Volume-outcome relationships in cancer surgery: Evidence and policy implications

John D. Birkmeyer, MD
University of Michigan
Volume is old news

• Lee (*Lancet*, 1957)
  – surgical mortality at non-teaching hospitals twice that at teaching centers

• Luft (*N Engl J Med*, 1979)
  – importance of hospital volume
  – V-O relationships vary by procedure

• Flood (*Med Care*, 1984)
  – procedural volume more important than other hospital characteristics
Prior efforts to use volume as a quality lever

• Regulatory
  – e.g., Volume requirements for state-level certificate of need applications

• Payer-based
  – e.g., Transplant reimbursement by Medicare

• Guidelines from professional societies
  – e.g., ACS trauma center accreditation
So what changed?

• Someone started telling the patients
Mexico's Maverick Reformer Takes Charge

U.S. News & World Report

America's Best Hospitals

Where to find the best care near you in 17 specialties—including Cardiology, Cancer, Pediatrics, and Orthopedics

Best Hospitals

Higher volume, fewer deaths

For a risky operation, head for a hospital that does it regularly

By Avery Comarow

Every year the operation involved in the study is performed by about 1,800 surgeons in 2,000 hospitals across the country. The surgeons and hospitals perform operations that involve a high risk of death or serious complications. The study, conducted by a group of 17 hospitals, found that the risk of death or serious complications is lower at hospitals with higher volumes of operations.

The study also found that hospitals with higher volumes of operations have better outcomes for patients. The study is funded by the federal government and conducted by the Agency for Healthcare Research and Quality.
NEED MAJOR SURGERY?

Bigger is better when it comes to choosing the right hospital for high-risk operations

WHEN IT comes to hospitals, bigger is better. You're far more likely to survive complicated operations at the larger hospitals, according to an eye-opening new study.

As many as 20,000 elderly patients die each year in the U.S. while undergoing high-risk surgery — but thousands of them could be saved.

"We estimate that 1,000 of these deaths could be avoided if the procedures were done at high-volume hospitals," said Dr. John Birkmeyer, who headed the study.

"You're a lot safer having high-risk surgery at hospitals that do a lot of them because the level of skill and care at these facilities is much greater than at hospitals that don't do many of them."

Dr. Birkmeyer, a professor of surgery at the University of Michigan, and his team looked at the death rates over a five-year period for 37,000 people who underwent two high-risk surgical procedures — for cancer of the pancreas and cancer of the esophagus — at what they called "high volume" and "low volume" hospitals in the U.S.

For pancreatic surgery, they considered a high-volume hospital a facility that did 50 or more of the procedures a year. A low-volume one did just one or fewer a year.

For esophageal surgery, a high-volume hospital did 20 or more of the operations a year. A low-volume one did two or fewer.

The difference was astounding.

The death rate for the pancreatic operation was 14 percent at low-volume hospitals, but only 4 percent at the high-volume hospitals.

And the death rate for the esophageal operation was 20 percent at the low-volume hospitals, but only 8 percent at the high-volume hospitals.

Dr. Birkmeyer said the results confirmed an earlier study his team did that looked at the death rates for 474,000 Medicare patients over a five-year period who had surgery at either a high or low volume hospital for 11 different high-risk procedures, such as bypass surgery, or surgery for lung, stomach, bladder and pancreatic cancer.

"The outcome in those procedures was striking," he said.

"For example, the likelihood of dying at the low-volume hospital for lung surgery was 24 percent greater than at the high-volume hospital; and nearly FOUR TIMES greater for pancreatic surgery.

"The reason: there's a higher mortality rate at the low-volume hospital is that the high-volume hospitals are better equipped and the surgeons doing the operations are more skilled," explained the expert. "Obviously, whether it's the 10th or the 100th operation, it's the skill that matters."

Dr. Birkmeyer's advice to patients?

"If you're facing high-risk surgery, pick a hospital where a lot of them are done. Ask your doctor where you should go. Your physician will know the best places."

— PHILIP SMITH

STICK WITH THE PROS

LARGE INSTITUTIONS, such as L.A.'s Cedars-Sinai (below), have a much better track record — and lower mortality rates — when it comes to performing complicated surgeries.
So what changed?

- Someone started telling the patients
- Payers got involved
Overview of lecture

• Evidence that hospital and surgeon volume are strong determinants of surgical outcomes
• Translating evidence into policy
  – Selective referral
    • Current initiatives, strengths and weaknesses
  – Quality improvement
    • Can we learn anything from V-O relationships that would improve care everywhere?
Volume and outcomes

• 50 years of volume-outcome studies
  – hundreds of articles

• Two large structure literature reviews
  – Dudley et al., *JAMA*, 2000
Synthesis of the evidence:
V-O Studies, 1988-98

<table>
<thead>
<tr>
<th>Outcomes at high volume hospitals</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Better (statistically significant)</td>
<td>98 (77%)</td>
</tr>
<tr>
<td>Better (non-significant trend)</td>
<td>25 (20%)</td>
</tr>
<tr>
<td>Worse (non-significant trend)</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Worse (statistically significant)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>128 (100%)</td>
</tr>
</tbody>
</table>

Dudley et al, *JAMA*, 2000
Is the volume effect just confounding by case mix?

• Do LVHs care for “sicker” patients?
  – Less affluent, more likely to be black, but not “clinically” different

• Results of the IOM synthesis
  – 16 “best” studies (clinical data) all showed significant V-O effect
“There can be little doubt that for a wide variety of surgical procedures and conditions higher volume (hospital or physician) is associated with better outcomes.”
Problems with prior studies

• Too small
• Too old
  – mortality risks have fallen considerably
• Not generalizable
  – single states (e.g., NY), atypical populations (e.g., VA)
• Heterogeneous volume “cutpoints”
HOSPITAL VOLUME AND SURGICAL MORTALITY IN THE UNITED STATES

Study Overview

• 2.5 million Medicare patients (1994-9)
• 14 operations (6 cardiovascular, 8 cancer)
• Hospital volume measure (procedures/ year)
  – patient quintiles (20%): very low, low, medium, high, very high
• Mortality (in-hospital or w/in 30 days)
• Adjustments
  – ASR, acuity, comorbidities, prior admissions, socioeconomic status
Cardiac Procedures

Mortality (%)

- CABG
- Aortic VR
- Mitral VR

V Low  Low  Med  High  V High
Vascular Procedures

Mortality (%)

Carotid End LE Bypass Elective AAA

V Low Low Med High V High

Vascular Procedures

Mortality (%)

Carotid End LE Bypass Elective AAA

V Low Low Med High V High
GI Cancer Resections

Mortality (%)

Colon | Stomach | Esophagus | Pancreas
--- | --- | --- | ---
V Low | Low | Med | High | V High

Graph showing mortality rates for Colon, Stomach, Esophagus, and Pancreas with different color codes for V Low, Low, Med, High, and V High.
Absolute Risk of Operative Mortality: Very Low vs. Very High Volume Hospitals

- Carotid endarterectomy: 0.2%
- Carotid endarterectomy: 0.5%
- Carotid endarterectomy: 0.9%
- Carotid endarterectomy: 1.1%
- Carotid endarterectomy: 1.6%
- Carotid endarterectomy: 2.1%
- Carotid endarterectomy: 2.9%
- Carotid endarterectomy: 3.4%
- Carotid endarterectomy: 5.5%
- Carotid endarterectomy: 11.9%
- Carotid endarterectomy: 12.5%
Surgeon Volume—General observations

• Surgeon volume explains large proportion of apparent hospital volume effect with some procedures
• Relative importance of hospital and surgeon volume varies by procedure
  – SV >> HV for cardiovascular surgery
  – SV = HV for cancer surgery
• Surgeon volume matters even at high volume hospitals
Role of surgeon volume at high-volume hospitals

1998-9 Medicare population, from Birkmeyer et al., *NEJM*, 2003
Surgeon volume vs. complications

Odds of complication, low vs. high cumulative surgeon volume

Overview of lecture

• Evidence that hospital and surgeon volume are strong determinants of surgical outcomes

• Translating evidence into policy
  – Selective referral
    • Current initiatives, strengths and weaknesses
  – Quality improvement
    • Can we learn anything from V-O relationships that would improve care everywhere?
AMERICAN BEAUTY
...look closer
“I just want to look good naked”
2 ways to improve surgical outcomes

Direct patients to the best places ("Selective referral")

Improve care by everyone ("Quality improvement")
Mechanisms for steering patients

• Selective contracting
• Financial disincentives for patients to choose non-COEs
  – E.g., higher patient co-pays, “tiered” health plans with variable premiums
• Public reporting and patient education
Launch of the Leapfrog Group

Preventing Costly Errors
Leapfrog's estimates of the benefits to the coalition's planned medical reforms

<table>
<thead>
<tr>
<th>PLAN</th>
<th>BENEFITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals should install computerized</td>
<td>522,000 serious medication errors avoided</td>
</tr>
<tr>
<td>prescription systems</td>
<td></td>
</tr>
<tr>
<td>Hospitals should staff ICU wards with</td>
<td>53,850 lives saved</td>
</tr>
<tr>
<td>intensive-care specialists</td>
<td></td>
</tr>
<tr>
<td>Employees should have certain high-risk</td>
<td>2,581 lives saved</td>
</tr>
<tr>
<td>surgeries done at high-volume hospitals</td>
<td></td>
</tr>
</tbody>
</table>

Source: Leapfrog Group

Business Consortium to Launch Effort
Seeking Higher Standards at Hospitals

BY BARBARA MARTINEZ
Staff Reporter of THE WALL STREET JOURNAL

A group of the nation's largest companies expects to unveil today an ambitious effort to force hospitals to substantially reduce medical errors, a move the companies hope will save lives and money.

The group's 60 corporate members—including General Electric Co., General Motors Corp., Delta Air Lines Inc., AT&T Corp., International Business Machines Corp., Boeing Co. and Xerox Corp.—plan to use their mammoth health-care-buying power to press for stringent new safety

companies' efforts to get employees to “leap forward” in their efforts to make use of high-quality providers, an official for the group said.

“We feel confident in our ability to make a difference by harnessing and leveraging our health-care purchasing power,” Mr. Campbell said. “It's a straightforward business approach to tackling a complex problem.” The Leapfrog Group plans to announce its initiative in Washington today.

The group was formed earlier this year to respond to a disturbing government report that noted that 1.5 million people die each year in the U.S. due to medical errors. The group's goal is to improve patient safety and reduce the number of errors. Throughout the country, patients are affected by the epidemic of medical errors, which is responsible for 50,000 deaths each year. (Source: Leapfrog Group)

November 15, 2000
### Leapfrog standards, 2007

<table>
<thead>
<tr>
<th>Procedure</th>
<th>R-A mortality better than national average in STS or HV &gt; 450/yr and all SV &gt; 100/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>R-A mortality better than national average in STS or HV &gt; 120/yr and all SV &gt; 22/yr</td>
</tr>
<tr>
<td>Aortic valve replacement</td>
<td>R-A mortality better than national average in ACC or HV &gt; 400/yr and all SV &gt; 75/yr</td>
</tr>
<tr>
<td>PCI</td>
<td>HV &gt; 50/yr and all SV &gt; 8/yr</td>
</tr>
<tr>
<td>AAA repair</td>
<td>HV &gt; 13/yr and all SV &gt; 2/yr</td>
</tr>
<tr>
<td>Pancreatic resection</td>
<td>HV &gt; 11/yr and all SV &gt; 2/yr</td>
</tr>
<tr>
<td>Bariatrics</td>
<td>HV &gt; 125/yr and all SV &gt; 20/yr</td>
</tr>
</tbody>
</table>
Volume and Centers of Excellence models

• Ongoing efforts by private payers to establish COEs
  – Interventional cardiology and cardiac surgery
  – Bariatric surgery
  – Breast cancer care
Advantages of volume-based referral

• Traction with patients
• Simple, expedient, and inexpensive
• Efficient and stable quality indicator
  – Process and outcome measures have their own issues
  – Volume predicts outcomes in multiple domains
  – Volume predicts future outcomes
• Practical for many operations (particularly uncommon, high risk operations)
Additional patient travel time if shut down very low volume centers

Pancreatic resection
- Patients %
  - 120+
  - 60-120
  - 30-60
  - 0-30

Esophagectomy
- Patients %
  - 120+
  - 60-120
  - 30-60
  - 0-30

Travel minutes

Birkmeyer et al., *JAMA*, 2003
Disadvantages

• Highly polarizing
  – Divides providers into winners and losers
• Perverse incentives?
• Procedure volume very unreliable in predicting outcomes of individual hospital and surgeons
Hospital volume vs. operative mortality: CABG

National Medicare population, 1994-9, Birkmeyer et al., *NEJM*, 2002
Hospital volume vs. operative mortality: CABG

Average Mortality Rate (5.4%)
Disadvantages

• Highly polarizing
  – Divides providers into winners and losers
• Perverse incentives?
• Procedure volume very unreliable in predicting outcomes of individual hospital and surgeons
• Prospects for major redistributions of patients are slim

P<.001  P<.001  P<.001  P<.001
Trends in Market Concentration for Cardiovascular Procedures, 1997-2003

<table>
<thead>
<tr>
<th>Procedure</th>
<th>1997</th>
<th>1999</th>
<th>2001</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA</td>
<td>40</td>
<td>38</td>
<td>36</td>
<td>35</td>
</tr>
<tr>
<td>CABG</td>
<td>30</td>
<td>28</td>
<td>26</td>
<td>25</td>
</tr>
<tr>
<td>CEA</td>
<td>35</td>
<td>33</td>
<td>32</td>
<td>31</td>
</tr>
<tr>
<td>AVR</td>
<td>30</td>
<td>28</td>
<td>26</td>
<td>25</td>
</tr>
</tbody>
</table>

p=.78  p=.06  P<.001  p<.001
Overview of lecture

• Evidence that hospital and surgeon volume are strong determinants of surgical outcomes

• Translating evidence into policy
  – Selective referral
    • Current initiatives, strengths and weaknesses
  – Quality improvement
    • Can we learn anything from V-O relationships that would improve care everywhere?
Specialty, outcomes and processes of care

- 3644 patients undergoing carotid endarterectomy in NY State (97-99)
- Detailed clinical data
- Outcome: Stroke or death

Hannan et al, *Stroke*, 2001
Specialty type vs outcomes with carotid endarterectomy

Unadjusted p=0.002
4 processes associated with better outcomes

- protamine
- shunt
- eversion endarterectomy
- patch graft

Hannan et al, *Stroke*, 2001
Use of “best processes” by different specialist groups

<table>
<thead>
<tr>
<th>Patients receiving process (%)</th>
<th>Vascular surgeons</th>
<th>Neurosurgeons</th>
<th>General surgeons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protamine</td>
<td>37</td>
<td>2</td>
<td>36</td>
</tr>
<tr>
<td>Shunt</td>
<td>49</td>
<td>0</td>
<td>56</td>
</tr>
<tr>
<td>Eversion end</td>
<td>23</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Patch graft</td>
<td>60</td>
<td>2</td>
<td>27</td>
</tr>
</tbody>
</table>

Hannan et al, *Stroke*, 2001
Specialty and volume effect largely attributable to four specific processes of care
“Structure, process, and outcomes in cancer surgery”

- Supported by National Cancer Institute
- Partnership between American College of Surgeons, Commission on Cancer, and University of Michigan
NCDB, 2006-7

- 6 selected procedures

1300 hospitals, 170,000 pts

- Rank hospital performance

**Best hospitals**
(20 hospitals, 3000 pts)

**Worst hospitals**
(30 hospitals, 3000 pts)
NCDB, 2006-7

1300 hospitals, 170,000 pts

6 selected procedures

Best hospitals
(20 hospitals, 3000 pts)

Worst hospitals
(30 hospitals, 3000 pts)

Rank hospital performance

Chart review & site visits

Cause-specific mortality

Aim 1
NCDB, 2006-7

1300 hospitals, 170,000 pts

Best hospitals
(20 hospitals, 3000 pts)

Worst hospitals
(30 hospitals, 3000 pts)

Cause-specific mortality

Chart review & site visits

Aim 1

6 selected procedures

Rank hospital performance

Incidence?

Failure to rescue?
NCDB, 2006-7

1300 hospitals, 170,000 pts

Best hospitals
(20 hospitals, 3,000 pts)

Worst hospitals
(30 hospitals, 3,000 pts)

Chart review & site visits

Cause-specific mortality

Aim 1

Aim 2

Structure and process of care

Incidence?

Failure to rescue?
Overview of lecture

- Evidence that hospital and surgeon volume are strong determinants of surgical outcomes
- Translating evidence into policy
  - Selective referral
    - Current initiatives, strengths and weaknesses
  - Quality improvement
    - Can we learn anything from V-O relationships that would improve care everywhere?