Benchmarking Outcomes in Plastic Surgery: National Complication Rates for Abdominoplasty and Breast Augmentation

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Background: The authors evaluated the use of national databases to track surgical complications among abdominoplasty and breast augmentation patients.
Methods: Their study population included all patients with abdominoplasty or breast augmentation in the Tracking Operations and Outcomes for Plastic Surgeons (TOPS) and CosmetAssure databases from 2003 to 2007. They evaluated the incidence of hematoma, infection, and/or deep venous thrombosis/pulmonary embolism. Chi-square and *t* tests were used for the analyses.
Results: The TOPS and CosmetAssure databases included 7310 and 3350 patients with abdominoplasty and 30,831 and 14,227 patients with breast augmentation, respectively. In the TOPS and CosmetAssure populations, the complication rates for abdominoplasty were 0.9 percent and 0.5 percent with hematoma ($p = 0.29$), 3.5 percent and 0.7 percent with infection ($p < 0.001$), and 0.3 percent and 0.1 percent with deep venous thrombosis/pulmonary embolism ($p = 0.05$), respectively. The complication rates for breast augmentation in TOPS and CosmetAssure were 0.6 percent and 0.7 percent with hematoma ($p = 0.21$), 0.3 percent and 0.1 percent with infection ($p < 0.001$), and 0.02 percent and less than 0.01 percent with deep venous thrombosis/pulmonary embolism ($p = 0.31$), respectively.
Conclusions: Complication rates for abdominoplasty and breast augmentation were similar in TOPS and CosmetAssure, providing a measure of cross-validation. The low complication rates support the safety of these procedures when they are performed by plastic surgeons. These data should be used by individual practitioners for outcomes benchmarking. (*Plast. Reconstr. Surg.* 124: 2127, 2009.)

Tracking surgical complications is crucial to ensuring high-quality care, patient safety, and informed patient choice. These outcomes are particularly important for elective cosmetic surgery. According to the American Society of Plastic Surgeons, more than 148,000 abdominoplasty and 347,500 breast augmentation procedures are performed annually.[1] In particular, breast augmentation is the most commonly occurring cosmetic procedure in the United States performed by Society members.[1]

Surgeons must have reliable information about surgical risks and outcomes that can be transferable to their own patient population. The current data on the safety of these procedures, however, are largely limited to single-surgeon or single-center studies. These types of studies demonstrate the efficacy of a procedure performed by a particular surgeon but do not provide data on the effectiveness of a procedure performed by different surgeons in diverse patient populations. Researchers have turned to national clinical regis-

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tries and administrative claims data to overcome the limitations of single-surgeon or single-center studies. National databases can provide information on surgical outcomes across a large cohort of patients, providers, and healthcare settings, thereby improving physicians' ability to generalize the results to their own patients.

Using national clinical registries or administrative claims data to track surgical outcomes is challenging for cosmetic surgery. Most national clinical registries are disease-specific, such as Surveillance Epidemiology and End Results Registry and the National Comprehensive Cancer Network, which only capture cancer patients. National administrative claims data, such as Medicare and the Hospital Cost and Utilization Project, are based on discharge data and do not capture self-paying patients. To confront these challenges, the American Society of Plastic Surgeons and the American Board of Plastic Surgery created the Tracking Operations and Outcomes for Plastic Surgeons (TOPS) database. Its primary purpose is to facilitate monitoring the quality of surgical care in plastic surgery. This database, however, relies on voluntary self-reported data, and its validity has not been evaluated. CosmetAssure is an insurance policy sold nationally that covers medical and surgical complications from cosmetic surgery. Thus, there is an incentive for participating surgeons to work with their patients who have a covered complication to submit claim information. To date, neither has been used to assess cosmetic surgery outcomes.

To address these issues, we used two national plastic surgery databases, TOPS and CosmetAssure, to benchmark surgical outcomes for commonly performed cosmetic surgery. Our specific goals were (1) to evaluate the safety of abdominoplasty and breast augmentation and (2) to assess the validity of using TOPS to track surgical outcomes.

METHODS

Database Characteristics

The TOPS program was launched in 2002 as a Health Insurance Portability and Accountability Act–compliant, secure, and confidential national database of plastic surgery procedures and outcomes and is sponsored by the American Society of Plastic Surgeons and the American Board of Plastic Surgeons. The purpose of the database is to provide valid clinical/practice information to plastic surgeons and their society. The database is only accessible to members of the American Society of Plastic Surgeons and plastic surgeons who are entering their case collection for the American Board of Plastic Surgeons. Surgeon participation is voluntary, the data are self-reported, and there are no financial or other types of incentives to contribute except as a requirement for board certification. Surgeons are asked to report on their entire case mix, including both reconstructive and cosmetic procedures. Approximately 400,000 cases were reported to the database from 2003 to 2007. Complications are reported within 4 to 6 weeks postoperatively and are inclusive of all complications (i.e., those treated in both the inpatient or outpatient setting).

CosmetAssure is a medical insurance program that covers selected elective cosmetic procedures performed by active or candidate members of the American Society of Plastic Surgeons. Surgeons participating with the program are required to enroll all of their patients undergoing one of the 17 covered procedures. The database includes approximately 36,000 consecutive cases from 2003 to 2007. Unlike TOPS, there is a financial incentive to report complications that are covered under the program's inclusion criteria. CosmetAssure will cover the patient's financial obligations that result from a complication covered by the policy. Coverage is limited, however, to complications requiring a hospital admission, emergency room visit, or an intervention in an accredited surgical center within 30 days of the procedure. Unlike TOPS, complications that are treated on an outpatient basis (i.e., with oral antibiotics or seroma drainage) are not captured in the database.

Study Population

We obtained data on all patients in both databases who underwent abdominoplasty or breast augmentation as a single procedure and all patients who had an abdominoplasty or breast augmentation combined with another procedure from July of 2003 to August of 2007. Both men and women of all ages were included. An operation was considered a combined procedure if either the abdominoplasty or breast augmentation was performed in conjunction with any other surgical procedure.

Measures

The independent variables of interest were patient demographic characteristics, comorbidities, and facility data. Patient age was analyzed as a continuous variable; patient gender was dichotomized. Available information on pa-

tient comorbidities was limited and only included diabetes and smoking history among CosmetAssure patients, which was reported as a dichotomous (yes/no) variable. Facility information was limited to the type of healthcare setting in which the service was provided. The databases used different terms for reporting care in the outpatient setting: the term used for TOPS was "ambulatory care" and for CosmetAssure it was "accredited centers." Analysis was limited to terms that were consistent between databases, which included hospital, office-based suite, and office/other/unknown.

The primary dependent variables of interest were surgical complications for single or combined procedures. Incidence data were available in both databases for hematoma, infection, and deep venous thrombosis/pulmonary embolus. Data on combined procedures represent overall complications and cannot be assigned to a particular procedure (i.e., to the abdominoplasty versus the procedure with which it was combined). It is important to note that CosmetAssure only reports complications if they require hospitalization, emergency room care, or surgical care in an accredited facility.

Statistical Analysis

We first described receipt of surgical procedure (abdominoplasty and breast augmentation, single and combined) across all sociodemographic, clinical, and facility factors. Pearson chi-square test was used for the bivariate analyses of dependent and independent factors by database, and Student's *t* test was used for continuous variables. In addition, we performed bivariate comparisons using the Pearson chi-square test of surgical complications between patients undergoing single and combined procedures.

RESULTS

Overall, the databases included 10,660 single- and 20,970 combined-procedure abdominoplasties and 45,058 single- and 25,691 combined-procedure breast augmentations.

Abdominoplasty

Patient and facility data for those having single- and combined-procedure abdominoplasty are listed in Table 1. Most of the patients were women in their early forties. The databases had statistically significant differences in patient age and gender. These differences, however, had minimal clinical significance. For example, the average age of patients undergoing single-procedure abdominoplasty in TOPS was 43.0 years and 42.0 years in CosmetAssure ($p < 0.001$). Among CosmetAssure patients, the incidence of diabetes ranged from 1.9 to 2.1 percent, and 5.8 to 6.5 percent had a history of smoking. The majority of patients in the TOPS database received care in a hospital (40.3 to 47.8 percent); however, the majority of CosmetAs-

Table 1. Abdominoplasty Complications in the Tracking Operations and Outcomes for Plastic Surgeons and CosmetAssure Populations, July of 2003 to August of 2007

	Single Procedure			Combined Procedure§		
Patient Characteristic	TOPS (n = 7310)	CosmetAssure (n = 3350)	p‡	TOPS (n = 13,193)	CosmetAssure (n = 7777)	p‡
Mean age, years	43	42.0*	<0.001	42.5	41.4*	<0.001
Female gender	95.0%	96.7%*	<0.001	96.5%	97.1%*	0.02
Diabetes	N/A	2.1%*		N/A	1.9%*	
Smoking history	N/A	5.8%*		N/A	6.5%*	
Hematoma	0.9%	0.5%	0.03	1.0%	0.39%	<0.001
Infection	3.5%†	0.7%	<0.001	3.4%	0.33%	<0.001
Deep venous thrombosis/ pulmonary embolus	0.3%	0.1%	0.05	0.4%	0.27%	<0.001
Facility						
Hospital	47.8%	31.0%*	<0.001	40.3%	30.2%*	<0.001
Accredited center	—	25.5%*	—	—	36.1%*	—
Ambulatory care	23.8%	—	—	27.0%	—	—
Office-based suite	27.1%	7.9%*	<0.001	31.1%	11.9%*	<0.001
Office/other/unknown	1.3%	35.6%*	<0.001	1.5%	21.7%*	<0.001

TOPS, Tracking Operations and Outcomes for Plastic Surgeons; N/A, not available.
*Data are only available for patients who have been enrolled since January of 2007.
†This category includes any infection requiring oral antibiotics, outpatient or inpatient intravenous antibiotics, or wound requiring surgical drainage.
‡Pearson chi-square test was used for differences in proportions; Student's *t* test was used for differences in means.
§Complications for combined procedures represent overall rates of a complication and cannot be assigned to a particular procedure.

sure patients were treated in an office/other/unknown facility for single-procedure (35.6 percent) and in an accredited center (36.1 percent) for combined-procedure abdominoplasty.

The complication rates for single- and combined-procedure abdominoplasty were low overall, but complication rates were significantly lower among CosmetAssure compared with TOPS patients (Table 1). Rates of hematoma ranged from 0.9 to 0.5 percent ($p = 0.03$) for single procedures and from 1.0 to 0.39 percent ($p < 0.001$) for combined procedures in TOPS and CosmetAssure, respectively. Rates of deep venous thrombosis/pulmonary embolus ranged from 0.3 to 0.1 percent ($p = 0.05$) for single procedures and from 0.4 to 0.27 percent ($p < 0.001$) for combined procedures in TOPS and CosmetAssure. Infection rates were significantly higher among TOPS patients compared with those in CosmetAssure. This was expected, however, as CosmetAssure did not include infections treated in the outpatient setting. Rates of infection ranged from 3.5 to 0.7 percent ($p < 0.001$) for single procedures and from 3.4 to 0.33 percent ($p < 0.001$) for combined procedures in TOPS and CosmetAssure, respectively.

Breast Augmentation

Table 2 displays the patient and facility information, along with the reported complications, for single- and combined-procedure breast augmentation. The majority of patients were women in their thirties. The two databases had statistically significant differences in patient age and gender. These differences, however, have minimal clinical significance. For example, the average age of patients with single-procedure breast augmentation was 33.3 years in TOPS and 33.7 years in CosmetAssure ($p < 0.001$). Among CosmetAssure patients, the incidence of diabetes ranged from 0.9 to 1.2 percent, and 7.3 to 11.0 percent had a history of smoking. The majority of TOPS patients received care in an office-based suite (41.2 to 44.2 percent); the majority of CosmetAssure patients were treated in an accredited surgery center (40.5 to 41.6 percent).

The complication rates for single- and combined-procedure breast augmentation were low overall and relatively consistent between databases (Table 2). Rates of hematoma ranged from 0.6 to 0.7 percent ($p = 0.21$) for single procedures and from 0.8 to 0.2 percent ($p < 0.001$) for combined procedures in TOPS and CosmetAssure, respectively. Rates of deep venous thrombosis/pulmonary embolus ranged from 0.02 to less than 0.01 percent ($p = 0.31$) for single procedures and from 0.1 to 0.06 percent ($p = 0.32$) for combined procedures in TOPS and CosmetAssure. As expected, infection rates were significantly higher among TOPS patients compared with those in CosmetAssure due to differences in infection reporting criteria between the two databases. Rates of infection ranged from 0.3 to 0.1 percent ($p < 0.001$) for single procedures and from 1.2 to 0.05 percent

Table 2. Breast Augmentation Complications in the Tracking Operations and Outcomes for Plastic Surgeons and CosmetAssure Populations, July of 2003 to August of 2007

	Single Procedure			Combined Procedure§		
Patient Characteristic	**TOPS (n = 30,831)**	**CosmetAssure (n = 14,227)**	**p‡**	**TOPS (n = 17,894)**	**CosmetAssure (n = 7797)**	**p‡**
Mean age, years	33.3	33.7*	<0.001	39.7	37.4*	<0.001
Female gender	99.7%	99.4%*	<0.001	99.8%	100%*	<0.001
Diabetes	N/A	0.9%*		N/A	1.2%*	
Smoking history	N/A	11.0%*		N/A	7.3%*	
Hematoma	0.6%	0.7%	0.21	0.8%	0.2%	<0.001
Infection	0.3%†	0.1%	<0.001	1.2%	0.05%	<0.001
Deep venous thrombosis/pulmonary embolus	0.02%	<0.01%	0.31	0.1%	0.06%	0.32
Facility						
Hospital	16.9%	18.1%*	<0.01	23.2%	22.1%*	0.05
Accredited center		40.5%*			41.6%*	
Ambulatory care	37.7%			33.8%		
Office-based suite	44.2%	12.9%*	<0.001	41.2%	13.7%*	<0.001
Office/other/unknown	1.2%	28.5%*	<0.001	1.8%	22.6%*	<0.001

TOPS, Tracking Operations and Outcomes for Plastic Surgeons; N/A, not available.
*Data are only available for patients who have been enrolled since January of 2007.
†This category includes any infection requiring oral antibiotics, outpatient or inpatient intravenous antibiotics, or wound requiring surgical drainage.
‡Pearson chi-square test was used for differences in proportions; Student's t test was used for differences in means.
§Complications for combined procedures represent overall rates of a complication and cannot be assigned to a particular procedure.

($p < 0.001$) for combined procedures in TOPS and CosmetAssure, respectively.

Figure 1 graphically displays the increased overall risk of surgical complications when breast augmentation is combined with other surgical procedures. In TOPS, the overall rates of hematoma for single- and combined-procedures were 0.6 and 0.8 percent ($p < 0.01$); for infection, 0.3 and 1.2 percent ($p < 0.001$); and for deep venous thrombosis/pulmonary embolus, 0.02 and 0.1 percent ($p < 0.001$), respectively. In CosmetAssure, the only complication that was significantly higher among the combined-procedure group was deep venous thrombosis/pulmonary embolus (<0.01 percent for single versus 0.06 percent for combined procedures, $p = 0.02$, Table 2). The overall complication rate for hematoma, infection, and deep venous thrombosis/pulmonary embolus was not significantly higher when abdominoplasty was combined with other procedures in either TOPS or CosmetAssure (Table 1).

DISCUSSION

This study uses national databases to describe surgical complications associated with abdominoplasty and breast augmentation among patients treated by multiple providers in diverse healthcare settings. We found that these two elective procedures had low overall rates of surgical complications. In general, the most commonly occurring complication for single- or combined-procedure abdominoplasty was infection (3.4 to 3.5 percent in TOPS and 0.3 to 1.7 percent in CosmetAssure), and for breast augmentation it was hematoma (0.6 to 0.8 percent in TOPS and 0.2 to 0.7 percent in CosmetAssure). Furthermore, the data from TOPS suggested an overall increased risk of surgical complications when breast augmentation was combined with other procedures. Finally, the outcomes data in TOPS and CosmetAssure were relatively consistent, which provides a measure of cross-validation for TOPS.

As a society, we are facing many challenges to the practice of plastic surgery. Reimbursement is declining,[2,3] payers are demanding that we document quality through pay for performance measures,[4,5] patients are expecting increased transparency in outcomes,[6–8] and professional competition has never been more intense.[9,10] One way our specialty can alleviate some of these pressures is by demonstrating excellences through benchmarking our surgical outcomes. Benchmarking is crucial to ensuring high-quality care, patient safety, and informed patient choice. This requires physicians to work together and gain strength in numbers. National databases are one tool we can use to document quality on a large scale across multiple patients and providers.

Outcomes research using national databases can help us understand an intervention's effectiveness rather than just its efficacy. In other words, we can understand an intervention's outcomes under real-world conditions, not just in the optimal setting.[11,12] Case series and clinical trials performed across a few academic centers are at risk for selection bias, and the results represent outcomes under optimal conditions. National databases, on the other hand, include patients and physicians from all types of healthcare settings,

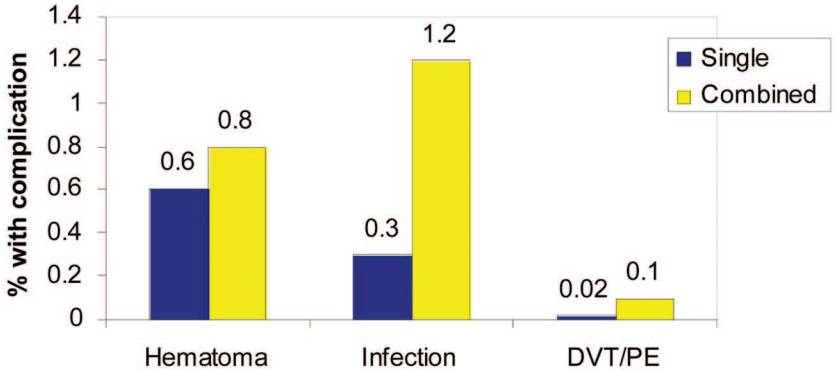

Fig. 1. The graph displays differences in overall complications for breast augmentation between single and combined procedures in the Tracking Operations and Outcomes for Plastic Surgeons database. Complications for combined procedures represent overall rates of a complication and cannot be assigned to a particular procedure. The rates of all the complications between single and combined procedures were significantly different ($p < 0.01$) using Pearson chi-square analysis.

allowing assessment of outcomes in the "real world." This was demonstrated with the clinical trials for endarterectomy procedures.[12] The clinical trials reported a very low mortality rate for these procedures. However, after the clinical trials concluded, the mortality rate following endarterectomy was substantially higher than that reported in the trials, even among those institutions that participated in the randomized studies. Furthermore, the mortality rate with endarterectomy was found to be inversely proportional to a center's volume. In summary, clinical trials generally do not represent real-world surgical outcomes.[12]

Adequate sample size is another key component to outcomes research. True differences in outcomes can only be detected when research studies are adequately powered through a large enough sample size.[13,14] Plastic surgery faces the difficulty of being a relatively low-volume provider compared with other specialties, such as those focusing on cardiovascular disease. Prior research on surgical complications associated with abdominoplasty and breast augmentation has largely been limited to small single-surgeon or single-center studies and, in general, reports higher complications than what we have found in the current study. For abdominoplasty, the previously reported incidence of hematoma ranged from 1.4 to 5.8 percent; that for infection ranged from 1.1 to 9.9 percent, and the incidence of deep venous thrombosis/pulmonary embolus ranged from 0.06 to 1.0 percent[15–19]; for breast augmentation, the incidence of hematoma ranged from 2.3 to 5.7 percent; infection, 2.3 to 2.5 percent; and deep venous thrombosis/pulmonary embolus, 0.2 to 6.5 percent.[20–23] Clinicians have limited ability to generalize these results to their own practice because clinical volume and patient characteristics may vary greatly from those of the individual studies. We, however, are in a unique position to have a national clinical registry designed by plastic surgeons for plastic surgeons to monitor our surgical outcomes across diverse healthcare settings.

This study supports the face validity of TOPS by cross-validating the results with CosmetAssure. The two databases have similar proportions of surgical complications despite dramatically different incentives for participation. It is important to realize differences in the collection of data when comparing outcomes. CosmetAssure did not capture any complication treated in an outpatient setting, thus resulting in a low incidence of infection, for example. Both databases lacked detailed information on surgical risk factors, such as body mass index and operative time. The new version of TOPS, however, does capture more information on comorbidities and other risk factors and will also assign complications to a particular procedure when cases are combined.

This study has several limitations worth considering. Information in both databases was self-reported and not subject to auditing. There is potential for unmeasured variables to affect the outcome of interest because the patient sample was not randomized. We were also unable to control for patient and surgeon level factors that may affect the outcome, such as body mass index, operative time, surgeon years in practice, and surgeon volume. We also did not have information on the use of prophylactic antibiotics and deep venous thrombosis/pulmonary embolus prophylaxis. Lastly, the CosmetAssure database did not include complications that were treated on a outpatient basis, such as with oral antibiotics.

Clinical Implications

Chantler had an insightful comment on the clinical implications of modern-day surgery: "Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous."[24] These data provide evidence that abdominoplasty and breast augmentations performed by members of the American Society of Plastic Surgeons are relatively safe procedures with a low incidence of complications. Future efforts should be directed at identifying specific risk factors that contribute to surgical complications, such as operative time. In addition, more outcomes data are needed to guide appropriate deep venous thrombosis/pulmonary embolus prophylaxis, especially for cosmetic procedures.

Plastic surgeons must be leaders in evaluating clinical risk, setting standards and monitoring outcomes. National databases are powerful tools that can be used to accomplish these goals by describing real-world surgical practice and documenting quality of care. It is important for plastic surgeons to support and contribute to Tracking Operations and Outcomes for Plastic Surgeons. This clinical registry will facilitate plastic surgery's national leadership efforts in benchmarking, quality improvements, and pay-for-performance initiatives. In the future, Tracking Operations and Outcomes for Plastic Surgeons will be of even greater value to clinicians as patient-reported outcomes will be linked to clinical data.

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