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Endovascular Repair of Ruptured Abdominal Aortic Aneurysms

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1. Introduction

Ruptured abdominal aortic aneurysms (AAAs) are catastrophic events with dismal outcomes. Even in the modern era, the overall mortality rate reaches 90%. Most ruptured aneurysms worldwide are repaired by conventional open surgery with a high operative mortality despite major medical advancements in diagnostic imaging and intensive care delivery. Over the past two decades, the in-hospital mortality rate for open repair of ruptured AAAs has remained steady at around 40%-50% (Noel et al., 2001).

Since its development in 1991 by Juan Parodi, endovascular aortic repair (EVAR) has been widely accepted as an excellent method to treat aortic aneurysms with suitable anatomy. Large prospective randomized studies have already demonstrated substantial improvements in perioperative morbidity and mortality for elective EVAR compared to elective open repair of AAA. Given the encouraging results and minimally invasive nature of EVAR coupled with yet observed dismal outcomes of open repair of ruptured AAAs, the use of EVAR in the emergent setting has been proposed. The first series of patients that successfully underwent endovascular repair of ruptured AAAs (rEVAR) with homemade grafts described by Ohki and Veith in 1999, demonstrated an operative mortality rate of only 16%, suggesting that rEVAR may potentially improve outcomes seen with open repair. In 2001, only 6% of patients with rupture AAA were treated using EVAR techniques in the United States, by 2006 that number increased dramatically to 19% (Greco et al., 2006). To put that number in some context, another recent study suggested that, as many as 33% of men, and 60% of women who present to the hospital in the United Kingdom receive no intervention at all for ruptured AAA (Filipovic et al., 2007). There are several reasons for centers to be slow to adopt the endovascular approach. These reasons include limited availability of the off-the-shelf devices on an urgent basis, lack of experienced endovascular surgical expertise, and unavailability of dedicated operating room facilities and ancillary staff who are adequately equipped to perform these procedures. As such, many patients who would qualify for EVAR still undergo the traditional open repair.

Regardless, EVAR continues to gain momentum as the preferred mode of repair for ruptured abdominal aortic aneurysms. The decision to proceed with EVAR is generally dependent upon the patient's hemodynamic stability, suitable anatomy, and an experienced center that can perform the procedure. Although no randomized controlled trials currently

exist, evidence from both prospective and retrospective reviews demonstrate the feasibility and potential benefit of rEVAR. There is mounting evidence showing EVAR to be a safer, less invasive alternative to open surgery with the potential to significantly reduce in-hospital mortality and morbidity in EVAR suitable candidates despite the inherent biases that accompany the comparison.

2. A Standardized approach to endovascular repair of ruptured abdominal aortic aneurysms

To successfully treat patients with ruptured AAA using endovascular means, the practicing institution must have resources to support a multidisciplinary team approach to managing patients with ruptured AAA. Strict protocols from the emergency room to discharge planning need to be put in place to streamline patient throughput. A comprehensive protocol should address the following issues – appropriate triage and expedient imaging in the emergency department; equipment needs and necessities of the operating suite; a systematic approach to post-operative care and the management of the most common post-operative complications; a method for ensuring that the protocol includes the most up-to-date evidence-based measures; and finally, a delineation of required ancillary resources. Figure 1 below illustrates a proposed protocol for the management of patients with a suspected ruptured AAA.

A well organized team of vascular specialists should be able to address any ruptured AAA that is admitted to the hospital at any time of day or night. In order to accomplish this goal, the team must be multidisciplinary, familiar with working with each other in the context of AAAs, and have enough trained members to include 24 hour per day, 365 days per year coverage. While not an exhaustive list, the specialties required of the vascular team are vascular surgeons, vascular anesthesiologists familiar with both open and endovascular ruptured AAAs, vascular scrub nurses or technicians who have experience in both open operations and endovascular interventions, critical care nurses, surgical intensivists who are familiar with endovascular interventions, radiology technicians well versed in rapid CT protocols for delineating AAA anatomy, emergency medicine physicians familiar with ruptured AAA pre-operative requirements, a liaison in the blood bank familiar with massive resuscitation (should the case need to convert to open), and bed control managers with authority to free up appropriate ICU resources.

Ideally there should be an up-to-date inventory management system so that missing or damaged equipment are known of with enough lead time to permit transfer of the patient to a hospital with appropriate and working resources. As with the often acknowledged “door-to-balloon” time with myocardial infarction, hospitals must seek to minimize the time from diagnosis to aortic control. This includes a standardized approach to activating a dedicated team, including experienced surgeons facile with both endovascular and open techniques, anesthesiologists, nursing staff, and radiology technicians. These individuals must be experienced in performing both EVAR and open aortic repair. In a recent international, collective report of rEVAR performed by 49 centers worldwide, it was noted that staff availability and skills were a major determinant of whether a rupture AAA patient would be treated by EVAR or open repair (Veith et al., 2009). Additionally, it is advisable to have a method for the emergency room physician to put the team on notice, at the time a ruptured AAA is first suspected.

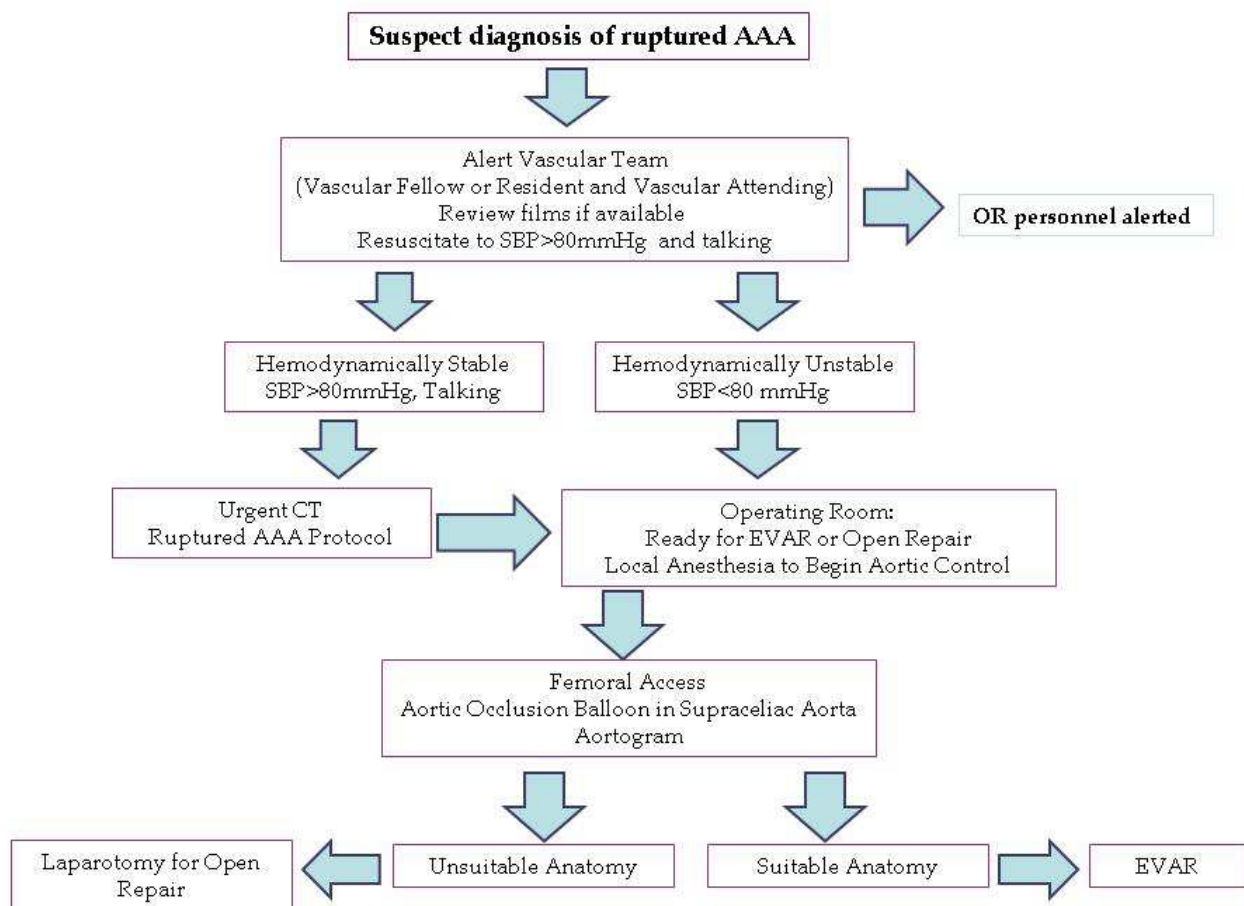


Fig. 1. Proposed protocol for rEVAR.

2.1 In the emergency room - Diagnosis and triage

When a ruptured AAA is suspected in the emergency room, the “aneurysm reflex” must be avoided where, historically, patients are aggressively resuscitated and then taken urgently to the operating room. There is evidence to suggest that a more controlled, thoughtful but expeditious approach is feasible and likely beneficial. For one, allowing “permissive hypotension” by limiting the resuscitation to maintain a detectable blood pressure (SBP > 80 mmHg) and maintaining mental status can help minimize ongoing hemorrhage and allow for expeditious imaging via computed tomography (CT).

The need for preoperative CT imaging prior to EVAR for ruptured AAA continues to be debated. Most centers consider such screening to be mandatory both for purposes of confirming the diagnosis as well as for morphological assessment. A few centers have developed protocols that provide for intraoperative assessment without CT delay using angiography or intravascular ultrasound. Realistically, time is usually available to send

patients for CT evaluation without undue risk. Current data suggests that the majority of patients with ruptured AAA have time to undergo a CT scan. The majority of patients who are admitted to the hospital with ruptured AAA survive for a number of hours. In 2004 Lloyd et al., examined the time to death in patients with ruptured AAA who did not undergo treatment. Their findings indicated that 88% (49 of 56) of patients died >2 hours after admission with diagnosis of ruptured AAA. The median time from the onset of symptoms to admission to the hospital was 2.5 hours, and the interval between hospital admission and death was 10 hours.

2.1.1 Diagnosis and determination of anatomic suitability

Although the diagnosis of rupture AAA is generally made by CT, it is important to consider that a history along with abdominal palpation has a sensitivity of between 90-97% for patients who eventually have an operation. Once the diagnosis is suspected and the vascular team activated, the next step is to triage hemodynamically unstable patients (SBP < 80mmHg) to the operating room, and hemodynamically stable (SBP > 80mmHg) patients to the CT scanner. Given the potential for rapid and significant deterioration, it is paramount for ruptured AAA patients to have priority for the CT scanner. CT is vital in confirming the diagnosis and properly delineating the aortoiliac anatomy for EVAR suitability. At most centers, 2 hours is ample time to obtain a CT scan to assess suitability for EVAR. In the case of patients who present with true hemodynamic instability, the decision must be made to either attempt to assess the morphology, and hence the candidacy for EVAR, without axial imaging using modalities available in the procedural suite or to commit to open reconstruction.

Investigators have begun to evaluate the use of fixed C-arm imaging systems and advanced rendering softwares in the hybrid operating room to generate three-dimensional roadmaps and perform computed tomographic (CT) imaging. Eide et al used the Siemens DynaCT to generate a CT immediately following EVAR and compared those images to a standard CT angiogram performed on a standard 16 slice multidetector CT (MDCT) scanner. The authors noted no statistical differences between the intra-operative C-arm generated completion DynaCT and the postoperative MDCT. When evaluating the preoperative anatomic assessment capability in EVARs however, Nordon et al found that DynaCT provided inferior visualization of mural thrombus and calcification and underestimates vessel size. Further studies assessing CT capability of fixed C-arms in the operating room are currently underway; and as imaging technology and software continue to evolve, it will not be long before accurate three-dimensional roadmaps can be rendered "on-table" to expedite assessment of anatomic suitability for EVAR.

Anatomic suitability has been reported in between 60% to 80% of patients presenting with a rupture AAA (Mehta, 2009). The range is accounted depending on strict versus liberal adherence to the generally acknowledged criteria - aortic neck length greater than or equal to 15 mm, infrarenal neck diameter less than or equal to 32 mm, aortic neck angulation less than 60 degrees, and need for both iliac arteries to be greater than 5 mm in diameter to achieve an optimal infrarenal fixation (Chaikof et al., 2009). Advancements in endograft technology continue to push the indications for use (IFU) and determination of anatomic suitability is generally dependent upon the judgment and comfort of the vascular surgeon. Accepting normally unsuitable anatomy has led a number of investigators to develop the

concept of endovascular damage control, which accepts a suboptimal radiographic result in exchange for temporizing the emergency. In short, some patients will still require laparotomy for failed EVAR or for the treatment of abdominal compartment syndrome. The damage control approach can only be adopted provided patients consent to undergo vigilant late follow-up examination and understand the potential need for “preventative maintenance”.

2.1.2 Triage

In the hemodynamically unstable patient taken directly to the operating suite, each respective institution should determine whether or not to proceed directly to an open operation, or alternatively attempt to determine anatomic suitability fluoroscopically or via intravascular ultrasound. The determination of whether a patient is hemodynamically unstable should not be made on an ad hoc basis, but should be explicit within the protocol beforehand. The determination of instability is based upon the level of physiologic compromise that the surgeons, anesthesiologists, emergency medicine physicians, and intensivists are comfortable and experienced with handling. In the recent 2009 survey by Veith et al., centers providing rEVAR reported a wide range of hemodynamic criteria for when a patient was too unstable to be offered EVAR:

1. All comers, regardless of hemodynamics, receive attempt at EVAR
2. Systolic blood pressure (SBP) <90 mm Hg
3. SBP <80 mm Hg
4. SBP <70 mm Hg
5. Similar SBP lower limits as above but with requirement that the level is sustained
6. SBP <50 mm Hg
7. Any SBP measurement <90 mm Hg and/or who had contained ruptures

While not stated in the Veith et al. survey, it has previously been reported that cardiac arrest is an automatic indication to proceed directly to open repair (Alsac et al., 2005).

2.1.3 Resuscitation

Clear endpoints of resuscitation should be determined when designing a standardized approach to rEVAR. Currently, limited resuscitation also called hypotensive or damage control resuscitation (DCR) has fallen back into vogue. The concept was first documented during World War I when poor outcomes were reported in battlefield patients with intravenous fluid administration (Cannon, 1818). With the recent conflicts in Iraq and Afghanistan, DCR has been extensively studied by both military and civilian trauma surgeons. In one study of civilian trauma patients it was found that limited resuscitation with a goal of maintaining systolic BP at 90 mmHg, use of isotonic intravenous fluids were limited and fresh frozen plasma (FFP) and packed red blood cells (PRBC) were transfused in a 1:1 ratio. This retrospective study found a nearly 20% decrease in 30 day mortality as well as a 50% decrease in ICU length of stay and overall hospital length of stay utilizing DCR.

Considering the age demographic of most patients presenting with rupture AAA, a study of more than 3,000 trauma patients at the Cedars-Sinai Medical Center concluded that “judicious fluid resuscitation is especially important in the elderly [age >70 years]” because the use of crystalloid volumes greater than 3 liters is associated with an 8.6 fold decrease in survival (Ley et al., 2011). Although no studies directly address the issue of survival and

limited resuscitation in rupture AAA, one Dutch feasibility study found that hypotensive resuscitation with a goal SBP of 50-100 mm Hg was achievable in the majority (54%) of cases (van der Vliet et al., 2007).

2.1.4 Additional preoperative considerations

The goal of standardizing a preoperative management scheme for patients with ruptured AAA should be to make the diagnosis and get the patient safely to the operating room in 20-30 minutes. Some considerations to allow for expediency are (1) if at all possible, avoid central lines, namely femoral lines, and arterial lines (2) EKG, Chest X-rays, and Ultrasound should be avoided unless the diagnosis is in question (3) an agreed upon goals for permissive hypotension or limited resuscitation, (4) the ability to start advanced-level real time hemodynamic monitoring to minimize delays once the patient arrives at the operating suite.

2.2 In the operating room - Equipment and technical considerations

It is the authors' belief that a hybrid operating suite, which incorporates both the ability to do advanced endovascular interventions as well as traditional open operations, is essential to successfully treating ruptured AAAs. Furthermore, logistics require that the operative suite be stocked with wide range of graft sizes and types, balloons, sheaths, wires, and catheters. While the imaging quality of the cardiac catheterization lab is equal to that of a hybrid operating room, the primary advantage of hybrid operating rooms is that they permit the surgeon to emergently convert to an open procedure without the need to bring in additional equipment. Routine utilization of hybrid operating rooms should provide for a more liberal policy "EVAR first", while maintaining the option to institute an open repair should circumstances require.

2.2.1 Inventory

Concerning inventory management, there are two important considerations. First, there should be stocks of sheaths, wires, and catheters to fit various sizes of patients. There should also be a variety of sizes of aortic occlusion balloons, a power-injector, redundant back-ups for fluoroscopic equipment. A stock of endografts to match the largest aortic neck diameter and the shortest aneurysm length with a variety of iliac extensions for most AAA anatomic variations as well as a stock of Palmaz stents should be readily available. The second, and perhaps more important consideration, is that the inventory and functional status of all required equipment is must be known at all times. Because ruptured AAA are unpredictable, it must be known as soon as possible whether vital equipment (e.g. the power injector) is in disrepair so that the patient may be transferred to a hospital with the ability to carry out the intervention.

2.2.2 Anesthesia and aortic control

In rEVAR, aortic control can be performed under local anesthesia via percutaneous approach in experienced hands or general anesthesia and femoral artery cut-down. Use of local anesthesia helps to avoid the hemodynamic changes associated with muscle relaxation and general anesthesia. The significant inflammatory response related to cytokine release may be blunted with EVAR. Large doses of heparin can be avoided as well. While less

invasive, the percutaneous approach suffers several physiologic, mechanical, and logistic limitations. Physiologically, it may be difficult to quickly and accurately palpate a femoral pulse in a patient who is hemodynamically unstable or undergoing permissive hypotension. This may be obviated by the use of ultrasound guided access. From a device standpoint, the most common stents require at least an 18F sheath and may pose problems depending on patient anatomy. Logistically, cut-downs are almost invariably faster. As such, it is the recommendation of the authors to forego attempts at totally percutaneous access in any patient who is not hemodynamically stable, awake, and unable to cooperate with the operating room personnel.

2.2.3 Aortic occlusion balloons

After gaining access, an aortic occlusion balloon (AOB) is advanced via a 12-14Fr (45 cm) sheath placed into the juxtarenal aorta and advanced to the level of the supraceliac aorta. The aortic occlusion balloon is inflated as needed to maintain hemodynamic stability. A liberal usage policy with regard to AOB is recommended because of the difficulty associated with insertion at later points in the intervention. In one case series, the use of AOB was reported at 27% (Riesenman et al., 2008). It is important to remember to deflate the balloon just prior to stent deployment to prevent entrapment of the balloon between the graft and the aorta. This short period without aortic occlusion is usually insignificant to the patient's hemodynamics (Mehta et al., 2010).

2.2.4 Adjunctive procedures

The operating surgeon must be able to handle the need for unexpected adjunctive procedures as in the emergent setting, preoperative planning can be less than ideal. One such procedure that should be in the surgeon's armamentarium is knowledge and comfort in utilizing Palmaz stents to repair type I endoleaks (one of the most common operative complications of rEVAR). Further the surgeon should be comfortable with hybrid cases. For instance, if the decision is made to use an aortouni-iliac (AUI) graft or to convert a bifurcated stent graft to an AUI (as has been reported in 16% of patients), the surgeon should be comfortable performing both the primary EVAR and the femorofemoral bypass (Mehta et al., 2010).

3. Post-operative care considerations

The immediate post-operative considerations include the ability to monitor patients for the most common complications e.g. abdominal compartment syndrome. This necessitates a protocol re-activation of the operative team in the event of an emergent requirement to take the patient back to the OR.

3.1 Abdominal compartment syndrome

Abdominal compartment syndrome (ACS) is a significant complication resulting from a ruptured AAA. The pathophysiology is multifactorial resulting from existing retroperitoneal hematoma, ongoing, coagulopathic bleeding from aortic collaterals (lumbar and inferior mesenteric arteries from the disrupted aneurysm sac), and profound shock associated with ruptured AAA, which induce a systemic inflammatory response (SIRS) with

increased capillary permeability and hemodynamic compromise (Mehta M., 2005). The incidence of ACS after rupture AAA is as high as 18% and carries with it a 7 fold increased risk of death (Mehta et al, 2010). Additionally, ACS is a major contributor to post operative acute renal failure and intestinal ischemia. However, both acute renal failure and intestinal ischemia can occur outside of the setting of ACS. Risk factors include massive blood transfusions, intraoperative coagulopathy and use of aortic occlusion balloons. The debate is still ongoing as to the best method for diagnosing ACS. The various options center around some combination of clinical exam findings and bladder pressure measurements. By whatever criteria, the treatment has remained decompressed laparotomy.

4. Current data on endovascular repair of ruptured aortic aneurysms

The evidence to support EVAR for ruptured AAAs is largely drawn from results of single-center case series, systematic reviews, and more recently, population-based studies arising from the United States. Although encouraging mortality rates are published, significant biases exist. First, a direct comparison between EVAR and open surgery for ruptured AAA is difficult as not all patients are anatomically suitable for EVAR. Secondly, unstable patients are by in large, directed toward traditional open repair. In a recent retrospective institutional review, Lee et al. identified this selection bias in that hemodynamically unstable patients tended to undergo open repair even when potentially anatomically suitable for rEVAR (Lee et al., 2008). Such observations may be alluding to the fact that patients stable enough to undergo CT are already a self-selecting cohort compared to those that are in extremis and cannot proceed to preoperative imaging. As experience increases with EVAR, however, hemodynamic stability may not factor as much into repair selection or else may push the choice toward rEVAR for unstable patients as access and balloon occlusion can be rapidly attained to stop hemorrhage. Despite the inherent biases that exist in studying the outcomes of rEVAR, evidence to support an EVAR first approach to managing ruptured AAAs continues to mount.

Select studies in the literature representing current data on rEVAR are summarized in Table 1 below. Many institutions that have adopted the rEVAR first approach have seen significant benefits. Of the single-center experience observational studies, the most recent report by Starnes et al. comparing outcomes before and after implementation of a rEVAR-first protocol, showed that their overall 30-day mortality fell from 54.2% to 18.5% (Starnes et al., 2009). On a larger scale, outcomes of implementing a rEVAR first protocol was reviewed in a large co-operative multicenter cohort study by Veith et al. in 2009 spanning 49 institutions in 13 countries. The study showed superiority of EVAR over open repair in terms of 30-day mortality (rEVAR 21.2% vs. Open repair 35.8%) when collectively analyzed not accounting for differences in practice variability; most centers limited the use of rEVAR to “stable” patients or those with “contained” ruptures (Veith et al., 2009). The study re-examined the results of 13 centers that were committed to performing rEVAR for all ruptured cases despite hemodynamic instability. These centers were usually those with larger volume experiences. The report showed a median 30 day mortality of 19.7% with EVAR and 36.3% with open surgery ($P<0.0001$). The power of the study is significant (1037 cases) to support rEVAR as a better treatment to managing ruptured AAAs, however, with no defined standard of practice in any participating centers and with this being a purely an observational study, the evidence is still at best level 2b.

| Author, Date and Country | Study Type | Key Results |
|---|---|--|
| Starnes et al., (2009), J Vasc Surg, USA | Retrospective cohort study (level 2b) | Mortality reduction from 57.8% to 35.3% [absolute risk reduction 22.5%; odds ratio (OR) of 0.40] |
| Veith et al., (2009), Ann Surg, USA | Retrospective multi-center cohort study (level 2b) | 30-day mortality amongst EVAR repair=21.2% 30-day mortality amongst open-repairs=35.8% In centers treating 24–62 rAAA overall mortality=21.0% (range 7–39%). 30-day mortality amongst centers using EVAR for 11–18 rAAA per annum=22.5% (range 6–43%). 30-day mortality for centers performing EVAR on 5–10 rAAA per annum=30%. 30-day mortality for centers performing EVAR on 1–4 rAAA per annum=35% |
| Karkos et al., (2009), Arch Surg, Greece | Systematic review of non- randomized observational studies (level 2a) | Meta-analysis of 19 studies reporting results of concurrent open-repair, pooled mortality after open-repair = 44.4% (95% CI, 40.0–48.8%), and pooled overall mortality for endovascular or open repair= 35% (95% CI, 30–41%) |
| Vogel et al., (2009), Vasc Endovascular Surg, USA | Retrospective national cohort study (level 2b) | Mortality=45.1% EVAR vs. 52.4% open-repair (P=0.21) Length of stay not significantly different between EVAR and open-repair groups |
| Giles et al., (2009), J Endovasc Ther, USA | Multicenter cohort study (level 2b) | Mortality=24% EVAR vs. 36% open-repair (P<0.05) |
| Visser et al., (2009), J Vasc Surg, Netherlands | Multi-center prospectively- recruited cohort study (level 2b) | Thirty-day mortality=26% EVAR vs. 40% open-repair (P=0.06) |
| Sadat et al., (2009), Eur J Vasc Endovasc Surg, UK | Prospective cohort study (level 2b) | Group 1=17 eEVAR, 29 open repairs, 4 palliated (after the introduction of rEVAR), Group 2=54 underwent open repair and 17 were palliated Significant differences in 30-day operative mortalities between the two groups 13% in Group 1 vs. 39% in Group 2 (P=0.0003) |
| Verhoeven et al., (2008), J Vasc Surg, Netherlands | Prospective cohort study (level 2b) | Mortality after EVAR=13.9% vs. 28.1% open-repair (P=0.092) No significant difference in mortality over 25 months follow-up between EVAR and open-repair |
| Ockert et al., (2007), J Endovasc Ther, Germany | Retrospective cohort study (level 2b) | 30-day mortality=31% in both groups (P=1.0). Morbidity rate=55.2% EVAR vs. 62% open-repair (P=0.9) |
| Hinchliffe et al., (2006), Eur J Vasc Endovasc Surg, UK | Single center RCT (level 1b) | 30-day intention-to-treat mortality=53% rEVAR vs. 53% open-repair Moderate or severe operative complications=77% EVAR vs. 80% amongst open-repair. Renal complications=55% EVAR vs. 8% open-repair (P=0.02) 4 patients died prior to surgery |

Table 1. List of current data on endovascular repair of ruptured AAA.

Large national databases have also been used to examine the differences between open and endovascular repair for ruptured AAA. Egorova et al. examined the databases of 4 large states from 2000 to 2003 and found, even in those earlier years, that mortality in 290 rEVAR patients was lower than in 5508 open repair patients (39% versus 48%, $p < 0.005$) (Egorova et al., 2008). Analysis of another large nationwide inpatient sample from 2001 to 2006 showed the increase in the use of EVAR for ruptured AAAs increased over time (5.9% in 2001 to 18.9% in 2006, $P < .0001$) while overall ruptured AAA rates remained constant (Mcphee et al., 2009). In reviewing the database, the investigators showed that rEVAR had lower overall in-hospital mortality than open repair (31.7% vs 40.7%, $P < .0001$). The benefit of rEVAR, when stratified by institutional volume, was found to be augmented in that study. Investigators also found that rEVAR patients had a shorter length of stay (11.1 vs 13.8 days, $P < .0001$), higher discharges to home (65.1% vs 53.9%, $P < .0001$), and lower cost of care (\$108,672 vs \$114,784, $P < .0001$) (Mcphee et al., 2009). Although these large datasets give convincing arguments to support rEVAR, reports from population-based studies are misleading because they are not able to control for significant confounders of patient physiology and morphology. In addition, it is not known whether these studies are applicable outside the United States. The study, however, noted that because of the technical requirements of the procedure, the impact of annual volume on outcomes of ruptured AAA repairs is an important factor that cannot be assessed by single institutional series.

It has been shown that there is a significant relationship between higher surgeon and hospital volume and improved patient outcomes after open surgical repair for ruptured AAA (Dimick et al., 2002). Mcphee et al found a clear mortality advantage directly related to all volume measures analyzed: annual elective open repair volume, annual elective EVAR volume, and annual RAAA volume. For each of these metrics, mortality decreased significantly as annual surgical volume increased. The absolute mortality benefit was most pronounced when analyzed according to elective EVAR volume; institutions in the high elective EVAR volume (> 40 per year) had an absolute mortality decrease of $> 15\%$ (Mcphee et al., 2009). In the multicenter study by Veith et al, rEVAR related mortality is seen to be dependent upon the institutional volume of rEVARs performed. In centers treating 24–62 ruptured AAAs per year, the collective mortality rate reported is 21.0% (range 7–39%); 30-day mortality amongst centers performing 11–18 rEVARs per year is 22.5% (range 6–43%); 30-day mortality for centers performing 5–10 rEVARs per year is 30% (range 21–30%); 30-day mortality for centers performing 1–4 rEVARs per year is 35. In fact, a study by Giles et al. in 2009 showed lower mortality rates in higher volume hospitals for both open repairs and rEVAR, and a very large difference in endovascular outcomes. As such, the authors concluded that regionalization of referrals of ruptured AAA patients to high-volume centers preferentially may improve overall national outcomes.

The study by Hinchliffe et al from 2006 is the only paper published to date reporting level 1 evidence comparing rEVAR to open repair. This single-center a randomized control trial (RCT) study showed a higher EVAR related mortality compared to those reported in observational studies and did not find any overall survival advantage in the mid- to long-term with EVAR compared to open repair (Hinchliffe et al., 2006). Of those patients enrolled, 53% were deemed suitable for EVAR. The prerequisite for CT-scanning, interestingly, did not delay definitive surgery. As only 32 patients were enrolled, the study lacked sufficient power to provide definitive recommendations but did show that it

is possible to recruit patients to a randomized trial of open repair and EVAR in patients with ruptured AAA.

More randomized studies have since commenced. The Amsterdam (Acute Endovascular Treatment to Improve Outcome of Ruptured Aortoiliac Aneurysms [Ajax]) trial (ISRCTN66212637) recruited 80 patients, and being underpowered, showed no significant difference in primary combined end point of 30-day mortality and serious morbidity. Recruitment for the trial has therefore been extended. The Ruptured Aorta-Iliac Aneurysms: Endo vs Surgery (ECAR) trial (NCT00577616) is currently underway and both AJAX and ECAR have been designed to recruit only the most stable patients, all of whom will be anatomically suitable for EVAR. One can argue that randomization of patients after CT scanning will not delineate the role of an rEVAR first strategy compared to open repair on an intention-to-treat basis. In consideration, the UK study Immediate Management of the Patient with Rupture: Open Versus Endovascular repair (IMPROVE) aneurysm trial (ISRCTN 48334791) will randomize patients at the time of diagnosis of ruptured AAA, either to immediate CT scan and endovascular repair whenever anatomically suitable (endovascular first), or to open repair, with CT scan being optional (normal care). The trial is set on a background of guidelines for emergency care, CT scanning and anesthesia, which incorporate the protocol of permissive hypotension. Recruitment started in October 2009 and 600 patients are required to show a 14% survival benefit at 30 days (primary outcome) for the endovascular first policy.

With the given evidence to date, the only reasonable conclusion that can be drawn is that the role of rEVAR in the management of patients with ruptured AAA remains to be proven. Due to the lack of quality data, determining the subgroup of patients that will truly gain benefit from rEVAR remains to be elucidated and we will have to await the results of level 1 evidence to answer this question.

5. Conclusion

Despite the inherent biases, information is emerging to suggest that there is a clear role for EVAR for ruptured AAA in select patients. There are a number of clear advantages to the endovascular approach given patient suitability. Patients undergoing EVAR can be treated using local anesthesia, which helps avoid the hemodynamic changes associated with muscle relaxation and general anesthesia. In addition, the morbidity associated with dissecting the aortic neck, damage to peri-aortic structures, and bleeding, can be avoided. The current literature has demonstrated decreased procedure times, reduced blood loss, and improved overall and intensive care unit lengths of stay following EVAR for ruptured AAA when compared to open surgery, but also suggests that these results are seen in select centers with adequate EVAR and open experience; supporting a direction towards regionalization of care and the management of all ruptured AAAs in large vascular centers. The routine use of EVAR for ruptured AAAs, however, remains to be proven with forthcoming level 1 evidence.

The technology behind stentgrafts continues to evolve and will further the potential for improved patient survival. If rEVAR can significantly reduce the mortality rate of patients presenting to hospital with ruptured AAA, the management of ruptured AAA would have to change as well as the organization and delivery of emergency and vascular services. The capability of performing rEVARs requires significant investment in institutional infrastructure. If feasible, however, the implementation of rEVAR capability and protocols

could potentially benefit all types of repairs as the awareness and response to the arrival of a ruptured aneurysm patient is streamlined.

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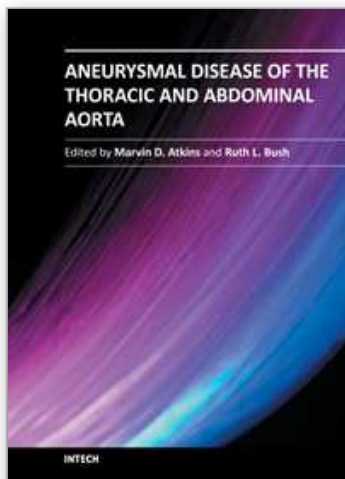
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Aneurysmal Disease of the Thoracic and Abdominal Aorta

Edited by Dr. Ruth Bush

ISBN 978-953-307-578-5

Hard cover, 226 pages

Publisher InTech

Published online 16, December, 2011

Published in print edition December, 2011

The first successful open surgical repair of an abdominal aortic aneurysm was in 1951 by Dubost and represented a tremendous milestone in the care of this challenging disease. The introduction of endovascular repair in 1991 by Parodi furthered the care of these patients by allowing for lower morbidity and mortality rates and also, enabling surgeons to extend surgical treatment to patients traditionally deemed too high of a surgical risk. This new book on Aortic Disease covers many interesting and vital topics necessary for both the practicing surgeon as well as a student of vascular disease. The book starts with background information on the evolution of aortic management from traditional open surgical repair to modern endovascular therapies. There is also a chapter covering the data supporting current treatment modalities and how these data have supported modern management. Also, the use of endovascular means for care of the challenging situation of ruptured aneurysms is discussed. In addition to management of abdominal aneurysm, there is a chapter on treatment of aneurysms of the ascending aorta. Along with surgical treatment, one must also understand the molecular basis for how blood vessels remodel and thus, the role of cathepsins in aortic disease is elucidated. Lastly, chapters discussing the perioperative management of radiation exposure and ultrasound-guided nerve blocks as well as the need for high-quality postoperative nutrition will lend well to a full understanding of how to management patients from presentation to hospital discharge. We hope you enjoy this book, its variety of topics, and gain a fuller knowledge of Aneurysmal Disease of the Thoracic and Abdominal Aorta.

How to reference

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Cheong J. Lee, Andrew Gonzalez and Mark D. Morasch (2011). Endovascular Repair of Ruptured Abdominal Aortic Aneurysms, *Aneurysmal Disease of the Thoracic and Abdominal Aorta*, Dr. Ruth Bush (Ed.), ISBN: 978-953-307-578-5, InTech, Available from: <http://www.intechopen.com/books/aneurysmal-disease-of-the-thoracic-and-abdominal-aorta/endovascular-repair-of-ruptured-abdominal-aortic-aneurysms>

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