Abdominal Aortic Aneurysm

Stent Graft vs Clinical Pathway for Direct Retroperitoneal Repair

David A. Rigberg, MD; Amir Dorafshar, MD; Abiram Sridhar, MS; William Quinones-Baldrich, MD; Wesley S. Moore, MD, FACS

Background: Endovascular repair (EVAR), while not reducing mortality, has the advantages of reduced morbidity, shorter hospitalization, and quicker recovery when compared with open repair. These advantages must be balanced against increased cost, the risk of early- and late-onset endoleak, and the occasional need for secondary intervention or conversion to open repair. While continuing to offer EVAR, we have also developed a clinical pathway for open repair, which includes a retroperitoneal (RP) approach, nonroutine intensive care unit stay, no nasogastric tube, oral feedings beginning on the first postoperative day, and a hospital discharge between 3 and 5 days postoperatively.

Hypothesis: Direct repair using the RP approach and a clinical pathway is competitive with EVAR.


Results: Eighty-nine RP and 61 EVAR abdominal aortic aneurysm repairs were performed. There were no deaths in either group.

Conclusion: Results suggest that a clinical pathway including an RP approach resulted in a safe, effective, and rapid hospital discharge in most patients. While EVAR continues to yield a shorter hospital stay and fewer complications when compared with open repair, these benefits may be offset by the need for costly continual computed tomographic scan surveillance, the occasional need for late intervention or conversion to open repair, and the small but finite risk of late rupture.

Arch Surg. 2004;139:941-946

Endovascular repair (EVAR) of infrarenal (IR) abdominal aortic aneurysms (AAAs) has become an alternative method of aneurysm repair in both tertiary medical centers and in many community hospitals. It was clear from some of the earliest reports that EVAR was associated with decreased hospital stay and morbidity when compared with open surgical procedures. These results have been confirmed in prospective trials. There has been a progressive increase in the number of EVAR procedures following Food and Drug Administration approval of several devices. The less-invasive approach is particularly attractive to patients and referring physicians. However, in spite of a reduced hospital stay, conservation of costly resources, and reduced morbidity, EVAR has proven to be more costly than open repair.

Furthermore, not all patients with IR AAAs are candidates for EVAR. There are a number of technical and anatomical limitations to the use of EVAR, depending on which device is used. These include limitations on aneurysm neck length and diameter, tortuosity of the iliac arteries, angulation of the aorta, and caliber of the femoral and iliac arteries. There are also patient factors that may make open repair a more appropriate treatment. The retroperitoneal (RP) approach to the aorta was first described by Rob more than 40 years ago. It has been applied to IR AAA, and an increasing number of surgeons prefer this approach to the classic transperitoneal (TP) technique. We have used the RP approach exclusively for standard IR AAAs since publishing our center's last series of patients with AAA. A clear advantage to the RP approach was demonstrated in that report, although this view is not universally accepted.

Since publishing our early experience with the RP approach, we have instituted a de facto clinical pathway for our patients with IR AAA. This includes absence of nasogastric decompression, early resumption of feeding, early removal of the Foley...
The purpose of this study was to evaluate, retrospectively, how the adoption of a clinical pathway has affected morbidity and hospital course following RP AAA repair. In addition, we wished to examine whether the prior pronounced differences in the postoperative course of the patient with AAA undergoing EVAR vs RP repair were modified or reduced by this pathway approach.

METHODS

All patients who underwent repair of IR AAA at the University of California Los Angeles (UCLA) Medical Center in Los Angeles between January 2001 and December 2002 were included in this retrospective medical record review. Excluded were any patients requiring additional interventions at the time of the aneurysm repair. These included visceral (renal, mesenteric) bypasses, peripheral bypasses, or juxtarenal aneurysm repair that required suprarenal aortic clamping. Also excluded were patients with ruptured aneurysms or with aneurysm etiology other than atherosclerosis.

The medical records of these patients were retrospectively reviewed and risk factors noted (age, coronary artery disease, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, cigarette use). Operative factors, including total estimated blood loss and intraoperative complications requiring a change in plan, were also sought, including the need for conversion from an EVAR to an open approach.

The postoperative course was also obtained from the medical record, with particular notation of complications, including pneumonia, bleeding, myocardial infarction, renal failure, respiratory failure, and wound morbidity. Perioperative mortality, defined as death occurring within 30 days of the operation, was also sought. Hospital length of stay and intensive care unit (ICU) use and length of stay were also noted.

Surgical technique in the RP group of patients was performed in a standard fashion. Exposure was assisted by positioning the patients in a partial left lateral position on a beanbag device with the hips flat. The operating table was then “broken” so that the RP space was expanded. A curvilinear incision was made starting at the tip of the 11th rib and continuing obliquely to the lateral edge of the rectus sheath, at a point midway between the pubis and the umbilicus. Care was taken to limit the incision’s longitudinal travel to minimize the risk of denervating multiple dermatomes. We believe this technique can prevent the troublesome wound “weakness” or bulge sometimes associated with these incisions. Bifurcated grafts were used in the presence of aneurysmal disease of the iliac arteries. Otherwise, Dacron tube grafts were placed.

Endovascular repair procedures were performed using either the Guidant Ancure System (Guidant, Indianapolis, Ind) or Medtronic AneuRx (Medtronic, Minneapolis, Minn) grafts. All were done via bilateral common femoral arterial access without the use of arterial conduits. The technique for insertion of these grafts has been well-described elsewhere.

This study was conducted with the full approval of the University of California institutional review board.

RESULTS

One hundred fifty patients, as defined earlier, underwent repair of IR AAs at UCLA Medical Center between January 2001 and December 2002. The RP approach was used in 89 and EVAR in 61. No midline TP approaches were used in this period for IR AAA repairs. Table 1 compares the demographic data between the 2 groups. There were no statistically distinct differences between the groups for any of the studied preoperative variables. For the patients in the RP group, the de facto pathway was determined to have consisted of the following: no routine use of ICU or nasogastric decompression, resumption of oral intake on postoperative day 1, removal of the Foley catheter on postoperative day 2, and selective use of monitored or ICU beds. Analgesia was provided by patient-controlled analgesia or epidural catheter with early transition to oral analgesics. Twenty-eight percent of the patients who underwent the RP approach spent some time in an ICU. There were no 30-day postoperative or in-hospital deaths in either the RP or EVAR groups. Length of hospital stay for the patients who underwent RP repair was a median of 5 days vs 1 day in the EVAR group. The mean±SD length of hospital stay in the RP group was 6.70±4.56 days vs 2.50±2.71 days in the EVAR group. The mean±SD length of hospital stay in the EVAR group was 5 days vs 1 day in the EVAR group. We noted that 10 (11.2%) of the patients who underwent RP repair were discharged from the hospital on postoperative day 3 and that by postoperative day 1, removal of the Foley catheter on postoperative day 2, and selective use of monitored or ICU beds. Analgesia was provided by patient-controlled analgesia or epidural catheter with early transition to oral analgesics.

Table 1. Preoperative Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Retropertoneal Approach</th>
<th>Endovascular Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>18 (20.2)</td>
<td>8 (13.1)</td>
</tr>
<tr>
<td>Age, y, mean</td>
<td>73.8</td>
<td>74.9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>58 (65.2)</td>
<td>34 (55.7)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>13 (14.6)</td>
<td>7 (11.5)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>37 (41.6)</td>
<td>28 (45.9)</td>
</tr>
<tr>
<td>COPD</td>
<td>8 (8.9)</td>
<td>5 (8.2)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>6 (6.7)</td>
<td>2 (3.3)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>24 (26.9)</td>
<td>13 (21.3)</td>
</tr>
<tr>
<td>Smoking history</td>
<td>29 (32.6)</td>
<td>21 (34.4)</td>
</tr>
</tbody>
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Abbreviation: COPD, chronic obstructive pulmonary disease.

Table 2. Postoperative Discharge Data

<table>
<thead>
<tr>
<th>Postoperative Discharge Day</th>
<th>Retropertoneal Approach</th>
<th>Endovascular Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>30 (49.2)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>16 (26.2)</td>
</tr>
<tr>
<td>3</td>
<td>10 (11.2)</td>
<td>3 (4.9)</td>
</tr>
<tr>
<td>4</td>
<td>15 (16.9)</td>
<td>4 (6.6)</td>
</tr>
<tr>
<td>5</td>
<td>23 (25.8)</td>
<td>2 (3.3)</td>
</tr>
<tr>
<td>6</td>
<td>19 (21.3)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>7</td>
<td>6 (6.7)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>8-13</td>
<td>9 (10.1)</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>&gt;13</td>
<td>7 (7.9)</td>
<td>3 (4.9)</td>
</tr>
</tbody>
</table>

*Values are expressed as number (percentage) of patients.
dures, both secondary to tortuous iliac arteries. There were no deaths in patients requiring conversion.

Of the patients who underwent RP repair, 25 (28.1%) required a postoperative ICU course vs 6 (9.8%) in the EVAR group. Of the patients needing ICU care, the average length of hospital stay was 3 days for the patients who underwent RP repair and 4 days for the patients who underwent EVAR.

Complication rates were also calculated as to their effect on hospital length of stay. For patients undergoing RP repair, 7 (7.9%) had a complication requiring a hospitalization greater than 14 days compared with 1 patient (2.2%) in the EVAR group. The most common complication in both groups was respiratory compromise requiring an increase in the level of care.

**COMMENT**

Endovascular repair has clearly been established as a preferred means of IR AAA repair in many patients. Although long-term data are lacking, intermediate data attest to the durability of these grafts and the assumption can probably be made that this approach will be applied to even more patients in the future. Nonetheless, there continue to be a number of reasons for selecting open AAA repair. These include anatomical considerations such as inadequate proximal aortic neck length, increased aortic neck diameter, excessive aortic neck calcification or thrombus formation, excessive aortic tortuosity, and inadequate femoral and/or iliac artery dimensions for access. In addition, for younger patients with AAA and long life expectancies, some believe that open repair is preferred because of the extensive long-term experience and results with this approach. This must be weighed against the possible adverse effect on sexual function using open approaches as opposed to EVAR. Thus, elective open repair will continue to be an important part of the vascular surgeon’s armamentarium.

The decreased perioperative morbidity and hospital stay associated with EVAR are often cited as major benefits to this approach. In an early UCLA experience with EVAR, we reported a mean hospital stay of 8.1 days with EVAR, we reported a mean hospital stay of 8.1 days with EVAR. Of the patients needing ICU care, the average length of hospital stay was 3 days for the patients who underwent RP repair and 4 days for the patients who underwent EVAR.

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Finally, several studies have suggested that there is actually a cost benefit to open vs EVAR procedures. Data from our own institution support this contention. Quinones-Baldrich et al\textsuperscript{5} reported similar costs between RP and EVAR approaches in the perioperative period. Clearly, the follow-up and surveillance required for EVAR cases subsequently pushes these costs higher. The authors’ conclusion in this 1999 report was that EVAR approaches were unlikely to lead to cost savings. More recently, Angle et al\textsuperscript{1} examined hospital costs for RP vs EVAR approaches, also at our hospital.

Using actual variable direct-cost analyses, the authors showed the in-hospital cost of EVAR was 1.74 times that of RP approaches. Calculations of hospital profit margins showed that for EVAR the average was 49.5\% vs 88.6\% for the RP cases. Dryjski et al\textsuperscript{16} published data supporting these findings, with total costs for EVAR cases of $17536 vs $9042 for open AAA repair.

There are several criticisms of the RP approach, but most of these are not entirely valid or not relevant for the repair of an IR AAA. Often cited is the inability to inspect the abdominal viscera for the presence of bowel ischemia after taking the inferior mesenteric artery. It is easy to inspect the viscera by making a small hole in the peritoneum if the surgeon is concerned. This can be repaired simply with a single stitch after the brief surgical exploration is completed. Again, there were no cases of bowel ischemia or undiscovered intra-abdominal injuries in our series. Another concern with the RP approach is access to the right iliac artery. Both the common iliac and its bifurcation can be adequately exposed with correct retractor placement and dissection. We have found the use of the Omni-Tract (St Paul, Minn) self-retaining retractor system particularly helpful.

It is our conclusion from this experience, as well as current data from a literature review, that the RP approach is clearly superior to the TP approach for the treatment of IR AAA. But how does it compare with EVAR? In terms of the short-term data presented here, as well as in other series, EVAR has a shorter hospital stay, less ICU use, less intraoperative blood loss, and fewer overall complications. However, our series does show that these advantages are not as compelling as they were even 6 years ago. This is an important consideration for patients who are not candidates for EVAR or when contemplating IR AAA repair in a younger patient. An additional factor to consider when interpreting these data is that most of our patients with AAA and favorable anatomy received endografts; thus, there was a selection bias for more complex repairs in the open group. This factor can probably be generalized to all contemporary series of patients undergoing open AAA repair. Conversely, some patients who would not be considered for open repair because of prohibitive medical risks no doubt are undergoing EVAR procedures. An ongoing study should be able to address these concerns. The OVER trial (open vs endograft) is currently underway in the Veterans Administration hospital system. This is a randomized prospective trial designed to compare EVAR with open AAA repair, and it has recently started to accrue patients. Both RP and TP open approaches are being used, so this trial may provide compelling data comparing these 2 techniques as well.

In conclusion, our data support the use of the RP approach along with a postoperative pathway for IR AAA repair when the open technique is used. This series includes 89 such repairs, and they compare well with the EVAR approach. For the patient who is not a candidate for EVAR or the younger patient in whom a surveillance program and the concerns regarding endoleak are issues, these data provide compelling evidence for the safety and minimal morbidity of RP repair of AAA.

Accepted for publication May 20, 2004.

This paper was presented at the 75th Annual Meeting of the Pacific Coast Surgical Association; February 15, 2004; Maui, Hawaii; and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

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REFERENCES


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DISCUSSION

Samuel Eric Wilson, MD, Orange, Calif: In recent years the membership of the Pacific Coast Surgical Association has been privileged to learn firsthand the clinical results of one of the most important new techniques in vascular surgery—endovascular repair of the aortic aneurysm via bilateral femoral artery incisions. Rigberg et al set out to compare the perioperative course of endovascular repair vs that of open retroperitoneal repair. The results are clear-cut and conform to previous studies; with endovascular repair, the hospital stay is shorter, fewer patients enter the ICU [intensive care unit], blood loss is less, and complications are half those of open repair. Overall, 30-day mortality is similar.

But it is unlikely that in this retrospective series the 2 sets of patients are directly comparable, either in anatomical considerations or general risk factors. The open surgery group would be presumably those unable, because of anatomic reasons such as a short infrarenal aneurysm neck, to undergo endovascular repair. On the other hand, patients undergoing endovascular repair may have serious adverse risk factors such as chronic respiratory disease or myocardial ischemia, which pushes the clinician towards an intervention which is minimally invasive.

Nevertheless, it would appear that there is no disagreement among the surgical community with regard to Drs Rigberg, Moore, and colleagues' results. Indeed, the problems with endograft are almost entirely related to type I and type II endoleaks, which occur in up to 20% of patients, require periodic surveillance, and in a significant number, perhaps 10%, secondary intervention.

In the manuscript, the authors comment on the role of a randomized prospective trial of open repair vs endovascular repair. I would respectfully suggest this is not what is needed. First, you have shown us there is no clinical equipoise with regard to any of the major outcomes with each of these techniques. Further, the technology for endovascular repair is not settled. Devices recently thought state of the art are no longer available, and new devices will be designed to render our current methods obsolete. Rather, the clinical research in endovascular repair is still at an early phase in which outcome results continue to be collected with improved devices and delivery systems.

Could Dr Rigberg and colleagues specify exactly what benefits could be obtained from a randomized prospective clinical trial of open vs endovascular repair at this time? After all, you have told us there are no differences in procedural mortality, the types of complications between the 2 methods are quite different, and the major problem with endovascular repair is leak, which is not a problem at all with open repair. Lastly, late mortality of patients is far more likely to be related to other consequences of cardiovascular disease or malignancy since even the small aneurysm trials fail to show a longevity benefit in the comparison of selective operation with no operation.

Much of the paper extols the virtues of retroperitoneal repair with the enthusiasm of the recent conversion of the UCLA group to this technique. Did any of the authors' patients complain of lateral flank bulging, sometimes mistakenly called herniation, or neuralgia postoperative follow-up, especially those with larger aneurysms and longer incisions. How did you avoid this common problem? With regard to endovascular repair, what was the incidence of groin wound complications such as seroma, delayed healing, or infection? Almost one third of your patients had an elevated creatinine who had endovascular repair. Were there any episodes of acute renal failure?

Finally, 60% of aneurysms at UCLA were done as open procedures during this time period. Would the authors predict that this number will decrease in the future, or will the old-fashioned vascular surgeon still be needed?

Cornelius Olcott, MD, Stanford, Calif: I am concerned that we are looking only at a snapshot in time. We are treating patients for a longer duration, and I would like Dr Moore to comment, either now or in a future paper, as to how these groups do over 5 to 10 years. We don't know yet how durable EVAR [endovascular repair] is going to be. We do know that there is a very high percentage of reintervention. If memory serves me correctly, the data out of LA and out of other hospitals have shown that it is the more expensive of the 2 procedures, especially when one looks at the long term. A significant number of people who have endovascular repairs come back for some other intervention. When you talk to patients who have endovascular repair, one of their concerns after a couple of years is the amount it costs them out-of-pocket to keep coming back and having imaging studies performed. These are not small amounts of money. I believe we need to look at patients individually and make decisions as to what the best therapy is. I don't think anybody would argue that the 80-year-old on home oxygen probably is not a candidate for open repair. Whether or not he or she is a candidate for any kind of repair could be argued, I think. The 60-year-old who is very active in his work probably does better with a onetime operation so that everything is fixed once and for all.

Fred A. Weaver, MD, Los Angeles, Calif: How long do you spend with your informed consent? It is a 17-page informed consent for gastric bypass. It takes me an hour for consent of patients regarding the options between endovascular repair and open repair. The data about the durability and long-term interventions is critical. How do you handle these important issues in your informed consent?

Jeffrey L. Ballard, MD, Loma Linda, Calif: I agree that the retrospective approach is best for open AAA [abdominal aortic aneurysm] repair. Have you looked at your perioperative fluid management? The reason I ask this is because I have learned over the years that the less amount of fluid given to the patient, not only during the operation but after the operation, results in a very early hospital discharge. My patients are given Mannitol and Lasix in the operating room and their postoperative fluid orders actually say TKO [to keep open]. About 60% of our open AAA patients are leaving on postoperative day 2, and the average stay for our open AAA cases at Loma Linda is 3 days. Fluid management is key to early discharge.

Fred A. Weaver, MD, Los Angeles, Calif: I have a couple of questions about the details of your postoperative management of patients undergoing a retroperitoneal AAA repair. First, what is your preferred method of pain control? We have recently begun to use the ON-Q devices for pain instead of epidural catheters and have found that they are helpful in minimizing pain.

Could you tell us a little bit about your early feeding; exactly how do you begin a diet and how rapidly do you progress? How many of the patients needed NG [nasogastric] tubes ul-
Dr Moore: I would like to thank the discussants for their very insightful comments. Dr Wilson, thank you very much for your very clear-cut analysis of the presentation and also your generous comments.

You raised the issue about comparability and clearly this is a retrospective analysis. As such, there is likely to be a pre-selection bias. Obviously patients who, for anatomic reasons, would not be candidates for EVAR are obligatorily going to be treated with an open approach. We did not analyze the number of patients who were candidates for EVAR but elected retroperitoneal repair. The type of repair is often selected by patient expectation. Patients are usually referred to us because of our experience with EVAR. It is only after a discussion of the pros and cons of both procedures that a few candidates for EVAR will choose open repair.

With regard to the question of a randomized trial, I need to clarify that we are not advocating a randomized trial. In the manuscript, we acknowledged that a randomized trial is ongoing in the VA system. I would applaud the VA for doing so. It is probably the only hospital system in the country, perhaps in the world, that could take on that kind of a prospective study.

The issue concerning wound complications with the retroperitoneal approach is very important. The incisional bulge has been mentioned. We see bulges on rare occasion in our own series. Intercostal neuralgia is also rare. We think that the way to avoid the bulge is to avoid excessive vertical travel when making the incision. Keep the incision parallel to the intercostal bundle, and don't cross more than 1 dermatome. Be careful when you close the incision. If you can see the intercostal nerve, don't encompass it with a suture. Adhering to these measures will reduce the incidence of muscle denervation.

Minor inguinal wound complications in EVAR were very common. For a long time, I made the classical vertical incision to expose the femoral arteries. About a year ago, I switched to transverse incisions. This change has made a large difference in terms of the minor wound complications that we have seen in EVAR.

Are we ultimately going to push ourselves out of business with regard to open aneurysm repair, either transperitoneal or retroperitoneal? I don't think that we will. Even as driven as we are by patients and referring physicians to do EVAR whenever we can, I am not seeing more than 50% of the patients in my practice that are candidates for EVAR. You can try to push the envelope but every time I push the envelope, the envelope breaks. So I don't think that is a good idea. You ought to stick to good anatomic criteria, and if you do that, even if you offered it to everyone who is anatomically feasible, I don't think you are going to exceed 50% of the aneurysm population.

Dr Olcott brought up some extremely important points. All of us report on 30-day results, and yet we know very well with respect to EVAR, it's not the perioperative results that are a problem. The late complications of endoleak, migration, and endotension are the problems. In order to identify those complications to prevent an occasional late aneurysm rupture, you need to carry out a surveillance program. The surveillance program in our hands means obtaining a CT [computed tomographic] scan in 6 months. If there is no endoleak, the CT scan can be obtained yearly thereafter. We began this study thinking that we had blurred the differences between retroperitoneal open repair and EVAR sufficiently that I could now make the argument that there was no benefit of EVAR over open repair. We haven't shown that. We have shown that EVAR still carries a lower perioperative morbidity than open repair. Our indications for EVAR would be the patient with multiple comorbid factors but with an expected survival that can be improved by removing aneurysm rupture risk. In my opinion, good-risk patients should be treated with open repair.

Dr Ballard raised an interesting point about fluid management. We probably don't do a very good job regulating the fluid orders on our patients, and that may have an impact on early discharge.

Dr Weaver, I believe pain control in the retroperitoneal patient is best managed with an epidural catheter. Those patients are usually quite comfortable. As far as early feeding, obviously we are not giving them unrestricted feeding on postoperative day 1. We start sips of clear liquids on the first postoperative day. If that is tolerated, then they go to unrestricted liquids on the second day and usually to a regular diet by the third day. None of our patients have required nasogastric intubation. What about coexistent iliac artery disease and aneurysms? The retroperitoneal incision and a good self retaining retractor system have allowed us to deal with these problems. We have repaired right iliac aneurysms, right hypogastric artery aneurysms, and extend grafts to the right external iliac artery. ICU utilization is as indicated. Obviously, if somebody is unstable from a cardiodynamic standpoint, they will go to an ICU. Otherwise, patients will go to a regular room right after operation if everything is stable following the procedure or, at most, to a stepdown unit that has monitoring capability but is not an ICU.