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The impact of hemodynamic status on outcomes of endovascular abdominal aortic aneurysm repair for rupture

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Objective: To date, there are no published reports comparing hemodynamically (Hd)-stable and Hd-unstable patients with ruptured abdominal aortic aneurysms (r-AAAs) undergoing endovascular aneurysm repair (EVAR). This study evaluates outcomes of EVAR for r-AAA based on patient’s Hd status

Methods: From 2002 to 2011, 136 patients with r-AAAs underwent EVAR and were categorized into two groups based on systolic blood pressure (SBP) measurements before EVAR: 92 (68%) Hd-stable (SBP ≥80 mm Hg) and 44 (32%) Hd-unstable (SBP <80 mm Hg for >10 minutes). All data were prospectively entered in a database and retrospectively analyzed. Outcomes included 30-day mortality, postoperative complications, the need for secondary reinterventions, and midterm mortality. The effect of potential predictors on 30-day mortality was assessed by χ² and logistic regression.

Results: Of the 136 r-AAA patients with EVAR, the Hd-stable and Hd-unstable groups had similar comorbidities (coronary artery disease, 63% vs 59%; hypertension, 72% vs 75%; chronic obstructive pulmonary disease, 21% vs 26%; and chronic renal insufficiency, 18% vs 18%), mean AAA maximum diameter (6.6 vs 6.4 cm), need for on-the-table conversion to open surgical repair (3% vs 7%), and incidences of nonfatal complications (43% vs 38%) and secondary interventions (23% vs 25%). Preoperative computed tomography scan was available in significantly fewer Hd-unstable patients (64% vs 100%; P < .05). Compared with Hd-stable patients, the Hd-unstable patients had a significantly higher intraoperative need for aortic occlusion balloon (40% vs 6%; P < .05), mean estimated blood loss (744 vs 363 mL; P < .05), incidence of developing abdominal compartment syndrome (ACS; 29% vs 4%; P < .01), and death (33% vs 18%; P < .05). ACS was a significant predictor of death; death in all r-EVAR with ACS was significantly higher compared with all r-EVAR without ACS (10 of 17 [59%] vs 22 of 119 [18%]; P < .01).

Conclusions: EVAR for r-AAA is feasible in Hd-stable and Hd-unstable patients, with a comparable incidence of conversion to open surgical repair, nonfatal complications, and secondary interventions. Hd-stable patients have reduced mortality at 30 days, whereas Hd-unstable patients require intraoperative aortic occlusion balloon more frequently, and have an increased risk for developing ACS and death. (J Vasc Surg 2013;57:1255-60.)

The evolution of endovascular aneurysm repair (EVAR) has led to improvements in our ability to treat elective and ruptured abdominal aortic aneurysms (r-AAAs). However, even today, one of the biggest limitations in widespread acceptance of an EVAR-first approach for all patients with r-AAAs is our limited understanding in managing hemodynamically (Hd) unstable r-AAA patients by endovascular means and the lack of data on outcomes of Hd-stable vs Hd-unstable patients with r-AAA undergoing EVAR. This prospective nonrandomized study was based on an EVAR-first approach for all r-AAA patients and evaluates outcomes based on patient’s Hd status.

METHODS

In 2002, we established a protocol-oriented approach for treating patients with r-AAAs. In the emergency room, Hd-stable patients undergo expeditious computed tomography (CT) scan and are subsequently transferred to the operating room (OR), and Hd-unstable patients are directly transferred to the OR without a preoperative CT scan for an endovascular-first approach and conversion to open surgical repair (OSR) as needed. As long as the patients maintain a measurable blood pressure, the techniques of hypotensive hemostasis by limiting the resuscitation to maintain a detectable blood pressure can help minimize ongoing hemorrhage. Earlier in our experience
in Hd-unstable patients, we sometimes made the decision for ruptured EVAR (r-EVAR) without the availability of a preoperative CT scan. In such instances, aortic neck measurements were performed on the basis of intraoperative angiography only. In cases of juxtarenal r-AAAs, the decision for conversion to OSR vs one or both renal artery coverage was at the discretion of the vascular surgeon.

All procedures were performed in the OR with general, regional, or local anesthesia via a femoral cutdown or a percutaneous approach. The stent grafts used were currently approved by the U.S. Food and Drug Administration and available off the shelf and included the Excluder (W. L. Gore & Associates, Flagstaff, Ariz), Zenith (Cook Inc, Bloomington, Ind), and AneuRx and Talent (Medtronic AVE, Santa Rosa, Calif). Patient selection for EVAR vs OSR, as well as the selection of particular stent grafts, was at the discretion of the surgeon and determined primarily by the anatomic limitations of the patient’s aortoiliac morphology. The stent grafts were oversized 20% to 30% relative to angiographic aortic neck measurements.

All patients without a preoperative CT scan had a post-EVAR CT scan that confirmed r-AAA. Our algorithm for management of r-AAAs by EVAR has been detailed previously. Patient selection for EVAR or OSR depended on the surgeon’s discretion and experience. During r-EVAR, stent grafts were chosen on the basis of the availability and the patient’s aortoiliac morphology. With experience, particularly during the past 5 years, most vascular surgeons in our group have the ability and are comfortable with r-EVAR, resulting in less bias toward OSR in Hd-stable as well as Hd-unstable patients, and improvements in our ability to treat patients with increasing complexity of aortoiliac morphology. In this data set we accepted the real-world scenario clinical bias that vascular surgeons face when evaluating r-AAA patients for r-EVAR vs OSR. Patients who underwent OSR were not included in this analysis.

The r-EVAR procedure. The patients are placed supine and are prepared and draped. Femoral access (surgical cutdown or percutaneous) is obtained using a needle, floppy guidewire, and a guiding catheter. The floppy guidewire is exchanged for a super-stiff wire that can be used to place a large sheath (12F-14F, 30-45 cm length) in the ipsilateral femoral artery, and the sheath is used to place a large sheath (12F-14F, 30-45 cm length) in the ipsilateral femoral artery, and the sheath is ready to be delivered and support the aortic occlusion balloon (AOB), if needed. Access is subsequently obtained from the juxtarenal abdominal aorta so it is ready to be used to support the AOB, the tip of the stent graft main body is aligned with the lowermost renal artery, and the AOB is subsequently deflated and withdrawn back with the delivery sheath into the AAA, and the stent graft main body is deployed. The remainder of the EVAR procedure is performed similar to as in elective circumstances.

In patients with Hd instability or anatomic limitations that precluded expeditious exclusion of the r-AAA, modular bifurcated stent grafts were converted to aortouniiliac (AUI) devices by deploying aortic cuffs (AneuRx, Excluder, or Zenith Renu AUI converter) or a second aortic stent graft main body across the stent graft flow divider. The contralateral iliac artery was interrupted by open ligation, endoluminal occlusion, or placement of a covered stent from the internal iliac artery into the external iliac artery, and femorofemoral bypass was performed.

Patient Hd status was categorized according to vital signs any time before the r-EVAR; patients with systolic blood pressure (SBP) measurements of <80 mm Hg for >10 minutes in duration were categorized as Hd-unstable, and all other patients (SBP >80 mm Hg) were considered Hd-stable for this analysis. The diagnosis of abdominal compartment syndrome (ACS) was made on the basis of bladder pressures >35 mm Hg with severe abdominal distention, or cardiovascular collapse, or both. All data were prospectively collected, and statistical analysis was performed using χ² and life-table methods.

RESULTS

In our single-center experience, from 2002 to 2011, 283 patients presented with r-AAAs, of which 136 underwent r-EVAR and were categorized into two groups by their perioperative Hd status: 92 (68%) were considered Hd-stable, and 44 (32%) were Hd-unstable. Both groups were similar with respect to comorbidities, including coronary artery disease, defined as patients with prior cardiac workup who were deemed so by their cardiologist, presence of coronary artery disease (63% vs 59%), hypertension (72% vs 75%), chronic obstructive pulmonary disease, defined as anyone with asthma, emphysema, with or without home oxygen dependency (21% vs 26%), and chronic renal insufficiency, defined as creatinine level >1.8 mg/dL (18% vs 18%), and maximum AAA diameter (6.6 vs 6.4 cm; Table I). There were notable differences between the groups in that before r-EVAR, a preoperative CT scan was available in a significantly higher percentage of Hd-stable than in Hd-unstable
patients (92 of 92 [100%] vs 29 of 44 [66%]; \( P < .05 \)). Furthermore, when compared with Hd-stable patients, the Hd-unstable patients had a significantly higher intraoperative need for the AOB (18 of 44 [41%] vs 5 of 92 [5%]; \( P < .05 \)), higher mean estimated blood loss (744 vs 363 mL; \( P < .01 \)), a higher incidence of developing ACS (29% vs 4%; \( P < .05 \)), and a nonsignificant trend toward a higher incidence of conversion to OSR (3.2% vs 6.8%; Table II).

Of the 15 patients without a preoperative CTA, one patient was converted to OSR, three patients with normal renal function underwent unilateral renal artery coverage, and one patient with chronic renal insufficiency underwent bilateral renal artery coverage. The patient who required conversion to OSR died. All unilateral renal artery coverage patients survived without the need for dialysis, and the bilateral renal artery coverage patient survived and currently requires dialysis.

Table II also indicates there were no significant differences between the Hd-stable and Hd-unstable groups in the incidence of nonfatal complications, including myocardial infarction, ischemic colitis, bleeding, wound infection, pulmonary, renal insufficiency, or multisystem organ failure (43% vs 38%), and the need for secondary interventions, including proximal or distal stent graft extensions, use of Palmaz stents at the proximal aortic neck for treatment of type I endoleaks, translumbar embolization for type II endoleaks, or stent graft explant (23% vs 25%) over a mean follow-up of 29 months. In all r-AAA patients, the overall incidence of endoleaks, translumbar embolization for type II endoleaks, and one required embolization for type I endoleak. There were no differences among Hd-stable and Hd-unstable patients. Among survivors, secondary interventions for graft-related complications were performed in 21 of 91 patients (23.1%). Most were translumbar coil embolization procedures for persistent type II endoleaks (12 [13.2%]). Three patients (3.3%) with type I endoleaks had Palmaz stents placed at the aortic neck, one (1.1%) with stent graft migration from the proximal aortic neck required stent graft extension, and one (1.1%) required conversion to OSR. Two patients (2.2%) needed femorofemoral crossover for limb thrombosis. Three (3.3%) patients had major graft-related complications: two had stent graft infections and required explantation with an axillofemoral bypass, and one patient sustained a rupture at 29 months. Complications among the 91 survivors of EVAR for r-AAA were acute compartment syndrome or ACS (six [6.6%]), colon ischemia (five [5.5%]; three required colectomy), respiratory failure requiring ventilation (five [5.5%]), and small bowel obstruction, lower extremity thrombosis, acute renal failure requiring dialysis, multisystem organ failure, prolonged ileus, and pulmonary embolism in one patient (1.1%) each. Again, there were no significant differences among Hd-stable and Hd-unstable patients.

**DISCUSSION**

During the past decade, the proportion of r-AAA patients being treated by EVAR is steadily increasing, and there is ample evidence of safety and efficacy of these procedures in academic tertiary medical centers as well as in community hospitals.\(^6\)\(^-\)\(^11\) In 2002, we established a standardized r-EVAR-first approach for all patients presenting with r-As,\(^12\) and this enabled us to evaluate and compare outcomes of Hd-stable and Hd-unstable patients undergoing r-EVAR. Our findings of 136 r-EVAR patients...
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as OSR under these emergent circumstances.4,7
the early diagnosis of r-AAA, the ability to have an expedi-
tate a seamless transition of the patient from the emergency
department to the OR for r-EVAR. Although the standard-
ity for planning for an emergent OSR, most would agree
Although a preoperative CT scan is not considered a neces-
arming approach for select patients, particularly those who
are Hd-unstable.16 In Hd-stable patients, particularly in
the hands of experienced operators, these percutaneous
procedures are quite feasible, and this approach needs to
be individualized on the basis of the patient’s access suit-
ability and Hd status. In our experience, percutaneous
techniques were used in 43.2% (19 of 44) of Hd-
unstable patients during r-EVAR, and there were no signif-
icant differences on outcomes among these groups.

Today, most well-established centers performing emerg-
ent aortic procedures have developed strategies that facil-
tate a seamless transition of the patient from the emergency
department to the OR for r-EVAR. Although the standard-
ization of any approach will vary from one institution to
another, the fundamentals are simple: success depends on
the early diagnosis of r-AAA, the ability to have an exped-
tious CT scan to evaluate the aortoiliac morphology, and
quick transition of the patient from the emergency depart-
ment to the OR, which is equipped to perform EVAR as
well as OSR under these emergent circumstances.4,7

The Hd status of the r-AAA patient often influences
our decision about the type of repair, be it EVAR or OSR.
Although a preoperative CT scan is not considered a neces-
sity for planning for an emergent OSR, most would agree
that a preoperative CT is of paramount importance during
emergent EVAR planning. So the question is whether one
has the time to get an emergent CT scan before EVAR,
and if not, are other tools available that might help us
manage these Hd-unstable patients by endovascular means?
Lloyd et al.13 published data on a time-to-death study in
patients with r-AAAs who did not undergo treatment. Their
findings indicated that 88% (49 of 56) of patients died >2
hours after admission with the diagnosis of r-AAA. Similarly,
Sadat et al.14 in their meta-analysis of 23 published studies
on r-AAAs reporting 7040 patients, with 730 (10%) under-
going EVAR, found that most patients with r-AAAs had
time for a preoperative CT scan. In our experience before
r-EVAR, although 36% (15 of 44) of Hd-unstable patients
did not have a preoperative CT scan, this subset of patients
account for our earlier experience, and during the past
several years, it is rare for a patient not to have a CT scan
before arrival to the OR.

In patients without a preoperative CT, the proximal
and distal stent graft attachment site measurements were
based on angiography alone. In such instances, stent grafts
were oversized 20% to 30% according to angiographic find-
ings rather than the standard 10% to 20% as suggested by
most stent graft instructions for use. A subset analysis of
this patient cohort indicates no significant differences in
achieving successful r-EVAR and aneurysm exclusion in
patients with and without preoperative CT scans; however,
the overall Hd-unstable patient cohort did have a higher
mean estimate blood loss and a higher incidence of devel-
oping ACS, and there might be some unrecognized corre-
lations among these groups. Before r-EVAR we certainly
would recommend developing systems that allow for
obtaining a preoperative CT scan in all patients. During
the past 2 years, improvements in our r-EVAR protocol
have resulted in our ability to obtain preoperative CT scans
in all r-AAA patients.

Depending on one’s comfort level and the logistics,
EVAR for rupture can be performed under local anesthesia
via percutaneous approach to general anesthesia and
femoral artery cutdown. The potential benefits of local
anesthesia and a percutaneous approach are that it might
avoid the loss of sympathetic tone in the compromised
r-AAA patients.15 Although earlier in our experience we
routinely performed femoral artery cutdown for all r-AAA
patients, similar to others, we have evolved to a percuta-
neous approach for select patients, particularly those who
are Hd-unstable.16 In Hd-stable patients, particularly in
the hands of experienced operators, these percutaneous
procedures are quite feasible, and this approach needs to
be individualized on the basis of the patient’s access suit-
ability and Hd status. In our experience, percutaneous
techniques were used in 43.2% (19 of 44) of Hd-
unstable patients during r-EVAR, and there were no signif-
icient differences on outcomes among these groups.

Overall, 17% (23 of 136) of all r-EVAR patients required
the AOB. The need for AOB was significantly higher in Hd-
unstable patients than in Hd-stable patients (41% vs 5%;
P < .05), and 65% (15 of 23) of patients requiring the
AOB developed ACS. Univariate analysis indicated the
need for AOB during r-EVAR was an independent signifi-
cant risk factor for developing ACS.17 The appropriate use
of AOB is Hd-unstable patients is vital to the success of
EVAR in these emergent circumstances. Our preferred
method for placing AOBs is to use the femoral approach,
and we have found this to have several advantages:

1. It allows the anesthesia team to have access to both
upper extremities for arterial and venous access;
2. Patients who require the AOB are often hypotensive
and percutaneous brachial access in these patients can
be difficult and more time-consuming than femoral
cutdown; and
3. The currently available AOBs require at least a 12F
sheath, which requires a brachial artery cutdown
and repair, and stiff wires and catheters across the
aortic arch without prior imaging under emergent
circumstances might lead to other arterial injuries
or embolization causing stroke.

If inflation of the AOB is required to maintain a viable
blood pressure, then the remainder of the EVAR should be

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hd-stable, No. (%)</th>
<th>Hd-unstable, No. (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>91 (67.0)</td>
<td>45 (33.0)</td>
<td></td>
</tr>
<tr>
<td>ACS</td>
<td>4 (4.0)</td>
<td>13 (29.0)</td>
<td>&lt;.01</td>
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<tr>
<td>30-day mortality</td>
<td>17 (18.0)</td>
<td>15 (33.0)</td>
<td>&lt;.05</td>
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conducted expeditiously to limit the time of aortic occlusion, and further limit the development of complications of ongoing bleeding such as ACS and multisystem organ failure. During the procedure, just before deployment of the stent graft main body, the AOB should be deflated from the suprarenal level and withdrawn. The stent graft main body is subsequently deployed. This will avoid trapping the compliant AOB between the aortic neck and the stent graft. This temporary deflation of the AOB rarely results in Hd collapse and usually is of little consequence. In Hd-unstable patients, the occlusion balloon can be redirected into the aortic neck from the side ipsilateral to the stent graft main body and reinflated at the infrarenal aortic neck within the stent graft main body. This allows for aortic occlusion and does not interfere with the remainder of the endovascular procedure.

Implementation of a standardized protocol for emergent r-EVAR has been demonstrated to improve outcomes and allow for emergent treatment of Hd-unstable patients in our experience, as well as others. Moore et al demonstrated evidence of a significant reduction in mortality (17.9% vs 30%; \( P < .05 \)) after introduction on an emergency endovascular therapy protocol for r-AAA. A significant percentage of r-AAA patients present with Hd instability, and without a standardized protocol, these patients are often not considered suitable for EVAR and undergo OSR. It is these Hd-unstable patients who have the highest mortality of OSR and might be the ones to experience the greatest benefit of EVAR, and further studies on Hd-unstable r-AAA patients are needed. Lastly, health care cost implications play a major role in evolution of treatments and technology, and a recent report by Hayes et al in the cost-effectiveness analysis of EVAR vs OSR of r-AAA, based on worldwide experience, indicates significant cost reduction and improvements in quality-adjusted life-years in patients who undergo EVAR.

Our study has some inherent weaknesses. It is a nonrandomized study, and the Hd stability status was predetermined on the basis of sustained SBP of <80 mm Hg for >10 minutes before r-EVAR. Although we have defined preoperative Hd instability, the transient times from patient presenting to outside institutions vs our medical center where r-EVAR was performed are lacking, and there is a selection bias in the survivors of r-AAA who did undergo EVAR. We were not able to analyze anatomic inclusion and exclusion criteria for particular stent grafts to better understand the implications of favorable vs unfavorable aortoiliac morphology during emergent r-EVAR. Lastly, we could not account for the surgeon’s selection bias in treating the Hd-stable as well as Hd-unstable patient via EVAR; surely, many Hd-unstable patients during the course of this study with favorable and unfavorable aortoiliac morphology for EVAR underwent OSR who were not included in this analysis.

CONCLUSIONS

The findings of this study suggest that r-EVAR is feasible and relatively safe, regardless of the patient’s Hd status before repair. However, Hd-stable patients do have a significant early survival advantage. Our findings also suggest that the patient’s Hd status does not affect nonfatal complications and secondary interventions after EVAR. An evaluation of the outcomes of Hd-unstable r-AAA patients who undergo r-EVAR vs OSR was beyond the scope of this analysis; historically, it is well reported that emergent OSR in all-comers is associated with mortality rates of 40% to 70%. Even the most contemporary data would suggest that the lowest r-OSR mortality rates are ~35%. It would be reasonable to speculate that Hd-unstable patients who undergo emergent OSR would tend to have a higher mortality, substantially higher than the 33% mortality of r-EVAR. Therefore r-EVAR could be considered the first-line therapy in all r-AAA patients, regardless of their Hd status. Although future randomized studies will further enhance our understanding of how patients’ Hd status might impact outcomes, this nonrandomized study is the first r-EVAR analysis based on patient Hd status, and the outcomes identify several important variables that negatively affect survival after r-EVAR in Hd-unstable patients. The need for AOB and development of ACS are factors that negatively affect survival in an Hd-unstable patient. We hope that improvements in AAA awareness, diagnosis, and treatments will continue to evolve and improve our abilities to diagnose rupture early, and implement strategies to diagnose and prevent ACS.

AUTHOR CONTRIBUTIONS

Conception and design: MM, JB
Analysis and interpretation: MM, PP
Data collection: MM, RD
Writing the article: MM, PP
Critical revision of the article: MM, AL
Final approval of the article: MM
Statistical analysis: MM, JT
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Overall responsibility: MM, AL

REFERENCES


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