Individualized Risk of Surgical Complications: An Application of the Breast Reconstruction Risk Assessment Score

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Background: Risk discussion is a central tenet of the dialogue between surgeon and patient. Risk calculators have recently offered a new way to integrate evidence-based practice into the discussion of individualized patient risk and expectation management. Focusing on the comprehensive Tracking Operations and Outcomes for Plastic Surgeons (TOPS) database, we endeavored to add plastic surgical outcomes to the previously developed Breast Reconstruction Risk Assessment (BRA) score.

Methods: The TOPS database from 2008 to 2011 was queried for patients undergoing breast reconstruction. Regression models were constructed for the following complications: seroma, dehiscence, surgical site infection (SSI), explantation, flap failure, reoperation, and overall complications.

Results: Of 11,992 cases, 4439 met inclusion criteria. Overall complication rate was 15.9%, with rates of 3.4% for seroma, 4.0% for SSI, 6.1% for dehiscence, 3.7% for explantation, 7.0% for flap loss, and 6.4% for reoperation. Individualized risk models were developed with acceptable goodness of fit, accuracy, and internal validity. Distribution of overall complication risk was broad and asymmetric, meaning that the average risk was often a poor estimate of the risk for any given patient. These models were added to the previously developed open-access version of the risk calculator, available at http://www.BRAscore.org.

Conclusions: Population-based measures of risk may not accurately reflect risk for many individual patients. In this era of increasing emphasis on evidence-based medicine, we have developed a breast reconstruction risk assessment calculator from the robust TOPS database. The BRA Score tool can aid in individualizing—and quantifying—risk to better inform surgical decision making and better manage patient expectations. *(Plast Reconstr Surg Glob Open 2015;3:e405; doi: 10.1097/GOX.0000000000000351; Published online 28 May 2015.)*

The psychosocial benefits of breast reconstruction in the postmastectomy patient are well established.[1,2] This was recognized by federal law in the form of the Women's Health and Cancer Rights Act of 1998, mandating insurance coverage of breast reconstruction in patients treated with mastectomy.[3] Since the passage of the Women's Health and Cancer Rights Act, large-scale studies of mas-

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tectomy patients have shown steady yearly increases in the rate of reconstruction, leading to more than 90,000 reconstructions nationwide in 2011.[4,5]

Numerous modalities exist for reconstruction of the breast, and each carries its own advantages and disadvantages. A number of superb intrainstitutional studies have benchmarked rates and elucidated risk factors for complications in different modalities.[6–29] Further, recent years have seen a greater number of studies using either meta-analysis or large-scale clinical registries with greater statistical power and generalizability.[30–37] However, even given large-scale data, the reconstructive surgeon and mastectomy patient are still faced with the necessity of making an individualized decision based on these population-based measures of risk, which may over- or underestimate the actual probability of complications for the case at hand.

This conundrum has led to recent interest in online decision-making tools for patient and surgeon.[38–41] The utility of these calculators lies in their ability to add specific and objective measures of risk to the conversation between patient and surgeon. In the face of these benefits, the Centers for Medicare and Medicaid Services may provide incentives to surgeons who discuss patient-specific risks before elective operations.[42]

The Breast Reconstruction Risk Assessment (BRA) score is an online tool (http://www.BRAScore.org), developed previously using the National Surgical Quality Improvement Program (NSQIP) to help assess the probability of complications based on the choice of reconstructive modality. The Tracking Operations and Outcomes for Plastic Surgeons (TOPS) program, maintained by the American Society of Plastic Surgeons (ASPS), provides more granular detail with respect to complications of interest in breast reconstruction. Our goal in this study was to use the TOPS database to expand upon the current BRA score model to include calculators for surgical complications of particular interest in breast reconstruction: seroma, dehiscence, surgical site infection (SSI), flap failure, explantation, and reoperation. The BRA score will never supplant clinical decision making; however, it can serve as a useful adjunct by transforming robust statistical analysis into an easy-to-use tool for patient and surgeon alike.

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METHODS

Database

The TOPS database is a prospectively planned, Health Information Portability and Accountability Act (HIPAA)-compliant patient registry that was launched in 2002, with the goals of providing benchmarks and improving outcomes for members and candidate members of the ASPS.[29] Since it began, data have been reported by more than 1200 surgeons, for over 1 million procedures.[42] Data are self-reported and include procedure characteristics, clinical characteristics, and 30-day outcomes of interest to the plastic surgeon. Participation is voluntary and lacks financial incentives.

Patient Population

TOPS 2008–2011 dataset was queried for all patients undergoing immediate breast reconstruction. Patients undergoing autologous breast reconstruction were identified by Current Procedural Terminology codes 19361 (latissimus dorsi), 19364 (free flap), and 19367–19369 (pedicled Transverse Rectus Abdominus Myocutaneous [TRAM]). Patients undergoing prosthetic reconstruction were identified by Current Procedural Terminology code 19357. Procedures marked as "revisions" were excluded from analysis. In addition, patients marked as under 18 years old at the time of procedure, patients with outlier body mass index (BMI) of less than 10 or over 100, and duplicate cases were excluded from the cohort. Finally, patients without necessary preoperative data were excluded to allow for a robust analysis.

Clinical Characteristics and Outcomes

Variables of clinical interest tracked by TOPS include age, BMI, smoking status (30-day and lifetime), diabetes, and American Society of Anesthesiology (ASA) class. Outcomes of interest in this study were seroma, dehiscence, SSI, partial (10–90% of flap) or full flap loss, explantation (in the prosthetic cohort), and reoperation. SSI was defined as a superficial, deep, or organ space infection at the donor or recipient site. Flap failure was defined as partial (10–90%) or full (>90%) loss of the transferred tissue. More detailed information can be found in the TOPS Datapoint Definitions manual.[44] For each complication, incidence was determined within each modality and within the population as a whole. Clinical characteristics of patients with a complication and those without one were compared using chi-square tests (Table 1). *P* values reported are two-sided, with a threshold of statistical significance at <0.05.

Table 1. Clinical Comparison of Patients With Complications and Those Without

	No Complication		Any Complication		
	n = 3732		*n* = 707		
	n	%	*n*	%	*P*
Age*†	51.1 (44, 58)		51.9 (45, 59)		0.046
BMI*†	26.8 (22.6, 29.6)		28.9 (23.7, 33.0)		<0.001
Smoking					
Former smoker*	477	12.78	112	15.84	0.002
Current smoker*	321	8.60	79	11.17	0.001
Diabetes*	134	3.59	46	6.51	0.002
ASA > 2*	268	7.18	78	11.03	<0.001
Modality					
Tissue Expander*	2946	78.94	447	63.22	<0.001
Latissimus*	251	6.73	65	9.19	
Pedicled TRAM*	339	9.08	141	19.94	
Free Flap*	196	5.25	54	7.64	

*Statistical significance at $P < 0.05$. With respect to "modality," this indicates that there is a statistically significant difference between the cohorts in the distribution of patients across reconstruction types.
†Continuous variables, which were analyzed using Mann-Whitney *U* tests and reported as mean (25th percentile, 75th percentile).

Risk Modeling

A random-intercept fixed-slope generalized linear model was used to estimate the risk for each of the 6 outcomes of interest, plus one for overall complications. All clinical characteristics in Table 1 were included in each model. Each risk model was used to calculate a predicted probability for its respective complication for each patient. Statistical analyses were performed using SPSS version 21.0 (IBM, Armonk, NY) and R version 3.0.1 (R Foundation for Statistical Computing, Vienna, Austria).

Risk Model Performance and Validation

Hosmer-Lemeshow statistics and *c*-statistics were ascertained to assess the calibration and discriminatory capacity of each model, respectively.[45] Bootstrapping allows for the validation of a logistic regression model using the same dataset from which it was derived. It outperforms other commonly used validation methods.[45–47] Bootstrapping with 1000 iterations was used to provide optimism-corrected *c*-statistics which, taken with uncorrected *c*-statistics, validate or nullify the discriminatory ability of each model. Additionally, model accuracy was validated with the Brier score.[39]

Risk Calculator

Each model was used to develop a calculator of predicted probabilities of its respective complication, using the inverse logit function: Probability $= 1/(1 + e^{-}\beta)$, where β is equal to the model constant plus the covariates unique to a given patient. The online calculator (http://www.BRAScore.org) accepts clinical characteristics and provides predicted probabilities for each complication within each modality (Fig. 1).

This work is based on the TOPS program, which provides HIPAA-compliant, deidentified databases to members and candidate members of the ASPS.

RESULTS

Cohort Characteristics

A total of 11,992 prosthetic and autologous procedures were identified in the TOPS database files between 2008 and 2011. Four thousand four hundred thirty-nine met all inclusion criteria above and had no missing perioperative data. Of these, 3393 were prosthetic, 308 latissimus, 435 pedicled TRAM, and 230 free flaps. Overall incidence of complications was 3.4% for seroma, 4.0% for SSI, 6.1% for dehiscence, 3.7% for explantation, 7.0% for flap loss, and 6.4% for reoperation. Patients who experienced a complication were widely different from those who did not, in terms of clinical characteristics (Table 1).

Model Development and Risk Distribution

Seven binary logistic regression models were developed on the basis of the clinical characteristics displayed in Table 1. These models take into account 5 covariates in addition to reconstructive modality to determine a patient's probability of a given outcome: age, BMI, smoking status, diabetes, and ASA class of greater than 2. The models themselves, represented by their β values and intercepts, are displayed in Table 2. The minimum and maximum predicted probabilities are juxtaposed against the average or population-based risk estimate in Table 3. The broad spread of these values indicates that the population risk significantly over- or underestimates the risk for individual patients.

Model Performance

The model characteristics for that of each complication are shown in Table 4. The Hosmer-Lemeshow statistics showed all the models to be well calibrated (range, 0.167–0.609). The Brier score, which is 0

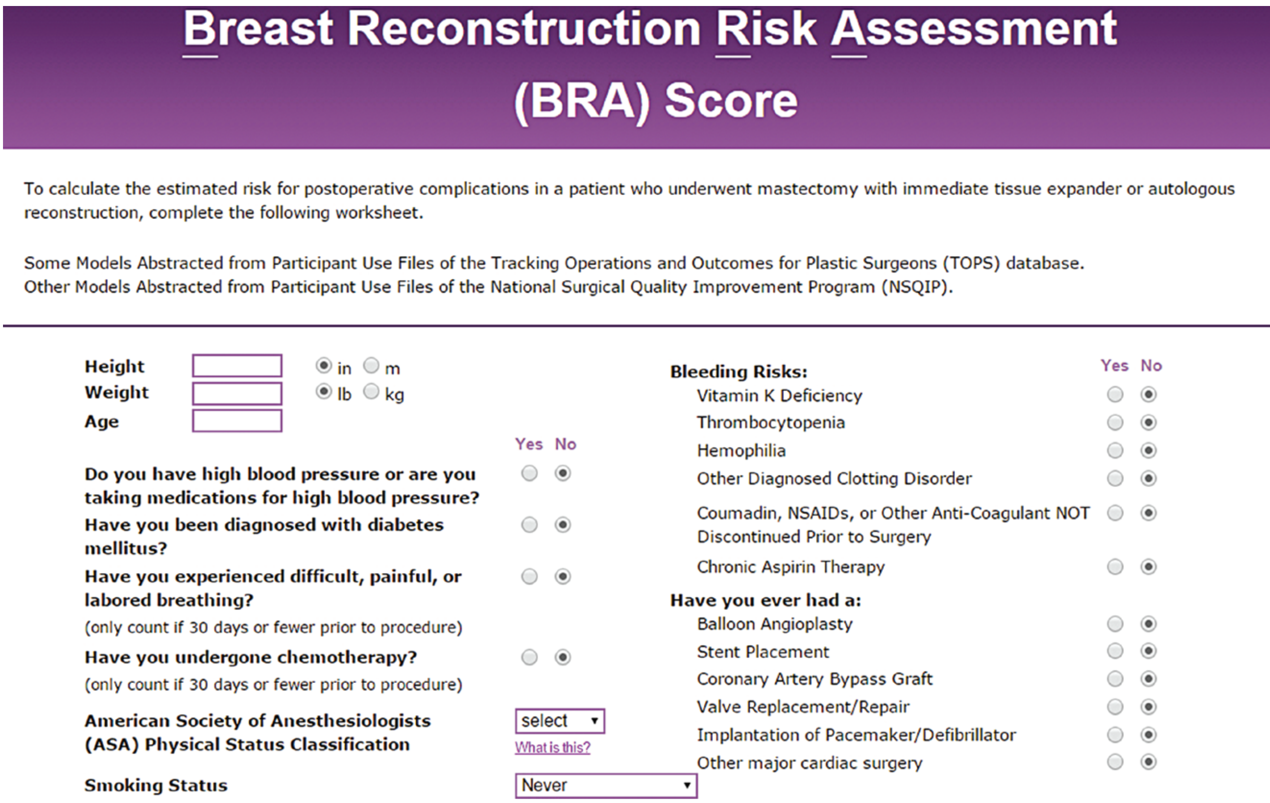

Fig. 1. Screen capture of online user interface upon populating all fields with relevant clinical characteristics, the user may click the "Calculate Risk" button and the breakdown of complication risk by reconstructive modality will appear.

Table 2. Betas for Each Predictive Model

	β Value within Model						
Characteristic	**Seroma**	**Dehiscence**	**SSI**	**Flap Loss***	**Explantation**	**Reoperation**	**Overall Complications**
Age (per year)	0.007	0.000	0.002	0.014	0.012	0.019	0.005
BMI (per point)	0.033	0.050	0.071	0.018	0.082	0.041	0.048
Former smoker	0.256	0.154	−0.345	0.899	−0.477	0.086	0.254
Current smoker	−0.218	0.666	0.344	0.515	0.202	0.572	0.450
Diabetic	0.141	0.074	0.294	0.588	0.435	−0.086	0.201
ASA > 2	0.436	0.364	0.185	0.218	−0.175	−0.338	0.216
Modality							
Latissimus	1.193	0.328	−0.208	—	—	−0.319	0.520
TRAM	0.565	1.390	0.092	1.399	—	0.503	0.965
Free flap	0.413	0.549	−0.745	1.303	—	0.607	0.589
Constants	−4.957	−4.581	−5.277	−5.181	−6.190	−4.949	−3.576

*Flap failure model uses latissimus as a reference, all others use tissue expander.

in an ideal model, ranged from 0.007 for the overall complication model to 0.063 for the flap failure model. Bootstrap validation yielded optimism-corrected *c*-statistics ranging from 0.603 for the reoperation model (0.612 uncorrected) to 0.677 for the flap failure model (0.699 uncorrected). Figures 2 and 3 consist of plots depicting observed versus expected outcomes for each model. Recent literature on risk modeling suggests that *c*-statistics in isolation may not represent a reliable measure of a model's validity.[47–48,52] Specifically, for models with more homogenous cohorts, like the current examination of only one procedure, the *c*-statistic must be considered with other measures of predictive power.[53] The optimism-corrected *c*-statistics demonstrate internal validity of all models. Further, Brier scores demonstrate predictive accuracy of all models.

Risk Calculator

These models served as the basis for an interactive risk calculator, which is freely available at http://www.BRAScore.org. The estimated risk of any of the

Table 3. Overall Incidences and Range of Predicted Probabilities

Complication	Overall Incidence (%)	Minimum Probability (%)	Maximum Probability (%)
Seroma	3.37	1.21	22.24
SSI	3.96	0.87	29.89
Dehiscence	6.13	2.22	50.19
Flap failure	7.0	1.24	50.57
Explantation	3.7	1.14	52.08
Reoperation	6.42	1.79	23.01
Overall	15.92	6.84	62.50

Minimum probability indicates the lowest predicted probability in the sample from which the models were derived. Maximum indicates the highest.

Table 4. Predictive Model Characteristics

Complication	H-L Statistics	*c*-Statistics	Optimism Corrected *c*-Statistics	Brier Score
Seroma	0.609	0.655	0.631	0.032
SSI	0.349	0.659	0.637	0.038
Dehiscence	0.167	0.672	0.661	0.055
Flap failure	0.230	0.673	0.632	0.063
Explantation	0.399	0.684	0.670	0.035
Reoperation	0.633	0.623	0.606	0.059
Overall complication	0.374	0.644	0.639	0.128

complications analyzed takes on a wide range of values that depend on patient-specific factors. The BRA score Web site allows patient and surgeon to input these factors into a calculator to ascertain the estimated risk of seroma, SSI, dehiscence, flap failure, explantation, and reoperation. Figure 1 represents the online platform. Example risk estimates taken from this online interface for 2 hypothetical patients are depicted in Figures 2 and 3. Figure 2 represents a relatively healthy patient who is 45 years old, has a BMI of 19.4 (5′6″ 120 lbs), has no history of smoking or diabetes, and has an ASA class of 1. Figure 3 represents a relatively ill patient, who is 70 years old, has a BMI of 32.3 (5′6″ 200 lbs), has a history of smoking and diabetes, and has an ASA class of 3. These illustrate the difference in risk that exists both between patients and between procedures within the same patient.

DISCUSSION

In recent years, several evidence-based risk calculators have come into clinical use.[49–51,54,55] Population-based estimates may not reflect the true magnitude of risk for patients at either extreme of the comorbidity spectrum, and the advantage of a risk calculator lies in its quantitative assessment of risk that is patient-specific. This obviates the need to rely on an impression that a patient is "low risk" or "high risk" and allows for a more precise dialogue between patient and surgeon. Further, the role of empirical and individualized data in surgical decision making and informed consent is growing increasingly important.[42,56,57] Faced with the absence of a risk calculator for breast reconstruction, we previously developed the BRA score, an online risk calculator for SSI and medical complications, using the NSQIP database.[40,41] Our goal in the current study is to expand on that model, using the TOPS database to add a risk calculator for surgical complications to the online interface.[43]

The clinical utility of this calculator to the reconstructive surgeon is best exemplified by the concrete clinical examples seen in Figures 2 and 3, which display risk profiles taken from the online interface for 2 hypothetical patients with different clinical characteristics. Figure 2 represents a 45-year-old patient with a BMI of 19.4, no history of smoking or diabetes, and an ASA class of 1. It is clear to us that this patient has a low risk of flap failure compared to the population average of 7.0% (Table 3). However, she would likely grasp the concept better if given a more granular estimate, for example, that her risk of failure with a latissimus flap is only 1.47% (Fig. 2).

Figure 3, on the other hand, represents a 70-year-old patient with a BMI of 32.3, a history of diabetes and smoking, and an ASA class of 3. Again, "intuition" tells us that she is at higher risk—but how high a risk? The pitfall of population-based risk is that we could inaccurately underestimate her individualized risk, in this case 27.7% for TRAM flap failure, a figure almost 5 times that of the population mean 7.0% (Table 3). Further, this risk is cut by two thirds when using a latissimus flap, with a failure risk of 9.1% (Fig. 3). In a case such as this, the resultant risk estimates may aid not only in the choice of flap type but also in the choice to delay or forego reconstruction.

Finally, the potential issues with overreliance on surgical intuition can come into play when there are patients with mixed risk profiles, for instance, how would we manage expectations in patients with a healthy gestalt profiles, but a single comorbidity? How do the vectors of risk in such a situation balance out? Quantitatively, this may be difficult to accurately assess and communicate. Further, a corollary to this is the question of how multiple risk factors interact. For example, what is the additive risk for someone with smoking history, diabetes, and obesity, and can we be more precise in capturing this summative risk? These questions and the hypothetical patients in Figures 2 and 3 highlight the importance of individualized risk scoring, and a simple and concrete tool such as the BRA score can facilitate decision making on the part of the surgeon and management of expectations on the part of the patient.

Estimated Risk of Complication:

Outcome	Reconstructive Modality			
	Tissue Expander	Pedicled Abdominal (TRAM) Flap	Latissimus Flap	Microvascular Reconstruction
Overall Medical Complications[1]	1.08%	3.98%	1.49%	8.15%
Overall Surgical Complications[2]	8.16%	18.90%	13.00%	13.80%
Surgical Site Infection[1]	1.61%	2.61%	1.19%	2.70%
Seroma[2]	1.22%	2.13%	3.93%	1.84%
Dehiscence[2]	2.63%	9.77%	3.61%	4.46%
Flap Loss (Partial or Total)[2]	n/a	5.40%	1.47%	5.22%
Explantation[2]	1.69%	n/a	n/a	n/a
30-Day Reoperation[2]	3.56%	5.75%	2.61%	6.34%

[1] Abstracted from NSQIP data
[2] Abstracted from TOPS data

Fig. 2. Risk output: healthy patient predicted probability of each complication for a 45-year-old patient with a BMI of 19.4 (5′6″ 120 lbs), no history of smoking or diabetes, and an ASA class of 1.

Estimated Risk of Complication:

Outcome	Reconstructive Modality			
	Tissue Expander	Pedicled Abdominal (TRAM) Flap	Latissimus Flap	Microvascular Reconstruction
Overall Medical Complications[1]	2.45%	8.69%	3.35%	16.91%
Overall Surgical Complications[2]	30.80%	53.88%	42.81%	44.51%
Surgical Site Infection[1]	7.56%	11.79%	5.65%	12.16%
Seroma[2]	2.44%	4.22%	7.62%	3.64%
Dehiscence[2]	13.44%	38.39%	17.73%	21.18%
Flap Loss (Partial or Total)[2]	n/a	27.69%	9.12%	26.97%
Explantation[2]	9.61%	n/a	n/a	n/a
30-Day Reoperation[2]	10.46%	16.19%	7.82%	17.65%

[1] Abstracted from NSQIP data
[2] Abstracted from TOPS data

Fig. 3. Risk output: ill patient predicted probability of each complication for a 70-year-old patient with a BMI of 32.3 (5′6″ 200 lbs), a history of diabetes and smoking, and an ASA class of 3.

The individual risk calculator based on the NSQIP database has strengths and weakness, and the TOPS database complements some of the weaknesses by providing surgical complications of particular interest to plastic and reconstructive surgeons. The TOPS database offers more granular complication data, including complications of particular interest to plastic and reconstructive surgeons. To our knowledge, this is one of the largest studies to examine surgical outcomes in breast reconstruction and the first study to provide a risk calculator for many of these surgical complications. The current analysis used 4439 patients from the TOPS database to augment the BRA score with a calculator for seroma, dehiscence, SSI, flap failure, explantation, and reoperation, as depicted in Figures 1–3. Average risk of each surgical complication in the overall cohort is displayed in Table 3. When comparing the TOPS rates with those of previous studies, the incidence of each complication was similar.[6–28] The rates of SSI, reoperation, and dehiscence, 3 variables also tracked in NSQIP, were comparable to past studies using that database.[32–36,40] There was some variation between procedure type, in keeping with recent literature.[9,13,26,27,35] More telling, though, is the wide range of predicted risk. The mean probability of each complication lies in the midst of a broad distribution of predicted probabilities. Table 3 provides a numeric summary of the range for each, along with the mean probabilities (baseline incidence) for comparison. Although population-based means have an important role in benchmarking outcomes for cross-institutional comparison, it is clear that they grossly over- or underestimate risks for an individual patient. The range of predicted probabilities implies that most patients have their risk overestimated by the mean, whereas the outliers with the highest risk have their risk underestimated. For example, the rate of flap failure was 7.0% overall in the autologous cohort. Were this reported to a relatively young and healthy individual, it may be up to a 6-fold overestimate of her actual risk (minimum predicted probability was 1.2%). Conversely, were it reported to a relatively elderly and ill patient, it may be up to a 25-fold underestimate of her actual risk (maximum predicted probability was 50.6%).

There are some limitations to the BRA score and the TOPS database that need to be addressed. First, although TOPS has significant complication data that were previously unavailable in this magnitude, no large registry can capture all variables of interest to the specific procedures it tracks. For example, radiotherapy, hypertension, and surgeon experience would have made useful additions to the models, as they have been shown to alter risk of adverse outcomes in the context of both prosthetic and autologous breast reconstruction.[23,25–27] Additionally, TOPS database classification precludes more specific classification of each reconstruction (eg, deep inferior epigastric perforator vs muscle-sparing TRAM) and control for mastectomy type. The BRA score was created with the goal of continuous improvement and developed to be easily modifiable, and any more granular information can be incorporated as it becomes available. Another limitation is the 30-day time course over which complications are tracked. While explantation and reoperation are 2 complications that may occur after this window, the authors feel that they remain adequately captured, particularly in the setting of emerging penalties for complications within this window. Finally, although these models were shown to be internally valid using the database from which they were derived, the ultimate test of their usefulness in clinical practice will come from analyzing their predictive power in other cohorts, a study that is currently under way.

Surgical complications lead to significant excesses in healthcare costs, length of hospital stay, and patient morbidity.[6,26] Furthermore, hospital penalties for readmission, a common endpoint of many of these complications, are already in effect.[57] For most patients, the risk is small. However, it is the outliers with high comorbidity burden for whom these calculators have the greatest clinical significance, allowing them to be identified and managed appropriately. The current analysis successfully used the robust cohort in the TOPS database to build on the previous BRA score with an individualized risk calculator for surgical complications: seroma, dehiscence, SSI, flap failure, explantation, and reoperation.

CONCLUSIONS

Management of expectations and honest, frank discussions of risk are a central tenet of the dialogue between patient and surgeon. The BRA score generated from the TOPS database follows the new and developing trend of moving beyond population-based metrics to a more individualized and quantitative discourse of risk and benefit. With the increasing emphasis on evidence-based medicine and quality measures, such individualized risk analysis can facilitate a better-informed discussion for our breast reconstruction patients.

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