Introduction of endovascular aneurysm repair into community practice: Initial results with a new Food and Drug Administration–approved device

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Purpose: The purpose of this study was to determine the outcome of endovascular aneurysm repair in a defined geographic region during the first 2 years after Food and Drug Administration approval of a new endovascular device.

Method: Clinical results of all attempted endovascular aneurysm repairs from 1999 to 2001 with the AneuRx stent graft in the northern California/Nevada region were reviewed. All cases performed in 23 hospitals by 21 endovascular treatment teams were included on an intent-to-treat basis. Community physician training, proctoring, and assistance in case selection was provided by the manufacturer, with outcome monitored by external physician observers and clinical vascular specialists. Results in 22 community hospitals were compared with concurrent results in the regional university hospital training center and with results from the controlled, multicenter AneuRx clinical trial.

Results: Endovascular aneurysm repair was attempted in 257 patients by 20 endovascular teams working in 22 community hospitals. The mean number of cases per team was $13 \pm 2$ (range, 1 to 36). Patient age was $74.1 \pm 6.5$ years (89% men and 11% women), and 29% of patients were not candidates for open surgical repair because of multiple medical comorbidities. Mean aneurysm diameter was $5.7 \pm 0.8$ cm. The endoluminal stent graft was successfully deployed in 254 patients (98.8%). In two patients, iliac access could not be obtained, and in one case, the iliac limb was misdeployed and the patient underwent successful open surgical repair. The surgical conversion rate was two of 257 patients (0.8%). The 30-day mortality rate was 1.2%, with one patient dying of stroke, one of multisystem organ failure, and one of cerebral hemorrhage. No device-related deaths occurred. Secondary procedures were performed in 8% of patients. Primary graft patency rate was 98%, and secondary graft patency rate was 100%. Concurrent university training center experience with 100 patients with similar characteristics and aneurysm size was not statistically different (deployment success rate, 100%; 30-day mortality rate, 0%; surgical conversion rate, 0%; secondary procedure rate, 8%). No aneurysm ruptures and no late surgical conversions have been seen in either the community or university experience, with follow-up periods extending to 2 years.

Conclusion: Early results of endovascular aneurysm repair introduced into community practice are favorable. Initial community experience, with clinical support from the manufacturer, does not appear to differ significantly from concurrent results in the university training center or from results reported from the multicenter controlled clinical trial with the same device. (J Vasc Surg 2002;36:226-33.)
all hospitals in a defined geographic area with a single FDA approved device, the AneuRx stent graft, in the 2 years since market approval and to compare it with the published results from the AneuRx clinical trial. Within this region, the results in 22 community hospitals were compared with the concurrent results in the regional university hospital, which had participated in the multicenter clinical trial for FDA approval and served as a training center for new users of the AneuRx stent graft.

METHODS

We reviewed the results of all patients considered for endovascular aneurysm repair with the AneuRx stent graft in the northern California/Nevada region from September 28, 1999, to September 20, 2001. The northern California/Nevada region was defined by the manufacturer (Medtronic AVE) for sales, marketing, training, and support purposes. The region was comprised of the northern third of California and the northern half of Nevada (Fig 1) and had a population base of 12 million people, which represented 4.3% of the US population (Table I). The Medicare population was 1.6 million and comprised 3% of the US Medicare population. The region contained 70 hospitals that had performed one or more aortic aneurysm repairs, including ruptures, from 1996 to 1997. During the years 1999 to 2001, 23 of these hospitals performed one or more endovascular aneurysm repairs with the FDA-approved AneuRx stent graft.

Each community hospital physician team implanting the AneuRx stent graft was trained at a clinical training center that had extensive experience with the device, having participated in the US AneuRx clinical trial. One of these centers, Stanford University Hospital, is located in the northern California region and served as a training center. The training session included didactic teaching, in vitro device deployment, case selection, and clinical case observation during a 2-day period. On-site proctoring of the cases at each new hospital was provided by physicians experienced in the use of the AneuRx stent graft. Assistance with film reading and case selection and ongoing clinical vascular specialist support was provided by the manufacturer. In addition, the manufacturer provided physicians with clinical updates and follow-up teaching seminars. Computed tomographic (CT) scan image and procedural data on each patient were provided by the treating physician, and completeness of case reporting was confirmed from device utilization data provided by the manufacturer. Postoperative evaluation was performed in accordance with the manufacturer’s guidelines; results were reported by the treating physicians and recorded in a central data registry. Community hospital results were combined and compared with concurrent results at Stanford University Hospital and with the published results from the multicenter US AneuRx Clinical Trial.

Results were expressed as the mean ± standard deviation, and differences between groups were compared with $\chi^2$ analysis. $P$ values of less than .05 were considered significant.

RESULTS

Community hospitals. Since September 28, 1999, 20 physician teams, working in 22 hospitals in the northern California/Nevada region, have been trained to perform endovascular aneurysm repair with the AneuRx stent graft and have begun using the device (Appendix, online only). The physician teams were comprised of multiple specialties that included: 11 vascular surgery-interventional radiology (55%) teams, four vascular surgery teams (20%), three vascular surgery-interventional radiology-interventional cardiology teams (15%), and two vascular surgery-interventional cardiology teams (10%). The average number of patients treated by each endovascular team was 13 ± 2, with a range of one to 36 cases (Fig 2). The average number of physician proctored cases per team was six, with a range of two to 10. The number of procedures performed by specialty-based teams in the community were as follows: vascular surgery-interventional radiology team, 147 procedures (57%); vascular surgery team, 76 procedures (30%);
vascular surgery-interventional radiology-interventional cardiology teams, 32 procedures (12%); and vascular surgery-interventional cardiology teams, two procedures (1%; Fig 3). Vascular surgeons were involved with all 257 procedures (100%), interventional radiologists with 179 cases (70%), and interventional cardiologists with 34 cases (13%). No difference was seen in outcome on the basis of the number of cases performed, specialty involvement in the treatment procedures, or whether or not physician proctors were present.

The 257 community patients included 228 men (89%) and 29 women (11%), with a mean age of 74 ± 7 years (Table II). Seventy patients (29%) were considered as non-candidates for open surgical repair because of the severity of medical comorbidities, including severe coronary artery disease, congestive heart failure, oxygen dependence, chronic obstructive pulmonary disease, morbid obesity, and future heart transplant (n = 2). Preoperative aortic diameter was 5.7 ± 0.8 cm, with a range of 3.5 to 9.8 cm. The indication for treatment of the 3.5-cm aortic aneurysm was for an enlarging 4-cm common iliac aneurysm. Endovascular device deployment was successful in 254 patients (98.8%). In two patients, satisfactory iliac access could not be obtained and the endovascular device could not be introduced into the aneurysm. One patient underwent successful open surgical repair of the aneurysm. The other patient’s procedure was terminated, and no further attempt to repair the aneurysm was carried out because the patient was believed to be at prohibitive operative risk because of severe three-vessel coronary disease for which the patient refused surgery. This patient remains well, and the 6.4-cm aneurysm has not ruptured. In one patient, the contralat-

Table II. Patient characteristics

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<thead>
<tr>
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<th>Community hospitals</th>
<th>University hospital</th>
<th>Phase II clinical trial</th>
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<tbody>
<tr>
<td>No.</td>
<td>257</td>
<td>100</td>
<td>416</td>
</tr>
<tr>
<td>Age (y)</td>
<td>74 ± 7</td>
<td>74 ± 6</td>
<td>73 ± 8</td>
</tr>
<tr>
<td>Range (y)</td>
<td>49 to 90</td>
<td>60 to 90</td>
<td>45 to 93</td>
</tr>
<tr>
<td>Men</td>
<td>89%</td>
<td>88%</td>
<td>89%</td>
</tr>
<tr>
<td>Women</td>
<td>11%</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>AAA diameter (cm)</td>
<td>5.7 ± 0.8</td>
<td>5.5 ± 0.7</td>
<td>5.6 ± 0.9</td>
</tr>
<tr>
<td>Range (cm)</td>
<td>3.5 to 9.8</td>
<td>3.9 to 9.0</td>
<td>3.3 to 9.0</td>
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Three patients died within 30 days of the procedure: one because of a stroke 6 days after the procedure, one because of multisystem organ failure 5 days after the procedure, and one because of cerebral hemorrhage on day 3 after the procedure. The 30-day procedure mortality rate was 1.2%. No device-related deaths occurred.

Six major events, including failure to successfully introduce the stent graft in three patients (with surgical conversion in two), and deaths in three patients were reviewed to determine whether low-volume hospitals or the early learning curve may have been factors. Only one of these events occurred among the first 10 cases performed by each endovascular team. This event was a death from multisystem organ failure and occurred in the fifth case performed by one endovascular team. Thus, patients treated early in the learning process with this new device do not appear to be at higher risk.

Completion angiography and postprocedure imaging with contrast CT scanning and abdominal radiographs were performed to confirm stent graft fixation and completeness of aneurysm exclusion (Fig 4). Endoleaks were identified in 30 patients (12%). Of these, five (2%) were type I endoleaks and 26 (10%) were type II endoleaks. Follow-up imaging was performed at 1 month, 6 months, and 12 months, as per the manufacturer’s recommendation. The average follow-up time since the endovascular procedure was 9.6 ± 5.6 months. Follow-up imaging studies revealed that three aneurysms increased in size (1%).

Secondary procedures were performed in 21 patients (8%). These included five extender cuff procedures to secure fixation, four catheter-based procedures to treat endoleaks, six procedures for limb thrombosis or correction of limb kinks, and six procedures to correct femoral artery or groin incision problems. All six limb thromboses occurred in hospitals performing one of their first 10 cases. These thromboses were primarily caused by femoral artery repair problems, suggesting that greater attention to closure techniques with endarterectomy or patching may have avoided these problems. Iliac conduit access was used in seven patients (3%) for introduction of the device, and no patient had a complication. The primary graft patency rate was 98%, and the secondary graft patency rate was 100%. No device-related deaths and no aneurysm ruptures occurred in follow-up to 2 years.

**University training center.** Stanford University Hospital was a clinical investigation site during the multicenter clinical trial and served as a training center for community hospitals after FDA approval of the AneuRx device. A total of 100 patients underwent treatment with the AneuRx stent graft at Stanford University Hospital in the 2 years since market approval (1999 to 2001). The physician team consisted of vascular surgery-interventional radiology for all 100 cases. Eighty-eight men and 12 women, with a mean age of 74 ± 6 years, participated (Table II). Preoperative aortic diameter was 5.5 ± 0.7 cm, with a range of 3.9 to 9.0 cm. The patient with the 3.9-cm aneurysm had symptoms and documented enlargement.

Endovascular device deployment was successful in all patients (100%). Iliac conduit access was used in four patients (4%) for introduction of the device or hypogastric artery revascularization without complication. No early or late surgical conversions occurred in these patients. No patients died within 30 days of the procedure, and no aneurysm ruptured.

Postprocedure imaging was performed with contrast CT scanning, duplex ultrasound scan imaging, and abdominal radiographs. Endoleaks were identified in 18 patients (18%). Of these, one type I endoleak (1%) and 17 type II endoleaks (17%) were seen. Follow-up imaging was performed at 1 month, 6 months, and 12 months, with a mean follow-up time since the procedure of 11.1 ± 4.3 months. Follow-up imaging showed that one aneurysm (1%) had increased in size, with 99% of aneurysms remaining stable or decreasing in size. Secondary procedures were performed in eight patients (8%). These procedures included six extender cuff procedures to secure fixation, one catheter-based procedure to treat a type II endoleak, and one thrombectomy for a limb thrombosis. Primary graft patency rate was 99%, and secondary graft patency rate was 100%. No device-related deaths or aneurysm ruptures occurred in follow-up to 2 years. No statistically significant differences were seen between university hospital results and the community hospital experience.

**DISCUSSION**

Endovascular aneurysm repair with the AneuRx stent graft was first performed on June 3, 1996, with the initiation of phase I of the US AneuRx Clinical Trial. Phase II of
the trial included 13 clinical centers that compared endovascular repair with standard open surgery. Six additional centers were added to the clinical trial during the phase III investigation, bringing the total number of clinical centers to 19. These centers were located throughout the United States and were selected because of their experience in open aneurysm surgery and skill and experience in endovascular treatments. Each clinical center was comprised of a multidisciplinary team, which included experienced vascular surgeons and interventional radiologists or interventional cardiologists or both. The results for all patients treated during the course of the AneuRx clinical trial in these centers, including patients for compassionate use and at high risk, excluded from the controlled clinical trial protocol, have recently been published. Among all 1192 patients enrolled in the clinical trial, successful device deployment was achieved in 98%, with a 30-day mortality rate of 2%. Only 1.5% of patients needed early surgical conversion, and aneurysm rupture was prevented in 99.5% of patients.

Excellent results with elective open surgical repair of aortic aneurysm have consistently been reported from high-volume clinical centers with low operative mortality rates. However, population-based experiences report higher operative mortality rates for open aneurysm repair, and evidence shows that low-volume centers and low-volume surgeons have inferior results with open aneurysm repair compared with high-volume hospitals. This has led some to question whether the new endovascular treatment technology should be rapidly disseminated into community practice or whether this new approach to treating aortic aneurysms should be limited to high-volume multidisciplinary aneurysm treatment centers that have proved to be effective in clinical trials. Clearly, endovascular aortic aneurysm repair requires a new skill set, using imaging methods and both open surgical and endovascular/interventional techniques, which have not been part of physician-training programs in the past. Therefore, how effective endovascular aneurysm repair would be in the hands of inexperienced new users, once the new endovascular devices were released to the market, was unclear. This report provides the first comprehensive regional data on early results after introduction of this new endovascular technology to community practice.

In accordance with FDA stipulations at the time of market approval, the manufacturer (Medtronic AVE) instituted a physician-training program and provided trained clinical vascular specialists along with experienced physician proctors to each new endovascular treatment team. The training program included training of vascular surgeons, interventional radiologists, and interventional cardiologists, with a focus on training of the team rather than the individual to address the issue of combination of skills necessary for endovascular repair. The effectiveness of this training program, which included on-site proctoring, assistance with case selection, and vascular specialist technical support, is apparent in the results presented in this report.

We found that no significant difference was seen in deployment success or early results in the northern California/Nevada region community hospitals from concurrent results obtained in the university hospital training center or from results reported from the phase II clinical trial (Tables II and III) or the overall 4-year AneuRx clinical trial. Importantly, only one postoperative death occurred among the first 10 patients treated by each of the 20 new endovascular teams (200 patients), suggesting that the learning curve is safe and that low-volume early stent graft users can have excellent results if proper training and support are provided. Combining both community hospital and Stanford University hospital experience with 357 patients since FDA approval of the AneuRx device, stent graft deployment was successful in 99% of patients and the 30-day mortality rate was only 0.8%. Surgical conversion rate was only 0.6%. Secondary procedure rate was 8%, no different from the AneuRx clinical trial. Endoleaks were found in 13% of the 357 patients; however, whether endoleaks, in and of themselves, are predictors of long-term adverse outcome of endovascular aneurysm repair is not clear.

The somewhat higher endoleak rate found in the university experience may be the result of more extensive imaging than is available or practiced in the community. No aneurysm ruptures or device-related deaths were seen in this experience. Although this early experience was favorable, long-term outcomes are yet to be determined.

The population base for the northern California/Nevada region was 12 million, and of this population, 1.6 million persons are Medicare beneficiaries. Seventy hospitals performed at least one open aneurysm repair from 1996 to 1997, and the total number of aneurysms repaired in this region during that year was 1342. Of these, 1070 (80%) were elective aneurysm repairs. Thus, the average number of elective aneurysm repairs per hospital, with the capability of treating aneurysms in 1996, was 16. The average number of endovascular aneurysm repairs per endovascular team, in one third of these hospitals in the 2-year period from 1999 to 2001, was 13. However, it should be noted that hospitals and surgeons with only an occasional aneurysm repair were unlikely to be interested in or selected for the endovascular training program, leaving this to hospitals or surgeons with aneurysm referrals and practices. What proportion of the total regional aneurysm volume

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<th>Table III. Outcomes</th>
<th>Community hospitals</th>
<th>University hospital</th>
<th>Phase II clinical trial</th>
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<tr>
<td>No. of patients</td>
<td>257</td>
<td>100</td>
<td>416</td>
</tr>
<tr>
<td>Deployment success rate</td>
<td>99%</td>
<td>100%</td>
<td>98%</td>
</tr>
<tr>
<td>Mortality rate (30 day)</td>
<td>1.2%</td>
<td>0%</td>
<td>2%</td>
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<tr>
<td>Surgical conversion rate</td>
<td>0.8%</td>
<td>0%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Secondary procedure rate</td>
<td>8%</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Endoleak rate</td>
<td>12%</td>
<td>18%</td>
<td>13%</td>
</tr>
<tr>
<td>Primary patency rate</td>
<td>98%</td>
<td>99%</td>
<td>98%</td>
</tr>
<tr>
<td>Secondary patency rate</td>
<td>100%</td>
<td>100%</td>
<td>99%</td>
</tr>
<tr>
<td>Aneurysm rupture rate</td>
<td>0%</td>
<td>0%</td>
<td>0.5%</td>
</tr>
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was performed by these relatively high-volume centers is not known. The current number of elective aneurysm repairs performed in the northern California/Nevada region is not yet known; however, if the number of elective open aneurysm repairs in the northern California/Nevada region 5 years earlier (1996) is used as the denominator, then this early AneuRx experience represents approximately 17% of the number of aneurysms treated each year in this region. Whether endovascular repairs are replacing open surgical repair or whether the total number of aneurysms being treated has increased is unclear. Reports from individual centers that have begun endovascular treatment programs suggest that the total number of aneurysms treated has increased, but this increase may be the result of changes in referral patterns rather than an overall increase in the number of aneurysms being treated. However, it is possible that a true increase in the number of aneurysms treated exists because of the inclusion of older and sicker patients with severe medical comorbidities who previously would have been excluded from consideration for aneurysm treatment. Indeed, in this northern California/Nevada experience, 29% of patients treated were considered to be nonsurgical candidates because of prohibitive surgical risk. Further study will clarify whether the total number of aneurysms treated will increase because more patients at poor risk will be offered treatment.

Lawrence et al reviewed the National Hospital Discharge Survey data for the year 1994 and reported 32,389 nonruptured abdominal aortic aneurysms that were treated surgically, with an operative mortality rate of 8.4%. The authors proposed that this could be used as a national standard of comparison for endovascular aneurysm repair. The northern California/Nevada region’s 30-day mortality rate of 0.6% for endovascular aneurysm repair in a broad-based regional experience shows a much lower mortality rate for endovascular repair than that expected for open surgical repair.

Lawrence et al also found that the number of aneurysm operations per thousand population varied by region, with surgery rates more frequent in the Northeast and less frequent in the West. This regional difference was confirmed with data from the Dartmouth Atlas of Vascular Health Care. The rate of aortic aneurysm repairs in the northern California/Nevada region per 1000 Medicare enrollees from 1996 to 1997 was 0.84 compared with the rate for the entire United States of 1.09. The explanation for this difference is unclear. Whether the regional differences in aneurysm repair noted for open surgery will also be found for endovascular repair is unknown.

No aneurysm ruptures occurred in the 357 patients treated with the AneuRx stent graft in the northern California/Nevada region, and thus, the primary objective of aneurysm treatment has been achieved. Ruptures have been reported from the clinical trial and have been primarily related to an early prototype stiff bifurcation stent graft, which was used in the first phase of the clinical trial. Ruptures that occurred in clinical trial patients have been attributed to poor patient selection or imprecise placement, resulting in insecure fixation of the device proximally, distally of the modular junction. Evidence of poor fixation can be seen on postimplant imaging studies well before rupture occurs, thus providing an opportunity to place endoluminal stent graft extender cuffs to secure fixation and prevent rupture. This is the rationale for follow-up imaging studies after endovascular repair. These lessons, learned from careful follow-up of clinical trial patients, have been published and are taught during training for new device users and during proctoring, case selection consultations, and follow-up seminars. Nationwide, more than 9500 patients have been treated with the AneuRx stent graft since FDA approval. Only two aneurysm ruptures were reported in the United States after successful device implantation during the first 18 months of clinical use. Freedom from aneurysm rupture at 4 years with Kaplan-Meier method analysis of clinical trial patients was 99%.

Similarly, the surgical conversion rate in our experience has been low, with only two of the 357 patients (0.6%) needing open surgical repair. This rate compares favorably with the 1.5% early surgical conversion rate in the AneuRx clinical trial and is lower than the reported surgical conversion rate with other endovascular devices of up to 10%.

The initial community experience with the AneuRx stent graft was favorable, with a 99% technical success in device implantation and a low perioperative 30-day mortality rate, despite its application to a large number of patients who were not candidates for open surgical repair. Thus, the initial results of community endovascular treatment programs are encouraging. Long-term follow-up is needed to determine the ultimate long-term success of endovascular aneurysm repair and its effectiveness compared with open surgery and its role in overall aneurysm treatment strategies.

REFERENCES


Submitted Oct 4, 2001; accepted Jan 28, 2002.

Additional material for this article may be found online at www.mosby.com/jvs.

DISCUSSION

Dr Kaj Johansen (Seattle, Wash). The rate at which a new technology is introduced into the practicing medical community and the extent to which this occurs is poorly characterized and documented. Dr Zarins provides us with interesting and potentially useful data regarding diffusion of endovascular graft (EVG) technology into the practicing vascular community in northern California and northwestern Nevada over a 24-month period ending in September 2001. He concludes that outcomes from EVG insertion in a series of community hospitals in this geographic region are highly technically successful, the effects of the learning curve on outcomes appear to be modest, the results appear to be volume-independent (that is, outcomes were not better, or worse, in high-volume versus low-volume sites), and postintervention aneurysm expansion and rupture rate—the only critical endpoint—was low during a mean follow-up of 9.6 months. Dr Zarins demonstrates that the results in this series are not different than those from his previously reported prospective trial of the AneuRx device nor of a large cumulative experience with these devices.

However, it is becoming increasingly clear that, although these devices can be inserted safely and with a high likelihood of early technical success, these are in fact the least of the issue regarding this form of treatment for aortic aneurysm. Data from the Eurostar registry and Veith’s recent report to the American Surgical Association (Ann Surg 2001;234:323-5) clearly suggest that there is a steadily increasing risk of aneurysm expansion/rupture or of major prosthesis complication requiring intervention, probably at a 3% to 4% rate for each remaining year of the patient’s life. Thus, it seems unreasonable to draw any conclusions from Dr Zarins’ report, other than that of immediate technical success with EVG insertion in community hospitals.

EVG was originally conceptualized for patients considered too sick from various medical comorbidities to undergo an anesthetic or an open operative repair of their aneurysm. In Dr Zarins’ series, less than a third of patients (28%) underwent EVG placement for this indication: almost three quarters could have undergone standard open aneurysm repair, those for which seems most reasonable, should be treated in this fashion. Eurostar data regarding EVG treatment of such high-risk patients (Lancet 2000;356:832) suggest that such intervention may accelerate their ultimate demise in comparison with their life expectancy had they simply been left alone. Would Dr Zarins comment on this observation?

Third, it is not even clear that those too sick to undergo a standard open aneurysm repair, those for which seems most reasonable, should be treated in this fashion. Eurostar data regarding EVG treatment of such high-risk patients (Lancet 2000;356:832) suggest that such intervention may accelerate their ultimate demise in comparison with their life expectancy had they simply been left alone. Would Dr Zarins comment on this observation?

It has become abundantly clear that safe and successful insertion of an EVG, which Dr Zarins demonstrates can occur in the community hospital setting, is not really the point. Rather, meticulous, expert, and repetitive imaging studies of both the graft and the treated aneurysm are obligatory in these patients. The persistence or even late development of endoleaks, strut fractures, or component dislocations must be aggressively sought and treated. How confident can we be that the excellent technical expertise demonstrated by these community hospital teams in inserting...
EVGs will be accompanied by equivalently fastidious follow-up of treated patients?

Dr Christopher K. Zarins. Thank you, Dr Johansen, for your comments. It is important to note that the results we are reporting are the early results in community practice using an FDA-approved endovascular device. The data from the Eurostar registry and from Veth’s report to the American Surgical Society, to which you refer, reflect endovascular experiences which include a wide variety of endovascular devices, most of which are not FDA-approved and many of which were early designs which have subsequently been modified or withdrawn from use. Thus their observations on the long-term outcome may not accurately reflect outcomes using FDA-approved devices. We found that the early results in community hospitals using an FDA-approved device were no different from the results seen in the controlled clinical trial using the same device. While we do not yet have long-term data on these community patients, the published 4-year results from the AneuRx clinical trial are quite favorable and there is no reason to suspect that the long-term community results will be different.

Dr Johansen’s comments reflect a common belief among surgeons that endovascular repair is a short-term palliative procedure whereas open surgical aneurysm repair provides a permanent cure. The literature, however, is replete with reports of anastomotic aneurysms, graft thromboses, graft infections, aortoenteric fistulas, and aneurysm ruptures following open repair. In our own experience at Stanford, there was no difference in the need for a secondary surgical procedure between patients undergoing open or endovascular aneurysm repair. Open surgery patients, however, had a higher mortality rate for both primary and secondary procedures and had a significantly higher aneurysm-related death rate. Precise comparisons between the two procedures will require long-term prospective trials, however, at this point, we cannot guarantee a patient a permanent cure with either open surgery or endovascular repair and all aneurysm treatments are palliative and require long-term follow up.

In this regard, the low (1%) operative mortality rate for endovascular aneurysm repair in this community series is very encouraging and is indeed the point of this paper. The mortality rates in statewide or national databases for nonruptured open surgical aneurysm repair are 7% to 8% with higher rates in hospitals which perform few aneurysms repairs. While it is not possible to know what the mortality rate would have been had the patients in this series undergone open repair, it is highly unlikely that it would have approached the 1% mortality observed, particularly since 29% of the patients were too frail to undergo open surgery. Thus endovascular aneurysm repair by properly trained and supported teams may prove to be a safer procedure than open repair, particularly in hospitals where surgeons perform few open repairs.

In response to the question of whether endovascular repair may have accelerated some high-risk patients’ demise, I would say that this certainly would be true for the three patients who died shortly after the procedure. The purpose of any aneurysm treatment is to prevent death from rupture and a risk benefit assessment considering the risk of rupture in light of the patient’s comorbidities and life expectancy must be made for each patient.

I agree with Dr Johansen’s comments on the need for follow-up surveillance imaging and long-term follow-up of these patients. While the early results of endovascular repair are very promising, the long-term outcomes are not yet known. The good news is that with physician training and proctoring, careful patient selection, clinical support by the manufacturer, and ongoing education of both the patient and physician, endovascular aneurysm repair can be successfully introduced into community practice with excellent early results.