Volume-Outcome Relationships and Abdominal Aortic Aneurysm Repair

Bruce E. Landon, MD, MBA, MSc; A. James O’Malley, PhD; Kristina Giles, MD; Philip Cotterill, PhD; Marc L. Schermerhorn, MD

Background—There is a well-established literature relating procedure volume to outcomes, but incorporating such information into clinical decision making is problematic when there is >1 treatment option for a condition.

Methods and Results—We used data from the Medicare program to investigate the relationship between institutional volume for open and endovascular abdominal aortic aneurysm (AAA) repair and outcomes, examine trends in volume, and explore the implications for physicians making referrals for AAA repair. Trends in institutional volume were measured for the time period 2001–2006, whereas outcomes were assessed with the use of a previously assembled propensity score–matched cohort covering the time period 2001–2004. Between 2001 and 2006, there were a total of 230,736 repairs of either an intact or ruptured AAA for traditional Medicare beneficiaries. During this time, the proportion of endovascular cases increased from ~22% in 2001 to >50% of AAA repairs in 2006, but there was little shift in procedure volume to high-volume institutions. For endovascular repair, adjusted mortality by quintile showed a marked decrease between the first and second quintile, with continued smaller decreases over quintiles 3 to 5. For open repair, adjusted mortality showed a steady decrease across the quintiles of volume.

Conclusions—We found a steady increase in survival with increasing volume of open repair but relatively little improvement after reaching a relatively low threshold for endovascular repair. Because hospital experience with one repair method does not translate into improved outcomes for the alternative method, referring clinicians must consider both treatment options when making referral decisions. (Circulation. 2010;122:1290-1297.)

Key Words: aneurysm ■ peripheral vascular disease ■ surgery ■ survival

There is a well-established literature relating the volume of particular procedures to outcomes of care.1,2 It is generally agreed that higher-volume operators and institutions generally achieve better outcomes. This issue is especially pertinent for the treatment of abdominal aortic aneurysm (AAA). Ruptured AAA is the 10th leading cause of death in men aged >55 years in the United States, with mortality of ruptured AAA >80%.3 Elective AAA repair is typically performed with mortality of ≤5% and is recommended for aneurysms of sufficient size such that there is a high likelihood of rupture within the next 5 years.4,5

Clinical Perspective on p 1297

There are now 2 methods for performing elective AAA repair: traditional open repair (open) and endovascular aneurysm repair, complicating decision making by referring physicians. When a clinician makes a decision to refer a patient for elective AAA repair, the patient may ultimately be treated by either method. Generally, the choice of approach is decided by the surgeon after referral and is influenced by factors including institutional and operator experience, comfort with the competing approaches, and patient preferences. Furthermore, in some cases, anatomic considerations might require a specific approach. Consequently, because the approach is not known at the time of referral, it is not clear whether the referring clinician should consider overall volume or specific volumes of open and endovascular repair when making a referral because some institutions or surgeons might have less experience and therefore worse outcomes with one or the other approaches. To the extent that surgeons favor one approach over the other, their outcomes for the other approach might not be as good. In addition, institutions with modest volume in each method might be regarded as having “high” volume when both methods are counted, which could also be misleading if the outcomes across procedures are not related.

Currently, there are no data examining the volume-outcome relationship in AAA repair that take into consideration these competing methods of repair. In this study, we used comprehensive data from the Medicare program over...
the years 2001–2006 to investigate the relationship between institutional volume and outcomes of AAA repair. In so doing, we used alternative approaches that incorporate different measures of volume and also examined how hospital volumes for each of these approaches have evolved since the widespread introduction of endovascular repair in 2001.

Methods

Overview

We used comprehensive data from the Medicare program to identify all cases of AAA repair that occurred during the time period 2001–2006. Cases included open and endovascular repair as well as intact and ruptured aneurysms. We used these data to calculate institutional level volume for each type of repair for each year. To measure surgical mortality according to hospital volume, we examined cases of elective AAA repair confined to the abdominal aorta to compare similar patients across institutions.6 The latter analyses were conducted with a previously assembled propensity score–matched cohort spanning the time period 2001–2004. Prior analyses of these data did not show a significant time trend. On the basis of volume classifications that resulted from these findings, we then examined trends in hospital volume over time as well as the implications for volume-based referrals.

Hospital Volume

We identified all Medicare beneficiaries who underwent repair of an intact or ruptured AAA during the time period 2001–2006. Each case was assigned to a hospital on the basis of the provider of service codes contained in the administrative data. We then computed annual open, endovascular, and total AAA repair volumes for each hospital.7 The annual volumes we calculated for each hospital included repairs of both intact AAs and ruptured AAs because each type contributes to the volume and experience of the institution. To simplify the presentation of results, hospital volumes were divided into quintiles with the use of cut points that most closely separated the patients into groups of equal size. The quintiles were set with the use of average annual volume across all the years, which would allow for a shift over time. We computed volume cut points on the basis of total AAA repairs, including open and endovascular repair, open repair alone, and endovascular repair alone, and assigned each hospital to a volume quintile for each year of the study on the basis of the actual number of repairs of that type performed at that hospital during that calendar year.

To simplify our presentation of trends in hospital volume over time, we classified hospitals on the basis of our analyses as having no endovascular procedures, 1 to 9 procedures per year (low volume, quintile 1), or ≥ 10 cases per year (high volume, quintiles 2 to 5). For open repair procedures, in which the relationship was more linear, we classified hospitals as having no open repair cases, a low volume of open repair cases (quintile 1), a medium volume (quintiles 2 to 4), or a high volume (quintile 5).

Outcomes Assessment

To assess the relationship between outcomes and volume, we measured outcomes by focusing on the repair of intact AAs among patients who were considered medically similar and could therefore have undergone either procedure and for whom we had at least 2 years of prior Medicare experience that could be used to control for various comorbidities that might influence the outcomes of AAA repair. We thus applied several restrictions to the population used to measure volume to create a homogeneous sample and thus minimize the influence of confounding by case mix across institutions and procedure types. For this purpose, we used a subset of Medicare cases from 2001 to 2004 that had been assembled via propensity score matching.6

We identified patients aged ≥ 67 years with a discharge diagnosis of AAA without rupture (International Classification of Diseases, Ninth Revision, Clinical Modification code 441.4) who also had a procedure code for open surgical repair (38.44 [resection of abdominal aorta with replacement] or 39.25 [aorto-iliac-femoral bypass]) or for endovascular repair (39.71 [endovascular implantation of graft]). We excluded all those with diagnosis codes for AAA rupture (441.3), thoracic aneurysm (441.1, 441.2), thoracoabdominal aortic aneurysm (441.6, 441.7), or aortic dissection (441.0*). We also excluded those with procedure codes for repair of the thoracic aorta (38.35, 38.45, 39.73) or visceral/renal bypass (38.46, 39.24, 39.26).

Our primary outcome measure of interest was perioperative mortality, defined as death within the index hospitalization, including contiguous transfers to other acute care facilities, or within 30 days of the date the procedure was performed. Mortality was assessed with the use of the Medicare denominator file.

To improve the coding accuracy of endovascular versus open repair, we identified physician claims corresponding to the time period of the hospitalization. In cases in which the hospital and physician codes were in conflict (< 5.5% of the sample), we assigned patients on the basis of physician claims because we thought it more likely that physicians would accurately identify the procedure they performed. As a sensitivity analysis, we repeated our analyses after excluding these. The study was approved by the institutional review board at Harvard Medical School.

Statistical Analyses

We first examined hospital volumes for each procedure over time. We then compared the admission characteristics of the matched cohorts according to quintiles of hospital volume using χ² tests for categorical variables or t tests for continuous variables. We defined adjusted mortality for each hospital quintile as the average over all patients in the sample of the predicted probability of perioperative death evaluated under the counterfactual assumption that all patients attended a hospital in that quintile. Adjusted mortality rates were estimated by fitting hierarchical models that controlled for clustering at the hospital level and then evaluating predictive probabilities with the use of the estimated model parameters. These models included baseline beneficiary demographic and clinical characteristics obtained from claims during the 2-year period before but not including the index admission. We measured clinical comorbidities using a version of the Elixhauser algorithm that was adapted to also include diagnoses that occurred only in the outpatient setting.8,9

We first estimated models that included a hospital volume aggregate measure of the specific procedure the patient underwent (eg, open versus endovascular). All models were adjusted for baseline clinical and demographic characteristics. We then estimated models that also included a measure of aggregated hospital procedure volume for the alternate procedure (eg, aggregated endovascular volume for models estimating open repair mortality) to look for cross-volume effects. The latter series of models enable testing the hypotheses that substantial experience with one type of procedure carries over to improved performance with the other procedure. If the cross-volume effects are statistically significant, this supports the existence of a carry-over effect between procedure types, implying that the factors affecting procedure quality include a component related to general experience in performing AAA repair. Observed mortality in each quintile was compared with predicted adjusted mortality computed under the counterfactual assumption that all procedures occurred at a hospital in the lowest-volume quintile.

Results

During 2001–2006, there were 230 736 repairs of either an intact or ruptured AAA for Medicare beneficiaries. Total annual volume was highest in 2001 (40 700) but thereafter remained fairly constant over the ensuing years at ~ 37 000 to 38 000 repairs per year. Of these, 45 660 conducted during 2001–2004 were included in the outcomes analyses, including 22 830 propensity score–matched patients who underwent each type of repair.
Demographic and clinical characteristics of patients treated over the time period 2001–2004 eligible for the outcomes analysis did not vary much according to strata of hospital volume, although, when there were differences, patients at higher-volume hospitals tended to have more comorbidities (Table 1). Approximately 25% of both endovascular and open repair patients were aged ≥80 years. Eighty percent of patients were male, and 3% were black. Clinical comorbidities were common, including two thirds with hypertension, 15% with diabetes mellitus, and 20% with coronary artery disease.

### Mortality by Hospital Volume

Predicted and adjusted actual mortality by volume quintile for each procedure in isolation for patients treated during 2001–2004 is presented in Figure 1. Predicted mortality for each quintile was defined as the risk-adjusted expected mortality if the patients had been treated at a low-volume (quintile 1) hospital. For endovascular repair, predicted mortality was essentially constant across the quintiles at 2.5%. Actual mortality by quintile, after adjustment, showed a substantial decrease between the first and second quintile (2.5% versus 1.6%), with continued smaller decreases over quintiles 3 to 5.

For open repair, predicted mortality was again roughly similar across the quintiles at slightly >7%. Actual mortality, however, showed a monotonic decrease across the quintiles, with an absolute difference of >3 percentage points between the highest- and lowest-volume hospitals.

We also performed 2 analyses examining cross-volume effects. In contrast to the same procedure effects, there were no cross-volume effects (data not shown). Thus, endovascular volume did not predict outcome of open repair after adjustment for open repair volume and vice versa.

Finally, we performed a sensitivity analysis after eliminating cases in which there was a coding conflict between the hospital and physician coding. There was no effect on the observed relationship for open procedures. For endovascular repair, however, the volume-outcome relationship was slightly attenuated, suggesting that some cases with coding conflicts began as endovascular aneurysm repair cases but required conversion to open repair and therefore had higher associated mortality. We therefore elected to keep these cases in our main analyses.

### Hospital Volumes Over Time

Table 2 shows hospital volumes for each procedure arrayed by quintiles of open repair volume, endovascular volume, and
total AAA volume for 2001 and 2006. The overall data do not suggest a regionalization of AAA repair over the study years. The number of procedures by quintile when total volume of AAA repairs is measured remains fairly constant between the 2 years. Although the proportion of endovascular repairs performed at high-volume hospitals was almost identical between 2001 and 2006 (∼20%), the proportion of endovascular repairs performed at low-volume hospitals declined from 23.2% to 15.8%, with increases spread across the middle 3 quintiles. In contrast, the proportion of open repairs performed at high-volume open repair hospitals fell over this time period from 27% to 21%.

Between 2001 and 2006, the proportion of endovascular cases increased across the board, growing from ∼22% in 2001 to >50% of total AAA repairs in 2006. In 2001, there were 25 high-volume endovascular hospitals, which performed a total of 1879 repairs, whereas in 2006 there were 56 high-volume endovascular hospitals, which performed 4086 repairs. There was also an absolute increase in the number of hospitals performing endovascular repair across each of the volume quintiles.

In contrast, the trends for open repair were in the reverse direction. In 2001, 110 high-volume open repair hospitals performed 8587 open repairs out of a total of 11 377 repairs performed at these hospitals (ie, ∼25% of the repairs at these hospitals were endovascular). In 2006, only 31 hospitals were considered high volume for open repairs, and 43% of their AAA repairs were endovascular. As opposed to endovascular repair, the number of hospitals performing open repair decreased across the quintiles, as did the total volume of open repairs (in all except the third quintile). Almost 400 hospitals stopped performing open repair over the time period, and many of these were likely low-volume hospitals. When volume of total AAA repairs was measured, the number of low-volume hospitals declined from 2001 to 2006, and the numbers in the other quintiles were relatively stable.

**Hospital Volume and Referrals**

Although endovascular and open procedure volumes are generally correlated within hospitals ($r=0.49$), Figures 2 and 3 show that being classified as high volume for either
endovascular or open repair does not necessarily mean that a hospital will be classified as high volume for the other method. In fact, there are discordant pairs in both directions. In 2006, most high-volume endovascular hospitals were classified as either low or medium volume for open procedures, although almost all high-volume open repair hospitals were also classified as high volume for endovascular repair. In addition, a substantial minority of medium-volume open repair hospitals were classified as low volume for endovascular repair.

**Discussion**

In this study, we used comprehensive data from the Medicare program to investigate the relationship between institutional volume and outcomes of AAA repair. We found several notable results. First, since 2001, the total number of AAA repairs has stayed roughly constant, although there has been a substantial migration to the endovascular approach. Second, although highly correlated, hospital volume with one approach did not necessarily equate with hospital volume with the alternative approach. Third, there was a monotonic decrease in mortality when moving from low- to high-volume open repair facilities, but this pattern was not observed for endovascular repair, for which above a relatively low threshold of volume there appears to be relatively little effect of volume on mortality. Therefore, hospitals must be proficient in both approaches if they are going to serve the entire population of AAA repair patients optimally.

**Table 2. Hospital Volumes by Year for Open, Endovascular, and Total Repairs Calculated Including All Repairs**

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>2001</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of hospitals</td>
<td>683</td>
<td>795</td>
</tr>
<tr>
<td>Mean No. of endovascular cases per hospital</td>
<td>37.1</td>
<td>48.9</td>
</tr>
<tr>
<td>Total endovascular cases</td>
<td>2079</td>
<td>2066</td>
</tr>
<tr>
<td>Total AAA repairs</td>
<td>22,041</td>
<td>22,041</td>
</tr>
<tr>
<td>% Endovascular cases</td>
<td>9.4</td>
<td>33.5</td>
</tr>
<tr>
<td>% Of all endovascular cases</td>
<td>23.2</td>
<td>15.8</td>
</tr>
<tr>
<td>Open repair volume per quintile</td>
<td>1–9</td>
<td>1–9</td>
</tr>
<tr>
<td>No. of hospitals</td>
<td>1248</td>
<td>1246</td>
</tr>
<tr>
<td>Mean No. of open repair cases per hospital</td>
<td>3.8</td>
<td>3.7</td>
</tr>
<tr>
<td>Total open repair cases</td>
<td>4797</td>
<td>4585</td>
</tr>
<tr>
<td>Total AAA repairs</td>
<td>5635</td>
<td>4585</td>
</tr>
<tr>
<td>% Endovascular cases</td>
<td>14.9</td>
<td>51.6</td>
</tr>
<tr>
<td>% Of all open repairs</td>
<td>15.1</td>
<td>16.4</td>
</tr>
<tr>
<td>Total volume per quintile</td>
<td>1–14</td>
<td>1–14</td>
</tr>
<tr>
<td>No. of hospitals</td>
<td>1446</td>
<td>1246</td>
</tr>
<tr>
<td>Mean No. of cases per hospital</td>
<td>5.2</td>
<td>3.7</td>
</tr>
<tr>
<td>Total cases</td>
<td>7497</td>
<td>4797</td>
</tr>
<tr>
<td>% Endovascular cases</td>
<td>8.5</td>
<td>51.6</td>
</tr>
<tr>
<td>% Of total repairs</td>
<td>18.4</td>
<td>15.8</td>
</tr>
</tbody>
</table>
Our findings also suggest an optimal approach for referring physicians. Evidence-based referral criteria from the Leapfrog group suggest referring to hospitals with a total volume of ≥50 AAA repairs per year. Our results, however, suggest that focusing on total volume could be misleading. The relationship between volume for open repairs and mortality appears to be relatively constant, with decreasing mortality across all quintiles of volume, and a volume cutoff of 50 open repair cases per year identifies hospitals with the best outcomes for open repair. Conversely, for endovascular repair, there appears to be a significant drop-off in mortality between the first and second quintiles, after which improvements in mortality are small across the remaining quintiles of volume, suggesting that for endovascular repairs, a reasonable volume cutoff would be ≥10 cases annually. Thus, although all hospitals with ≥50 total cases were classified as high volume for endovascular repair, many of these were not in the highest-volume quintile for open repair. A patient referred on the basis of a reasonable cutoff for endovascular volume of ≥10 cases would most likely end up at non–high-volume open repair hospitals if open repair was required, whereas a patient referred to a facility with ≥50 open repairs would virtually be assured of ending up at a high-volume endovascular facility. Accordingly, a decision strategy to make referral decisions based on open procedure volume alone, even in cases in which the patient might receive an endovascular repair, is preferable to a strategy based on endovascular volume alone or on total volume of ≥50 repairs.

In contrast to our hypothesis, our findings do not show a consistent pattern toward regionalization of AAA repair. Although the proportion of endovascular repairs performed at hospitals in the top 2 quintiles of endovascular volume (defined over the entire time period) increased slightly from 39% in 2001 to 45% in 2006, the commensurate percentages for open repair decreased from 48% to 31% over the same time period. There was evidence, however, that some low-volume hospitals (<300) stopped performing open repairs altogether. Otherwise, when we examined total repairs, there was very little change in either the number of hospitals or the case volume of hospitals across the remaining quintiles of hospital volume. Not surprisingly, there was also an across-the-board increase in the...
number of hospitals in each quintile of endovascular repair. Our analyses suggest, however, that once hospitals are performing a relatively small number of repairs (>10), there is relatively little change in mortality. Thus, as opposed to open repair, optimization of perioperative outcomes does not require concentration of endovascular repair in a small number of institutions. Our data suggest the possibility that as endovascular repair increasingly replaces open repair, fewer hospitals will have adequate open repair volume to maintain the experience needed to achieve optimal outcomes.

Volume-outcome relationships have been shown for multiple surgical procedures and suggest a potential role for the regionalization of services.\textsuperscript{1,7} For instance, some have called for the regionalization of coronary artery bypass graft surgery to improve outcomes for coronary revascularization.\textsuperscript{11,12} Opponents to regionalization argue that volume is a poor proxy for quality (ie, many low-volume facilities achieve excellent outcomes, and other high-volume facilities might achieve poor outcomes). Furthermore, regionalization would limit access to a local program in many areas of the country. The case of AAA repair presents several additional challenges to regionalization. First, patients with ruptures require immediate intervention and might not survive transfer to a regional referral center.\textsuperscript{13,14} Thus, maintaining surgical capacity in more hospitals might enhance survival for AAA ruptures. Second, our data suggest that hospitals performing endovascular repair need only a modest number of cases annually (>10) to achieve reasonable outcomes. Thus, high volumes are not necessarily required to achieve good outcomes after endovascular repair.

Our results highlight an issue that has heretofore not been addressed in the medical literature and suggest that referring physicians must consider all potential treatment options when choosing a hospital for procedures. AAA is not the only condition for which >1 approach to repair is available. For instance, as noted above, coronary artery disease might be treated via percutaneous approaches (eg, stenting) or coronary artery bypass graft surgery. Similarly, cholecystectomy might be performed laparoscopically (currently the procedure of choice) or via open repair. Thus, when incorporating volume-outcome relationships into decision making, we suggest that all possible repair approaches should be considered and that referral guidelines should consider all possible alternatives.

Our study is subject to several limitations. First, our outcomes analyses relied on observational data encompassing the time period 2001–2004. We performed careful matching using propensity scores, but there might still be residual confounding from unobserved predictors.\textsuperscript{15} We expect, however, that this would not bias our analyses based on volume. If anything, it appears that high-volume institutions see sicker cases, which would suggest that our bias would be against high-volume institutions. Second, as noted above, volume is an inexact marker of quality. There are examples of low-volume institutions that achieve superior outcomes and vice versa. Thus, when outcome data for individual hospitals become more widely available, such data should drive referral decisions. Finally, our analysis focused on institutions and did not account for operator volume or type of operator. In many cases, however, institutional practices drive referral decisions.\textsuperscript{10}

In conclusion, we studied patterns and outcomes of elective AAA repair since the introduction of endovascular approaches to AAA repair. We found a monotonic increase in survival with increasing volume of open repair but relatively little improvement after a relatively low threshold for endovascular repair was reached. Our results suggest that in the case of AAA repair, hospital experience with one repair method does not translate into improved outcomes for the alternative method. Thus, referring clinicians must consider both treatment options when making referral decisions.

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References
CLINICAL PERSPECTIVE

There is a well-established literature relating procedure volume to outcomes of care, but incorporating such information into clinical decision making is problematic when there is >1 treatment option for a particular condition. In the case of abdominal aortic aneurysm repair, surgeons may choose traditional open or endovascular repair. Because the approach is decided by the surgeon after referral, it is not clear whether the referring physician should consider overall abdominal aortic aneurysm repair volume or specific volumes for open and endovascular repair in their referral decisions. In this study, we used comprehensive data from the Medicare program over the years 2001–2006 to investigate the relationship between institutional volume and outcomes of abdominal aortic aneurysm repair. We found that whereas there is a relatively constant relationship between open repair and perioperative mortality, for endovascular repair there is a significant improvement in mortality from the lowest quintile of volume to the second lowest, but improvements beyond that volume are small. Because virtually all high-volume open repair facilities have at least modest endovascular repair volume, referral decisions should be made on the basis of open repair volume rather than total or endovascular repair volume. Our data also suggest the possibility that as endovascular repair increasingly replaces open repair, fewer hospitals will have adequate open repair volume to maintain the experience needed to achieve optimal outcomes.
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