 3 | 1 | |
| Pneumonia | 2 | 0 | |
| Multisystem organ failure | 2 | 0 | |
| Pulmonary embolism | 1 | 0 | |
| Stroke | 1 | 0 | |
| Secondary procedure | 14% (6/41) | 0/27 | <.05 |
| Multisystem organ failure | 3 | 0 | |
| Cardiac | 2 | 0 | |
| Respiratory failure | 1 | 0 | |

*Data are number of patients. Includes only those patients who had their procedure performed at Stanford University.

**Table III.** Aneurysm-related death rate following open and endovascular repair*

| | *Open surgery* (*n* = *243*) | *Endovascular repair* (*n* = *174*) | P *value* |
|---|---|---|---|
| Primary procedure mortality | 3.7% (9/243) | 0.6% (1/174) | <.05 |
| Secondary procedure mortality | 5% (1/20) | 0 (0/24) | NS |
| Aneurysm related death rate | 4.1% (10/243) | 0.6% (1/174) | <.05 |

*The aneurysm-related death rate was calculated using only those patients who had their primary and secondary procedure at Stanford University.

open and endovascular repair were 97%, 93% and 94% , 55%, respectively. When the early prototype stiff bifurcation AneuRx stent graft (not commercially available) is excluded from the analysis, there is no difference in freedom from secondary procedures at 1 and 3 years by Kaplan Meier analysis (Fig 2) for open (97% and 93%) and endovascular repair (100% and 90%).

Secondary procedures following open repair were performed for anastomotic pseudoaneurysm (n = 18), infected graft (n = 6), aortoenteric fistula (n = 5), anastomotic hemorrhage (n = 4), lower extremity amputation (n = 4), graft thrombosis (n = 3), and distal revascularization (n = 1). These secondary procedures presented within 30 postoperative days in 11 patients (4.2%) and by late follow-up in 30 patients (11.3%) (Table V).

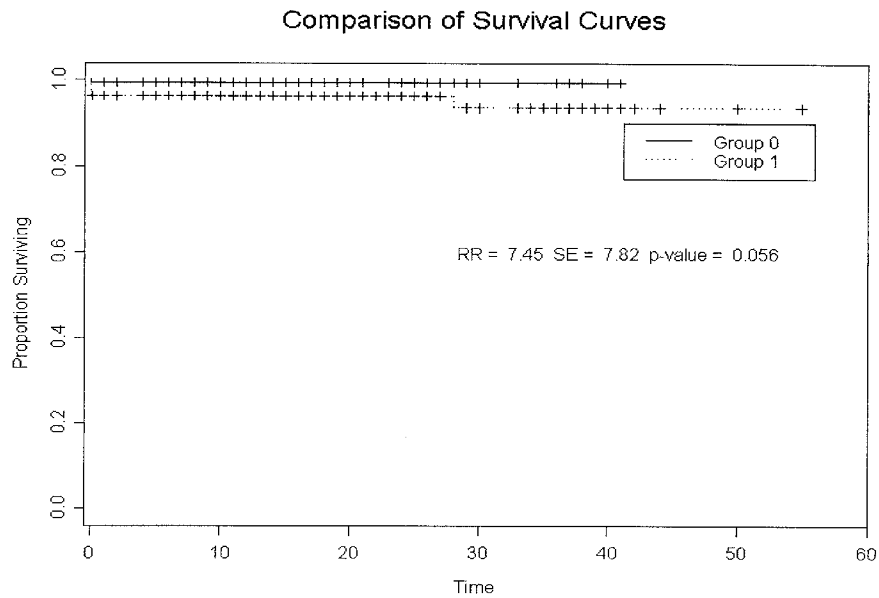
Secondary procedures following endovascular repair included placement of proximal extender cuffs (n = 11) and distal extender cuffs (n = 11) to secure stent–graft fixation, thrombectomy for unilateral limb thrombosis (n = 3), and surgical conversion (n = 2). These complications presented within 30 postoperative days in five patients (2.8%) and by late follow-up in 27 patients (15.2%) (Table VI).

**Magnitude of secondary interventions.** Secondary procedures following open aneurysm repair included 27 intraabdominal procedures, nine groin procedures, and five peripheral procedures (Table V). Secondary procedures following endovascular aneurysm repair included two intraabdominal procedures and 25 groin procedures (Table VI). Secondary procedures following open surgery had significantly longer mean operative time (292 ± 89 minutes for open vs 129 ± 33 minutes for endovascular) ($P < .0001$), more blood loss (3382 ± 4278 mL for open vs 851 ± 114 mL for endovascular) ($P < .0001$), and longer hospital length of stay (13.1 ± 9.9 days for open vs 2.1 ± 1.6 days for endovascular) ($P < .0001$).

## DISCUSSION

The objective of infrarenal abdominal aortic aneurysm repair is to prevent rupture and death. Successful aneurysm treatment prolongs life only if aneurysm rupture was destined to occur. It is currently not possible to accurately predict which aneurysms will rupture, although the risk increases with increasing aneurysm size.[17-19] Thus prolongation of life is not a primary objective of aneurysm repair, but rather the goal is prevention of premature death resulting from aneurysm rupture. To objectively compare two procedures (open and endovascular) to treat infrarenal abdominal aortic aneurysm it is important to utilize the same primary outcome measure for both treatment groups. We defined this outcome measure as *aneurysm-related death rate*. Aneurysm-related death considers deaths caused by the aneurysm itself (treated or untreated) as well as any mortality caused by treatment (primary or secondary). We then analyzed the mortality directly attributed to the aneurysm or its repair for both open and endovascular surgery.

We found that patients undergoing open surgical repair had a seven-fold higher risk of aneurysm-related death than those patients undergoing endovascular repair. This risk is the result of significantly higher 30-day operative mortality for both the primary procedure as well as for secondary surgical procedures. At 3 years, the freedom from aneurysm-related death for patients who had their primary and secondary procedures at Stanford was 99% for patients




| Months | 0 | 6 | 12 | 18 | 24 | 30 | 36 |
|---|---|---|---|---|---|---|---|
| **Group 0(EVR patients)** | 174 | 135 | 91 | 43 | 40 | 20 | 15 |
| **Estimate** | 0.99 | 0.99 | 0.99 | 0.99 | 0.99 | 0.99 | 0.99 |
| **Group 1(Open patients)** | 243 | 195 | 144 | 89 | 82 | 56 | 20 |
| **Estimate** | 0.97 | 0.97 | 0.97 | 0.97 | 0.97 | 0.94 | 0.94 |

**Fig 1.** Kaplan-Meier estimates of freedom from aneurysm-related death following endovascular and open repair in patients who had their primary procedure performed at Stanford University.

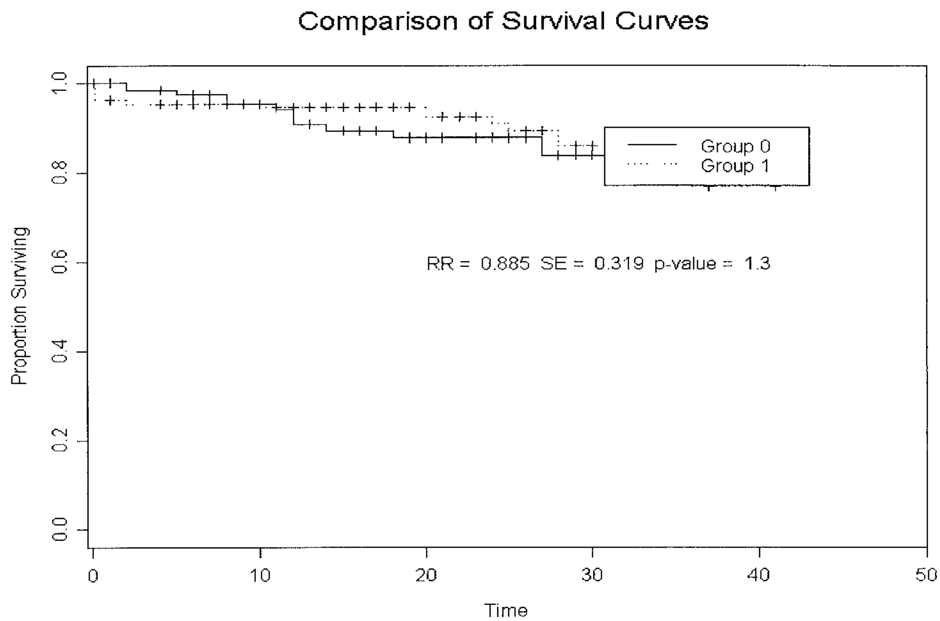
**Table IV.** Procedure related morbidity following open and endovascular aneurysm repair

| | *Open* | *Endovascular* | P *value* |
|---|---|---|---|
| Primary procedure | 11.1% (27/243) | 9.7% (17/174) | NS |
| Cardiac (CHF, MI, arrhythmia) | 15 | 10 | |
| Pneumonia/PE | 6 | 0 | |
| TIA | 1 | 1 | |
| ATN renal failure (transient) | 4 | 1 | |
| Local (wound seroma) | 1 | 5 | |
| Secondary procedure | 17% (7/41) | 7% (2/27) | NS |
| Cardiac | 3 | 0 | |
| Pneumonia | 2 | 0 | |
| ATN renal failure (transient) | 2 | 0 | |
| Local (wound seroma) | 0 | 2 | |

Data are number of patients. *ATN*, author to provide; *CHF*, congestive heart failure; *MI*, myocardial infarction; *PE*, pulmonary edema; *TIA*, transient ischemic attack.

undergoing endovascular repair and 94% for patients with open repair, a difference that nearly reached statistical significance (P = .056). Analysis beyond 3 years was not performed with Kaplan-Meier analysis, as the number of endovascular patients with 4-year follow-up was small.

In our experience, 8% of patients undergoing open surgery required a secondary procedure. Secondary procedures following open surgery are often catastrophic, with a much higher mortality rate than with the primary procedure.[13-16] The mortality rate of 14% for patients undergoing secondary operations following open aortic aneurysm repair compares favorably to that reported in the literature. Hallet et al[13] reported a graft-related complication rate of 9.4% following open aneurysm repair, with a 28% (8/29)




| **Months** | **0** | **6** | **12** | **18** | **24** | **30** | **36** |
|---|---|---|---|---|---|---|---|
| **Group 0(EVR patients)** | 154 | 115 | 74 | 39 | 27 | 18 | 11 |
| **Estimate** | 0.1 | 0.98 | 0.98 | 0.90 | 0.90 | 0.90 | 0.90 |
| **Group 1(Open patient)** | 243 | 195 | 144 | 89 | 82 | 56 | 20 |
| **Estimate** | 0.1 | 0.97 | 0.97 | 0.97 | 0.96 | 0.94 | 0.93 |

**Fig 2.** Kaplan-Meier survival curve for freedom from secondary procedures comparing open surgery to the current flexible bifurcated AneuRx stent graft.

mortality among patients treated for graft-related complications after open surgery. In this population-based study of patients from Olmsted County, Minnesota, the primary procedure 30-day mortality was 5% in 234 elective infrarenal aneurysm repairs. The mortality rate for open aneurysm, including emergent aneurysms, was 9.4%. Thus, the aneurysm-related death rate was 12% (37/307) for all patients and 8.5% (20/234) if emergent cases were excluded.[13] This rate was slightly higher than the 4.1% aneurysm-related death rate for patients undergoing open infrarenal aneurysm repair in our own series.

Johnston et al[14] and the Canadian multi-center aneurysm study group reported a 6-year experience with a late aneurysm death rate of 1.5%.[14] Primary procedure mortality among 680 patients was 5.4% and aneurysm-related death rate was 5.8%. Plate et al[15] reported a late death rate of 6.3% associated with complications following aneurysm repair. Crawford et al[16] reported a 3% late death rate associated with secondary interventions and complications following aneurysm repair during a 25-year experience, with a mean follow-up of 4.5 years. Thirty-day mortality among 860 patients was 4.8%, resulting in a 7.8% aneurysm-related death rate.[16] These deaths resulted from late complications such as recurrent aneurysm formation, false aneurysms, aortoenteric fistula formation, and graft infections.

In our analysis of aneurysm-related death, we compared patients undergoing elective open and endovascular aneurysm repair while specifically excluding patients who presented with ruptured abdominal aortic aneurysms. There were 59 such patients during the study period with a 30-day mortality of 27% (16/59). All patients were treated with open repair. In this study comparing open and endovascular repair, there were no patients who underwent endovascular repair for ruptured aneurysms. To include these patients would have unfairly increased the aneurysm-related death rate in the open surgery group since there was not an equivalent cohort in the endovascular group.

The incidence of secondary procedures following endovascular repair has been reported by a number of investigators.[20-24] The Eurostar collaborators[22] have reported an 18% incidence of secondary interventions following endovascular repair at a mean of 14 months and suggest caution in the broad application of endovascular repair. However, the majority of devices implanted were Vanguard (51%) and Stentor (24%), devices that are no longer avail-

**Table V.** Secondary procedures following open aneurysm repair

| *Procedure* | *Stanford patients (n = 20)* | *Outside patients* (n = 21)* | *All patients (n = 41)* |
|---|---|---|---|
| Intraabdominal | | | |
| Anastomotic pseudoaneurysm | 3 | 11 | 14 |
| Infected graft | 2 | 4 | 6 |
| Aortoenteric fistula | 0 | 5 | 5 |
| Anastomotic hemorrhage | 4 | 0 | 4 |
| Femoral | | | |
| Femoral pseudoaneurysm | 3 | 1 | 4 |
| Graft thrombosis | 3 | 0 | 3 |
| Peripheral | | | |
| Lower extremity amputation | 4 | 0 | 4 |
| Distal revascularization | 1 | 0 | 1 |

Data are number of patients.
*Outside patients had their primary procedure performed at another institution.

**Table VI.** Secondary procedures following endovascular aneurysm repair

| *Procedure* | *Stanford patients (n = 24)* | *Outside patients* (n = 3)* | *All patients (n = 27)* |
|---|---|---|---|
| Intraabdominal | | | |
| Surgical conversion | 2 | 0 | 2 |
| Femoral | | | |
| Proximal extender cuff | 9 | 2 | 11 |
| Distal extender cuff | 10 | 1 | 11 |
| Limb thrombosis | 3 | 0 | 3 |

Data are number of patients.
*Outside patients had their primary procedure performed at another institution.

able for implantation because of defined failure modes.[22] Outcomes following endovascular repair may be device specific and conclusions drawn from one device experience may not reflect what can be expected from another. Although the need for a secondary procedure following open surgery is usually mandated by a clinically apparent graft-related complication such as pseudoaneurysm, graft thrombosis, or infection, the need for a secondary procedure following endovascular repair is less clear. For example, secondary procedures are often performed for endoleaks of variable significance. Thus the true necessity and incidence is not yet known.

In our own series, using a single commercially available endograft, the AneuRx stent graft, we found that freedom from secondary procedures at 3 years was 90% by use of Kaplan Meier analysis, and was no different from open repair (93%) at 3 years. Secondary procedures were performed earlier in patients following endovascular repair and typically required only groin procedures. Secondary procedures following open aneurysm usually required intraabdominal exploration. The increased magnitude of the secondary procedures following open surgery is further confirmed by higher mortality rate, significantly longer operative time, increased blood loss, and greater length of stay following the procedure. The major morbities following open secondary surgery included cardiac, respiratory, and renal complications compared to predominantly local wound complications following secondary endovascular procedures.

There are several weaknesses with the present study. The first is that follow-up after open surgery is 5 months longer than that after endovascular repair, raising the possibility that longer follow-up accounts for a disproportionate number of secondary procedures after open surgery. However, the open surgery group was treated with a stable, well-established procedure, whereas the endovascular group was treated with a new procedure including a learning curve. The early endovascular experience also included a prototype stiff bifurcated stent graft, which is no longer clinically available. If we exclude our early experience with the stiff bifurcation design of the AneuRx stent graft, then freedom from secondary procedures is the same for open and endovascular repair (Fig 2). Nearly half of the patients with the stiff design needed a secondary procedure compared to only 12% in patients with the flexible stent–graft design.[23]

The second weakness is that the study period includes a period when only open repair was performed and when endovascular repair was not available. Furthermore, when both procedures were available, not all patients were candidates for both open and endovascular repair. Thus it is possible that differences in patient selection could bias the results. On the one hand, patients who were not anatomic candidates for endovascular repair were treated with open surgical repair. This potentially skews more complex and difficult aneurysms to open repair; however, all open surgery patients were treated with use of an infrarenal aortic cross-clamp. It is not known whether this potential of increased morphologic complexity results in a greater perioperative risk or a higher long-term open surgery failure rate. At the same time, patients at high operative risk were specifically selected for endovascular repair even if morphologic selection criteria were marginal because of the high risk of open repair. This would present potential adverse selection bias against endovascular repair. Although there is no statistical evidence for increased risk factors in the endovascular group, many individuals in that group were not deemed to be candidates for open surgical repair. This may explain the observation that there was no difference in long-term survival in our series and no difference in mortality rate between open and endovascular repair in prospective clinical trials.[6-9]

Long-term studies of open repair have reported late graft complications in 3% to 10% of patients.[13-16] However, many patients are lost to follow-up because patients treated in referral centers may not return for follow-up. In our own series, patients who were lost to follow-up in the open group may have had graft-related complications that were treated at other institutions. Similarly, our open surgical series included 21 patients who had previously undergone open aortic aneurysm repair at a different institution. Thus, the true incidence of secondary operations following open surgical repair is unclear. This was not the case for patients in the endovascular group because the majority were part of an ongoing clinical trial with 100% follow-up. Long-term follow-up of surgical patients usually does not include the radiographic scrutiny that is essential to the detection of occult anastomotic pseudoaneurysms. Therefore, the graft-related complications of open repair may be underestimated.

In conclusion, we defined aneurysm-related death as death within 30 days of a primary treatment procedure; death within 30 days of any secondary treatment procedure; or death related to aneurysm rupture, the vascular graft, or endovascular device. This primary outcome measure should be used as the objective endpoint to compare the results of open and endovascular repair in the treatment of infrarenal abdominal aortic aneurysms. In our experience, endovascular aneurysm repair has a significantly lower aneurysm-related death rate when compared to open surgical repair.

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