Part One: For the Motion. Young Patients with Good Risk Factors Should be Treated with EVAR

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INTRODUCTION

There has been significant improvement in endovascular repair (EVAR) of infrarenal aortic aneurysms over the last 22 years, since Juan Parodi first reported on his historic cases.[1] There are now several commercially available devices approved for EVAR throughout the world. Utilization of this technique for infrarenal abdominal aortic aneurysm (AAA) repair varies worldwide, but has been shown to be up to 80% of all AAA repairs done in the USA.[2,3] Despite its widespread use in most patients, there are still subgroups in which the benefits of EVAR have not clearly been demonstrated. The subgroup most often debated is the young patient with good risk factors, which serves as the basis for the following debate. While initially thought to be a rare occurrence, this is an important controversy because in the USA more than 5,000 patients a year between the age of 50 and 64 years undergo aneurysm repair.[4] There are substantial reasons why young patients with good anatomic characteristics and low comorbidities are very good candidates for EVAR, and it should be offered to this subgroup.

PERI-OPERATIVE OUTCOMES AND EXPERTISE

There have been several large randomized controlled trials comparing EVAR with open surgical repair (OSR). The EVAR-1,[5] DREAM,[6] and OVER trials[7] showed lower 30-day mortality in patients undergoing EVAR when compared with OSR. It should be noted that the first two studies began enrollment nearly a decade ago. Since that time, additional device advances, technique improvement, and understanding in management of patients has occurred.

The ACE trial,[8] a prospective trial of low-to-medium-risk patients, showed equivocal peri-operative mortality between OSR and EVAR. One significant criterion for involvement in the ACE trial was expertise in both EVAR and OSR. Based upon several articles,[9–11] including the ACE trial manuscript, this is generally defined as >30 cases/year. Currently, most vascular specialists outside of major aortic centers rarely deal with this number of cases.[12] It therefore calls into question the applicability of these outcomes to low-volume centers. Most practising physicians will only see a few young patients a year afflicted with aneurysmal disease; therefore, their outcomes would most likely not be the same as those conducted in the ACE trial. Therefore, the results of the ACE trial are only valid when comparing outcomes at large aortic centers where more than 30 cases per year are seen. This is further supported by the fact that none of the aforementioned EVAR trials showed a statistical difference in mid-to-long-term all-cause mortality rates between EVAR and OSR.[7,8,13,14] Thus, it is beneficial and logical for the practising physician in low-volume centers to perform the procedure with which he/she is most familiar. In almost all situations, based upon today's training and experience paradigm, that would be EVAR.[12]

Medical therapy has also improved outcomes for EVAR. A recent study showed an increased rate of sac regression after EVAR in patients who were on statin therapy.[15] Other studies have demonstrated a decrease in all-cause mortality with improved medical management, including statin therapy, over the last decade.[16] This suggests that some of the outcome and mortality data from the trials of a decade ago may need to be reinterpreted if the patients were not all on optimal medical therapy. Other medications, such as doxycycline, have also shown promise in improving outcomes following EVAR.[17] As the importance of medical management of aneurysm patients becomes more widely known, durability of repair in patients with EVAR will likely further improve and become inconsequential in choosing the best method of repair.

SECONDARY INTERVENTION RATES

Although there is a higher secondary re-intervention rate for EVAR than OSR, accurate data collection is difficult. Most EVAR interventions are typically managed by endovascular means. Patients who undergo OSR typically have more open surgical-related complications, such as bowel obstructions and hernias, which lead to in-patient hospitalization.[18] Additionally, there seems to be a decrease in secondary interventions from EVAR as experience grows, advanced devices become available,[19] and patient selection improves. Secondary intervention rates as low as 7.4% have been achieved.[20] This is especially true for open conversion rates, which have now been reported to be anywhere from 1.6% to 2.6%.[21,22] Recent data from the UK reveal that younger patients treated with EVAR may have similar rates of secondary interventions when compared with OSR if evaluated after several years.[23]

IMPACT OF PATIENT SELECTION

When considering the risk factors for a patient there are physiologic-, anatomic-, and patient-specific risk factors.

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Patient selection plays a critical role in determining outcomes for EVAR. Implantation of an endoprosthesis into a pre-aneurysmal neck or outside the instructions for use (IFU) does not convey the same protection against rupture and long-term outcome compared with published clinical trial results. To be ideal candidates, patients should have appropriate anatomical criteria for the specific endograft. However, a large number of endografts inserted over the last decade have been outside their defined IFU. Analysis of a large cohort of these patients has shown an alarming rate of aneurysm sac enlargement, a high percentage of Type I endoleaks, and an increase in all-cause mortality.[24,25] Patients with anatomy within the IFU have lower re-intervention rates.[24] As more advanced devices in the USA have not generally been available until recently, many patients were treated outside their IFU. While in most instances the intra-operative angiogram reveals sufficient aneurysmal exclusion, it is not until subsequent follow-up surveillance that many problems are identified.[26]

One of the most important aspects of EVAR is the crucial importance of follow-up evaluation. Young patients who are not willing to commit to long-term follow-up are not good risk patients for EVAR. Although the risk of postoperative migration and endoleak is small, it still exists. Patients who do follow-up on a regular basis should be less likely to experience ruptures from undiagnosed type I or type III endoleaks.

PATIENT PREFERENCE

To date, no clinical trial has demonstrated a detriment to the patient when performing EVAR with respect to long-term mortality. Additionally, most studies demonstrate a distinct advantage of EVAR during the initial years after repair. It is these two facts that drive most patients in their decision. Given the choice, the majority of patients will invariably choose EVAR over OSR. Several studies have demonstrated that patients focus on the lower peri-operative morbidity and mortality, and the shorter hospital stay with EVAR, even after weighing up the risk of higher future secondary interventions.[27–29] This also holds true for younger patients, as they may still be employed and want to return to work as soon as possible to provide for their families. This increased patient productivity may help reduce the overall economic impact of EVAR compared to OSR, and should be considered when comparing these different techniques.

COSTS

While cost comparative analyses between OSR and EVAR have been attempted, it is difficult to determine the economic impact unless loss of productivity and other factors are included in the analysis. Many older studies have stated that EVAR is less cost-effective than OSR based on examination of device and hospital charges.[30] However, a recent publication from the OVER trial showed that EVAR cost less than OSR in the peri-operative period.[7] When examining the initial 2-year postoperative period, there was no difference in cost. The outcome of this analysis is also constantly changing as supply and demand, as well as hospital costs, change depending on the economic situation.[7]

Additional costs are incurred during the follow-up period as axial imaging studies are used to assess the effectiveness of EVAR. There has been some concern that computed tomography (CT) scans may also increase the risk of induced malignancy; however, most patients with aneurysmal disease, even if they are young, would rarely live long enough to be exposed to this increased risk. As better knowledge of endograft behaviors and factors that affect endoleak complications are identified, alterations in follow-up have occurred. Many centers have altered the number of CT scans acquired for surveillance, as minimum benefit is added if an initial postoperative CT scan is found to be normal.[26] Institutions have also begun using a combination of an X-ray and color duplex for postoperative evaluation, further decreasing the costs after implantation.[31,32]

LIFE EXPECTANCY OF YOUNG PATIENTS WITH ANEURYSMS

A recently published article from the Nottingham group looked at midterm survival in young patients treated with EVAR and OSR.[23] When analyzing patients treated at their institution since 1995, nearly 40% of patients who were treated with either OSR or EVAR died within 6 years of surgery. The overwhelming majority of these patients did not die from aneurysmal disease. In patients who were treated with commercially available endografts, there was a trend towards improved long term survival versus earlier custom-made endografts (hazard ratio [HR] = 2.9, 95% confidence interval (CI) = 0.9–10.0; $p = .08$) and OSR (HR = 3.1, 95% CI = 0.9–10.3; $p = .07$); however, this was not statistically significant.[23] Patients with aneurysmal aortas may not have the same life expectancy as patients in the general population, and this may be a risk factor for early mortality.

CONCLUSION

In young, motivated patients with good anatomic and physiologic risk factors EVAR is as good as, if not better than, OSR when early mortality is factored into the equation. Open surgical outcomes are particularly dependent upon the surgeon's experience, which has become extremely limited in recent years. There are potential risks of future secondary interventions with EVAR; however, the majority of these are also repaired endovascularly and the chance of needing an open surgical revision is extremely low. The cost of EVAR and OSR are becoming comparable, especially when societal impact is considered, as hospital costs increase, graft costs decline with competition, and alternative postoperative surveillance occurs. As medical management, operator expertise, and endograft technology improves, the long-term outcomes of endovascular therapy should also continue to improve. Young patients with aneurysms may also not have the same long-term survival as the general population, and may benefit from a procedure

with lower peri-operative risk. The current data suggest that in young, good risk patients the long-term mortality in EVAR and OSR is equivocal. However, there tends to be less perioperative mortality in EVAR, especially if the center's open surgical volume is limited. Therefore, only in centers of excellence should both OSR and EVAR be offered to all young, good risk patients to allow the patients to decide. In almost all cases they will choose EVAR. In all low-volume practices, EVAR should be preferentially offered.

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