The Volume-Outcome Relationship for Immediate Breast Reconstruction

Neil Tanna, M.D., M.B.A.
John L. Clayton, M.D., Ph.D., M.P.H.
Jason Roostaeian, M.D.
Adam D. Perry, M.D.
Christopher A. Crisera, M.D.

Los Angeles, Calif.

Background: Efforts to improve the quality of surgical care in the United States have led many organizations to advocate the use of high-volume hospitals for complex surgical procedures and/or comprehensive multidisciplinary care. The benefits, if any, of selective referral to high-volume hospitals for immediate breast reconstruction are relatively unknown. It is this gap in knowledge that forms the basis for the current study.

Methods: Using California's Office of Statewide Health Planning and Development discharge database, all patients undergoing immediate breast reconstruction from January 1, 1998, to December 31, 1999, were identified. Information regarding demographic, comorbidity, complication, and hospital volume characteristics was obtained. Patient comorbidity was graded using a modified version of the Charlson score. Annual hospital volume was categorized into patient quartiles. Multivariate logistic regression was performed to identify predictors of surgical complications.

Results: A total of 2691 patients were included: 1271 had immediate autogenous tissue reconstruction and 1420 had immediate tissue expander placement. The complication rate was 11.6 percent among patients undergoing autogenous reconstruction and 2.4 percent among patients receiving tissue expanders. For autogenous reconstruction, complications were more likely in patients with comorbidities (odds ratio, 2.24) and in patients receiving care at very-low-volume (less than eight) and medium-volume (20 to 41) hospitals (odds ratio,1.81 and 1.90, respectively). For tissue expander reconstruction, patient comorbidity (odds ratio, 2.42) was the only significant predictor of complications.

Conclusions: Hospital volume appears to be an important predictor of patient outcome with regard to autogenous reconstruction but not tissue expander reconstruction. Patient comorbidity predicts complications for both autogenous and tissue expander reconstruction. (*Plast. Reconstr. Surg.* 129: 19, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, III.

Efforts to improve the quality of surgical care in the United States have led many organizations to advocate the use of high-volume hospitals. For example, the Leapfrog Group,[1] a consortium of over 170 private and public organizations that insures over 34 million individuals, incorporated volume standards for five operations (i.e., coronary artery bypass graft, coronary angioplasty, abdominal aortic aneurysm repair, esophagectomy, and pancreatic resection) into their hospital referral criteria. This paradigm shift toward the use of hospital procedure volume as an indicator for quality is fostered by numerous reports of a volume-outcome relationship suggesting that high-volume hospitals have better outcomes.[1–6] The operations and conditions that seem to benefit most from selective referral are those with complex surgical intervention or those requiring comprehensive multidisciplinary care.[7–11] This volume threshold relationship has already caught the attention of the media.[12–14]

Of the diseases that benefit from comprehensive care, breast cancer ranks as one where plastic surgeons play an important and definitive role.[15] Often, plastic surgeons are intimately involved in patient care both acutely during immediate re-

From the Division of Plastic and Reconstructive Surgery, David Geffen School of Medicine at UCLA.
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construction, as they work side by side with general surgeons, and in the long term for the entire duration of staged breast reconstruction. The proliferation of advanced microsurgical techniques for reconstruction and the complex multidisciplinary care required for breast cancer treatment may justify regionalization of breast cancer care. Of the surgical interventions, immediate breast reconstruction requires the most interservice coordination and hospital infrastructure. However, it is unclear how immediate breast reconstruction is delivered at a population-based level.

It is this gap in knowledge that defines the basis of the current study. Specifically, it is unknown whether regionalization of immediate breast reconstruction exists and whether quality varies by hospital and provider volume. To elucidate these issues, the authors have obtained data on all patients undergoing immediate breast reconstruction in California from 1998 to 1999. The objectives of this study are twofold. First, the authors examine patient and hospital characteristics with respect to immediate breast reconstruction. Second, important predictors of surgical complications in immediate breast reconstruction are identified by performing a multivariate logistic regression. In doing so, the authors evaluate the impact of hospital procedural volume, in addition to other case-mix variables, on patient outcomes. This population-based assessment provides a broad analysis of quality that single-institution studies cannot accomplish and offers directions for future research aimed at quality improvement for immediate breast reconstruction.

PATIENTS AND METHODS

Data Source

Discharge data from January 1, 1998, to December 31, 1999, were obtained from California's Office of Statewide Health Planning and Development. The Office of Statewide Health Planning and Development database is compiled annually and includes discharge abstracts from all licensed nonfederal hospitals throughout California. Each discharge abstract includes detailed information regarding patient hospitalization, including codes for up to 20 inpatient procedures and 24 diagnoses per hospitalization. All procedures and diagnoses are categorized by the *International Classification of Diseases, Ninth Revision, Clinical Modification* coding scheme. Also included are patient demographic information (i.e., race, Hispanic ethnicity, sex, age, and expected source of payment), outcomes (i.e., complications, length of stay, and hospital charges), and site of hospitalization (i.e., hospital unique identifier).

Data Analysis

All patients undergoing immediate breast reconstruction were identified based on diagnosis-related group and *International Classification of Diseases, Ninth Revision, Clinical Modification* coding. All patients with a diagnosis-related group of 257 or 258 were selected. Internal validity was confirmed by checking for an *International Classification of Diseases, Ninth Revision, Clinical Modification* code for mastectomy (85.4, 85.34, and 85.36). Selection of patients then proceeded by looking for a concurrent code for tissue expander (85.5, 85.95, 85.33, and 85.35) or autogenous tissue (85.7, 85.84, and 85.85). Patients with a code for both autogenous tissue and tissue expander were excluded on the presumption that these represented cases of latissimus reconstruction with tissue expander reconstruction. Patients undergoing autogenous tissue reconstruction were analyzed separately from those undergoing tissue expander reconstruction.

All patient data were then abstracted for that particular discharge (i.e., age, race, ethnicity, comorbidity, and expected source of payment). Age categories were divided into younger than 35 years, 35 to 44 years, 45 to 54 years, 55 to 64 years, 65 to 74 years, and 75 years and older. Both race and ethnicity are reported by the hospital based on patient self-report. The race and ethnicity response options are defined by the Office of Statewide Health Planning and Development, which were reclassified to form five mutually exclusive categories: non–Hispanic white (white), non–Hispanic black (black), Asian, Hispanic, and other. Patients reported as Hispanic were categorized as Hispanic, regardless of race. Complications were identified based on *International Classification of Diseases, Ninth Revision, Clinical Modification* coding for surgical complications and transfusions (998.x and 99.04). Patient comorbidity was graded according to (modified) Deyo's adaptation of the Charlson score[16] and was calculated from the primary and 24 secondary diagnosis codes. The original Charlson index consists of 17 diagnostic categories. These provide the basis for assigning weighted scores to each comorbid disease. The Deyo adaptation[16] describes a validated translation of each diagnostic category of the Charlson index to *International Classification of Diseases, Ninth Revision, Clinical Modification* codes. Insurance status, based on the expected source of payment, was

categorized to Medicare, MediCal, private insurance (any), self-pay, and indigent (charity, no charge).

Information regarding hospital volume was obtained by tabulating the average annual cases performed over the time period. The a priori decision was made that average annual volume represented an aggregate assessment of procedural experience. Annual hospital volume was divided into quartiles (i.e., high, medium, low, and very low) based on patients such that each group had approximately the same number of patients. Unadjusted complication rates were computed for each volume category: high-volume hospitals, medium-volume hospitals, low-volume hospitals, and very-low-volume hospitals.

Multivariate logistic regression was performed at the patient level to identify independent predictors of complications. The corresponding hospital volume category for each patient was entered into the regression as a categorical variable. Demographic characteristics, comorbidities, and hospital volume were the independent variables used to predict the probability of a surgical complication. This allowed for the evaluation of hospital volume as a predictor of outcome while controlling for differences in case mix. All values of $p < 0.05$ were considered significant. Microsoft Access (Microsoft Corp., Redmond, Wash.) was used for data management and Stata 7.0 (Stata Corp., College Station, Texas) was used for statistical analysis.

RESULTS

Demographics

A total of 2773 patients underwent immediate breast reconstruction between 1998 and 1999 (Table 1). Of these 2773 patients, 1271 (45.8 percent) had immediate autogenous tissue reconstruction and 1502 (54.2 percent) had immediate tissue expander reconstruction. The majority of the patients were between the ages of 35 and 54 years (63.2 percent), and 30.6 percent of the patients were between the ages of 55 and 74 years. Only 6.1 percent of patients were younger than 35 years old or older than 75 years. The vast majority of patients were white (79.9 percent); blacks, Asians, and Hispanics represented 4.1, 6.5, and 7.6 percent of the sample, respectively. Private insurance was the expected source of payment in 81.7 percent of patients, and Medicare was the expected source of payment in 12 percent. With respect to comorbidity, 93 percent of patients had a modified Charlson score of 0, and 7 percent of patients had a modified Charlson score of 1 or more.

Table 1. Patient Demographic Information

	Tissue Expander		Autogenous		Total	
	No.	%	No.	%	No.	%
Total	1502		1271		2773	
Hospital						
HVH	360	24.0	318	25.1		
MVH	386	25.7	320	25.2		
LVH	328	21.8	309	24.3		
VLVH	428	28.5	324	25.4		
Race						
White	1268	84.4	949	74.7	2217	79.9
Black	42	2.8	71	5.6	113	4.1
Asian	78	5.2	101	7.9	179	6.5
Hispanic	84	5.6	126	9.9	210	7.6
Other	30	2.0	24	1.9	54	1.9
Age						
<35 years	56	3.7	56	4.4	112	4.0
35–44 years	358	23.8	335	26.4	693	25.0
45–54 years	561	37.4	499	39.3	1060	38.2
55–64 years	299	19.9	268	21.1	567	20.4
65–74 years	180	12.0	103	8.1	283	10.2
≥75 years	48	3.2	10	0.8	58	2.1
Insurance						
Medicare	224	14.9	109	8.6	333	12.0
MediCal	37	2.5	42	3.3	79	2.8
Private	1196	79.6	1070	84.2	2266	81.7
Self-pay	6	0.4	19	1.5	25	0.9
Indigent	39	2.6	31	2.4	70	2.5
Comorbidity						
0	1386	92.3	1194	93.9	2580	93.0
1	105	7.0	68	5.4	173	6.2
2	11	0.7	9	0.7	20	0.7

HVH, high-volume hospitals; MVH, medium-volume hospitals; LVH, low-volume hospitals; VLVH, very-low-volume hospitals.

Hospitals and Volume Categories

There were 157 hospitals performing immediate autogenous tissue reconstruction and 188 hospitals performing immediate tissue expander reconstruction (Table 2). The vast majority of the hospitals fell in the very-low-volume hospital category. Only 3 percent of hospitals were high-volume hospitals for either autogenous tissue or tissue expander reconstruction. The top 10 percent

Table 2. Number of Hospitals by Volume Category and Volume Criteria

	Tissue Expander		Autogenous	
	Volume	No.	Volume	No.
HVH	>44	6	>42	4
MVH	17–44	15	20–42	12
LVH	9–16	27	8–19	27
VLVH	1–8	140	1–7	114
Total		188		157

HVH, high-volume hospitals; MVH, medium-volume hospitals; LVH, low-volume hospitals; VLVH, very-low-volume hospitals.

of hospitals (high-volume hospitals and medium-volume hospitals) accounted for 50 percent of patient volume. Very-low-volume hospitals accounted for approximately 75 percent of all hospitals but performed only 25 to 28 percent of the operations for either autogenous tissue or tissue expander reconstruction, respectively.

Average unadjusted complication rates were 11.6 percent for autogenous tissue and 2.4 percent for tissue expander reconstruction (Table 3). For autogenous tissue reconstruction, unadjusted complication rates were higher in medium-, low-, and very-low-volume hospitals when compared with high-volume hospitals. However, unadjusted complication rates were lower in high-volume hospitals and low-volume hospitals when compared with the complication rate for autogenous tissue reconstruction. Similarly, unadjusted complication rates for tissue expander reconstruction were lowest at high-volume hospitals when compared with medium-, low-, and very-low-volume hospitals.

Predictors of Serious Complications

For autogenous tissue reconstruction, multivariate logistic regression identified hospital volume, patient comorbidity, and race as significant independent predictors of complications (Table 4). Age was not an important predictor of complication. Asians and Hispanics were more likely to have a complication when compared with white patients, with odds ratios of 1.95 ($p = 0.02$) and 1.89 ($p = 0.02$), respectively. Patients with any comorbidity (Charlson score >0) were much more likely to have a complication compared with patients with no comorbidity (odds ratio, 2.23; $p = 0.01$). Even after controlling for age, race, and comorbidity, hospital volume remained an important predictor of outcome. Patients at very-low-volume hospitals (odds ratio, 1.89; $p = 0.02$) and medium-volume hospitals (odds ratio, 1.77; $p = 0.03$) were more likely to have a surgical complication compared with patients at a high-volume hospital. There was a trend toward higher risk of complications at a low-volume hospital when compared with a high-volume hospital, but this did not reach statistical significance ($p = 0.58$). It should be noted that patient comorbidity increased the odds of a complication more than either hospital volume or race.

For tissue expander reconstruction, multivariate logistic regression identified patient comorbidity and age as independent predictors of complications (Table 5). Race and hospital volume were not important predictors of complications. Patients older than 55 years were more likely to have complications when compared with the reference group (aged 45 to 54 years). However, this only reached statistical significance for patients between the ages of 55 and 64 years (odds ratio, 3.14; $p = 0.01$). The presence of patient comorbidity was an important predictor of surgical complications. Patients with any comorbidity (Charlson score >0) were 2.42 times more likely to have a complication than patients without any comorbidity ($p = 0.04$). After controlling for patient comorbidity, age, and race, hospital volume did not predict surgical complications.

Table 3. Unadjusted Complication Rates by Volume Category

	Tissue Expander (%)	Autogenous Tissue (%)
HVH	1.9	8.4
MVH	2.6	13.4
LVH	2.7	9.5
VLVH	2.3	14.6
Average	2.4	11.6

HVH, high-volume hospitals; MVH, medium-volume hospitals; LVH, low-volume hospitals; VLVH, very-low-volume hospitals.

Table 4. Predictors of Complications for Immediate Autogenous Tissue Reconstruction

	OR	95% CI	*p*
VLVH	1.89	1.11–3.18	0.02
LVH	1.17	0.66–2.06	0.58
MVH	1.77	1.04–2.99	0.03
Asian	1.95	1.10–3.41	0.02
Hispanic	1.89	1.12–3.18	0.02
Charlson score >0	2.23	1.20–4.12	0.01

OR, odds ratio; CI, confidence interval; VLVH, very-low-volume hospitals; LVH, low-volume hospitals; HVH, high-volume hospitals.

DISCUSSION

The current study highlights several important findings. First, with respect to immediate autogenous tissue reconstruction, hospital volume appears to play a role in outcome, with high-volume hospitals having the lowest complication rate. It

Table 5. Predictors of Complications for Immediate Prosthetic Reconstruction

	OR	95% CI	*p*
VLVH	1.17	0.43–3.15	0.75
LVH	1.39	0.50–3.80	0.52
MVH	1.21	0.45–3.27	0.70
Age			
55–64 years	3.14	1.28–7.64	0.01
65–74 years	2.03	0.68–6.01	0.20
>75 years	2.57	0.51–12.7	0.25
Charlson score >0	2.42	1.01–5.80	0.04

OR, odds ratio; CI, confidence interval; VLVH, very-low-volume hospitals; LVH, low-volume hospitals; HVH, high-volume hospitals.

should be noted, however, that the effect of patient comorbidity on the odds of a complication exceeds that of hospital volume. Second, hospital volume appears to have little effect on complication rates after immediate tissue expander reconstruction. Rather, patient age and comorbidity are much better predictors of surgical complications than hospital volume. Finally, the range of hospital volumes is vast, with a small minority of hospitals performing the majority of the operations. To the best of our knowledge, this is the first study to evaluate the significance of hospital volume on outcomes in immediate breast reconstruction and the first study to quantify the delivery of immediate breast reconstruction at a population-based level.

Our findings provide fairly compelling evidence to investigate the causes of variation in care between high-volume and low-volume hospitals with respect to immediate autogenous tissue reconstruction. This finding is consistent with much of the published literature regarding the volume-outcome relationship for complex surgery.[2–11] Similarly, it is not surprising that hospital volume had little effect on outcomes for tissue expander reconstruction because tissue expander placement is less complex than autogenous tissue reconstruction. In essence, autogenous tissue reconstruction may require more resources, better hospital infrastructure, and special expertise.

However, volume in and of itself does not equate with better care. In fact, some low-volume hospitals perform better than their high-volume counterparts. In our sample, the volume-outcome relationship was not perfect; rather, low-volume hospitals performed almost as well as high-volume hospitals and better than medium-volume hospitals. This finding is not unique. For example, the generally accepted norm for a high-volume coronary artery bypass grafting hospital is approximately 500 cases per year.[1] In *The California Report on Coronary Artery Bypass Graft Surgery 1999 Hospital Data* published by the state, three hospitals had risk-adjusted outcomes that were better than expected. Of these three hospitals, only one was a high-volume hospital.[17] In fact, both low-volume hospitals performed fewer than 60 percent of the "benchmark" case volume for coronary artery bypass grafting.

Although the current evidence may not be sufficient to warrant regionalizing immediate autogenous breast reconstruction, the differences in complication rates among hospital volume categories cannot be ignored. Hospital volume is more likely to represent a marker for quality than to have a direct, causal relationship with outcome. Potentially, volume may affect quality by acting as a catalyst for the development of specific processes of care that ultimately lead to better outcomes and quality. Simultaneous analysis of high-volume and low-volume institutions may offer insight regarding the causes of varying quality across institutions. Findings could be categorized into two fundamental components of quality: structure and process.[18] Structure refers to hospital attributes or hospital services that either directly or indirectly influence the care of patients (i.e., infrastructure). Examples of structural characteristics that may affect quality and outcome include competent and continuous flap monitoring, specialized flap monitoring rooms, and immediate availability of operating room staff for emergencies. Process refers to specific actions or treatments provided to patients that may influence a patient's outcome. Examples of process include giving preoperative antibiotics and providing adequate deep venous thrombosis prophylaxis. Clinical pathways may serve to ensure or increase the performance of beneficial processes of care. Within this taxonomy, differences in procedural volume would represent differences in a structural characteristic (infrastructure) between high- and low-volume hospitals.

Despite the important findings of our study, there are several limitations. The administrative data selected for this analysis do not include information on obesity or smoking history and do not differentiate between unilateral and bilateral reconstructions. However, for these missing data to negate the effect of procedural volume, high-volume hospitals would have had to systematically select for less obese, nonsmoking patients. Second, the data set only accounts for in-hospital complications, so postdischarge complications or readmissions are not captured. Although readmissions and postdischarge events constitute significant morbidity, in-hospital complications represent the most severe and immediate postoperative events for autogenous reconstruction. This may not be the case for tissue expander reconstruction, as morbidity from this procedure usually occurs following discharge. As such, our data may not entirely reflect the outcome-volume relationship of tissue expander reconstruction. Third, the Office of Statewide Health Planning and Development is exclusive to California, and findings based on this data set might not be generalizable to the United States. However, California is the largest state in the nation and represents approximately 12 percent of all hospital discharges in the United States. In addition, the authors recognize that the

data are from 1998 to 1999. However, at the time of data review and article preparation, the Office of Statewide Health Planning and Development had only finalized these data. The authors recognize that with increasing frequency of autologous breast reconstruction over the past decade, complications may have declined. Lastly, this study does not differentiate between microsurgical and pedicled autologous reconstruction. As all patients were identified by *International Classification of Diseases, Ninth Revision, Clinical Modification* codes for autogenous tissue reconstruction, it is not always possible to distinguish free tissue transfer from pedicled flaps. Even after accounting for some of its recognized limitations, discharge data such as those used in this study are well suited for population-based analyses of quality and outcomes. The large sample size and the inclusion of all hospitals within the state allow for the evaluation of surgical outcomes on a larger scale. Efforts should be made toward implementing strategies to improve quality for immediate breast reconstruction at all hospitals and to reduce variations in quality and outcomes.

In summary, this is the first study to our knowledge to evaluate predictors of complications following immediate breast reconstruction at a population level. For immediate autogenous breast reconstruction, hospital volume and patient comorbidity are important predictors of postoperative surgical complications. For immediate tissue expander reconstruction, patient age and comorbidity are the important predictors, whereas hospital volume appears to have little effect. These findings are significant as we look for ways to improve the quality of immediate breast reconstruction.

Christopher A. Crisera, M.D.
200 UCLA Medical Plaza, Suite 465
Box 956960
Los Angeles, Calif. 90095-6960
ccrisera@mednet.ucla.edu

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