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# Plastic Surgeon Compliance with National Safety Initiatives: Clinical Outcomes and “Never Events”

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**Background:** Venous thromboembolism and surgical-site infection have been identified as preventable complications that are addressed by the National Quality Forum and the Surgical Care Improvement Project. The authors examined compliance of faculty with venous thromboembolism and surgical-site infection prophylaxis and incidence of adverse outcomes in patients at risk.

**Methods:** The authors performed retrospective chart reviews on 243 patients who underwent abdominoplasty or panniculectomy from 2000 to 2007 and documented demographics and adverse outcomes. Analysis was completed using Pearson’s chi-square and Fisher’s exact test for categorical variables. Significance was set at  $p < 0.05$ . Obesity was defined as body mass index more than 30 and morbid obesity was defined as body mass index more than 40.

**Results:** Of 243 patients, 144 (59 percent) were obese. Seventeen patients (7 percent) suffered complications. All 243 patients received at least one form of venous thromboembolism prophylaxis. One patient had a deep venous thrombosis, and two had pulmonary embolism. These three patients were morbidly obese. Seventy-four percent of patients received appropriate antibiotics. Thirteen patients (5.3 percent) developed significant postoperative infection requiring hospitalization, 12 (92 percent) of whom received appropriate antibiotics. Eleven of these 13 patients (85 percent) were obese, and seven (54 percent) were morbidly obese. Obesity proved to be the only significant risk factor ( $p > 0.05$ ).

**Conclusions:** Despite very good compliance with safe practice initiatives, significant adverse outcomes occurred. Obesity was the only pervasive risk factor. This study highlights the potential need for compliance with quality measures and demonstrates that adverse outcomes may result despite adherence to best surgical practices. (*Plast. Reconstr. Surg.* 126: 653, 2010.)

Over the past decade, there has been increasing focus in medicine on issues regarding patient safety and quality. In 1999, the Institute of Medicine published “To Err Is Human,” which reported 98,000 preventable deaths per year attributed to medical errors.<sup>1</sup> Recommendations were provided for improvement of care, in-

cluding raising performance standards and implementing systems to promote safety at the level of the individual provider.

The National Quality Forum is a not-for-profit organization consisting of members from all areas of the health care system at the national, state, and local levels, including consumers, employers, providers, health plans, and accrediting bodies. Among the many practice initiatives identified by the National Quality Forum are reduction of venous thromboembolism with the use of appropriate prophylaxis and prevention of surgical-site infection. The Surgical Care Improvement Project, proposed by the Centers for Medicaid & Medicare

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Services and the Centers for Disease Control and Prevention, which includes the American College of Surgeons, the Joint Commission, the American Society of Anesthesiologists, and more than 30 other organizations, identified four areas of preventable surgical complications, including venous thromboembolism, surgical-site infection, adverse cardiac events, and adverse respiratory events.

Given the comparable focus of these two major national quality consortiums, we designed a project to examine the compliance of the clinical faculty in an academic community hospital with the initiatives for venous thromboembolism and appropriate antibiotic prophylaxis. Our institution has made significant investments in process improvement projects and information technology since the Institute of Medicine report.<sup>1</sup> Even though the actual quality initiatives under consideration were not established until 2003 and later, our institution had already introduced processes to address these issues as early as the year 2000. Therefore, compliance with these initiatives and adverse outcomes were studied in patients undergoing two procedures of equivalent severity (i.e., abdominoplasty or panniculectomy).

## PATIENTS AND METHODS

Institutional review board approval was obtained to perform a retrospective chart review, with patient identifiers removed from our data. Our database was queried for Current Procedural Terminology codes 15830, 15831, and 15847 for patients who underwent either cosmetic abdominoplasty or reconstructive panniculectomy by one of two board-certified attending plastic surgeons who used similar perioperative protocols. In an 8-year period from 2000 to 2007, 243 patients were identified. These patients were considered to be at risk because of their increased body mass index, with obesity being defined as body mass index more than 30 and morbid obesity being defined as

body mass index more than 40. Other circumstances that placed these patients at risk included the need for prolonged general anesthesia and relative postoperative immobility. Data extraction included prior venous thromboembolism, body mass index, age, length of operative procedure, type of anesthesia, diabetes, oral contraceptive use, smoking history, use of venous thromboembolism and antibiotic prophylaxis, and adverse outcomes (e.g., deep venous thrombosis, pulmonary embolism, infection, hematoma). Statistical analysis was completed using Pearson's chi-square and Fisher's exact test for categorical variables. Significance was set at  $p < 0.05$ .

## RESULTS

Of the 243 patients in our population, 99 (41 percent) had a body mass index less than 30 and 144 (59 percent) had a body mass index more than 30. Seventeen patients (7 percent) experienced a perioperative complication (Table 1).

All patients received at least one form of venous thromboembolism prophylaxis in the perioperative period. One patient had a deep venous thrombosis (0.4 percent), and two had a pulmonary embolism (0.8 percent). All three patients who experienced thromboembolic complications were morbidly obese ( $p < 0.05$ ).

Seventy-four percent of patients received appropriate antibiotic prophylaxis. Before the National Quality Forum, our compliance rate was 61 percent; whereas before the Surgical Care Improvement Project, our compliance rate was 73 percent. However, after initiation of the National Quality Forum program, our compliance rose to 95 percent, whereas it rose to 87 percent after initiation of the Surgical Care Improvement Project. Thirteen patients (5.3 percent), 11 of whom were obese, developed a postoperative infection requiring hospital admission and intravenous antibiotic therapy. Of these 13 patients, 12 (92 percent) received appro-

**Table 1. Complications (n = 17)**

Complications	No.	BMI	Prophylaxis	Comments
DVT	1	>40	SCD plus chemoprophylaxis	
PE	2	>40	SCD plus chemoprophylaxis	
Surgical-site infection	13			4 MSSA, 3 MRSA, 3 <i>E. nterococcus</i> , 4 no culture documentation
	2	<30	1 of 2	
	4	>30	4 of 4	
	7	>40	7 of 7	
Death	1	>40	VTE = IVC filter plus SCD plus heparin SSI = yes	CHF

BMI, body mass index; DVT, deep venous thrombosis; SCD, sequential compression device; chemoprophylaxis, heparin or enoxaparin; PE, pulmonary embolism; MSSA, methicillin-sensitive *Staphylococcus aureus*; MRSA, methicillin-resistant *Staphylococcus aureus*; CHF, congestive heart failure.

appropriate antibiotic prophylaxis. Of the 10 documented wound cultures, four were positive for methicillin-sensitive *Staphylococcus aureus*, three were positive for methicillin-resistant *S. aureus*, and three were positive for *Enterococcus*.

Six patients required intervention in the intensive care unit. One perioperative mortality occurred in a morbidly obese patient (body mass index of 56.5) as a result of acute congestive heart failure. Five patients required postoperative intubation for respiratory failure, all of whom were morbidly obese (body mass index >55). Obesity was the only significant variable ( $p < 0.05$ ) for any of these complications, as there was no association between adverse outcome and any other identifiable risk factor.

## DISCUSSION

It is estimated that each year more than 900,000 Americans develop deep venous thrombosis, 500,000 of which experience pulmonary embolism, ultimately resulting in approximately 300,000 deaths.<sup>2</sup> This condition remains the most common preventable cause of hospital death. Current estimates suggest that less than 50 percent of patients diagnosed and hospitalized with deep venous thrombosis had received prophylaxis.<sup>2</sup> Surgical-site infection is second only to urinary tract infection in hospital-acquired infections and leads to significant patient morbidity and increased health care costs.

In 1999, the Institute of Medicine challenged health care organizations to decrease medical errors by 50 percent over the ensuing 5 years.<sup>1</sup> Since this call to action, there have been ever-increasing initiatives to improve patient care and safety, particularly for patients who are hospitalized or undergoing invasive procedures. To address this issue, the Centers for Medicaid & Medicare Services and the Centers for Disease Control and Prevention established the Surgical Care Improvement Project, with the goal of reducing preventable morbidity and mortality by 25 percent by the year 2010, beginning with the prevention of venous thromboembolism and surgical-site infection.<sup>3</sup> The National Quality Forum has endorsed similar safe practice initiatives. National Quality Forum Safe Practice 17 requires clinicians to evaluate patients at admission and thereafter for the risk of venous thromboembolism and use clinically appropriate prophylaxis. National Quality Forum Safe Practice 21 requires administration, when indicated, of prophylactic antibiotics within 1 hour before surgery and discontinuation within 24 hours of surgery end time.

In 2008, the American College of Chest Physicians released their consensus statement on ev-

idence-based guidelines for prevention of venous thromboembolism.<sup>4</sup> Multiple authors have addressed both venous thromboembolism and surgical-site infection prophylaxis in a manner applicable to plastic surgery patients.<sup>5-10</sup>

Leveraging institutional information systems has had a significant impact on compliance with quality initiatives and clinical outcomes. However, adherence to quality improvement and patient safety guidelines is not a panacea for prevention of surgical complications. Mosen et al.<sup>11</sup> showed an 89.9 percent rate of prophylaxis before implementation of a computerized reminder system; after implementation, this rate increased to 95 percent ( $p < 0.0001$ ). They also found that although there was increased delivery of preventive care, this did not lead to a decrease in venous thromboembolism rates; 87 percent of their 46 symptomatic venous thromboembolism occurred despite performance of the recommended measures (based on American College of Chest Physicians–recommended prophylaxis). Patients who experienced venous thromboembolism despite appropriate prophylaxis had additional significant risk factors. Similarly, the surgeons in our study were almost universally successful in complying with National Quality Forum and Surgical Care Improvement Project safe practice initiatives, and a significant number of postoperative complications still occurred, particularly in obese patients. Our study therefore highlights the myth of a “never event.” Although the profession of medicine may recognize this as a statistical impossibility, this truism seems to be at odds with current opinion embraced by the public and its agencies.

State governments have begun to become involved in overseeing issues such as the prevention of surgical-site infection as a cause célèbre. The Pennsylvania Act 52, the Medical Care Availability and Reduction of Error Act—Reduction and Prevention of Health Care–Associated Infection and Long-Term Care Nursing Facilities, instituted in 2007, requires certain health care facilities to report health care–associated infections to the Pennsylvania Department of Health, the Pennsylvania Health Care Cost Containment Council, and the Pennsylvania Patient Safety Authority through the Centers for Disease Control and Prevention’s National Healthcare Safety Network. The Act was part of Governor Rendell’s “Prescription for Pennsylvania” plan to reduce and eliminate health care–associated infections.

Society’s view that issues such as surgical-site infection and venous thromboembolism should be preventable complications has a significant impact on the medical profession as reflected in the

decision that was rendered in August 5, 2008, by the Supreme Court of Missouri in the case of an occurrence of a “never event.” In *Sides v. St. Anthony Medical Center*, the Supreme Court of Missouri held that a plaintiff may file a malpractice case under the theory of *res ipsa loquitur* based on the occurrence of a postoperative infection. This is significant because most states have ruled that a postoperative infection could not give rise to an inference of negligence unless the plaintiff could prove that the infection would not have occurred in the absence of negligence. The court further ruled that expert testimony can be offered that the post-surgical-site infection would not have occurred without negligence. This is significant because the burden of proving negligence as the cause of a postoperative infection was a difficult hurdle for a plaintiff to overcome.<sup>12</sup>

Furthermore, as of October 1, 2008, the Centers for Medicaid & Medicare Services will no longer pay for deep venous thrombosis and pulmonary embolism following certain orthopedic procedures and surgical-site infection following bariatric surgery for treatment of obesity. This report emphasized not only the cost of patients’ lives as a result of medical errors, but also the cost of additional health care and the loss of income and productivity.

The population reflected in our study allowed for a reasonable comparison between the non-obese abdominoplasty patient and the obese panniculectomy patient. Obesity is a national health care crisis of epidemic proportions. Our study documented the fact that obese patients will experience complications despite adherence to best practice medicine. If a situation evolves wherein there is complete compliance with safe practice guidelines and a venous thromboembolism/surgical-site infection event occurs, will the misnomer of a never event be revisited by society to ensure that physicians are not penalized and by the Centers for Medicaid & Medicare Services so that providers are appropriately compensated? Alternatively, if it is society’s fiat that certain complications are never events and not to be tolerated, will society accept the possibility that certain interventions may not be offered to patients who are at risk for these never events? Renewed vigilance on patient selection and significance of presenting complaints will be required.

### CONCLUSIONS

In our series, body mass index more than 30 was the single most important risk factor for venous

thromboembolism and surgical-site infection. Despite good compliance with quality and safety outcome measures in this plastic surgery population at risk, several adverse outcomes occurred. This study highlights the potential need for increased compliance with these quality measures and documents the fact that adverse outcomes may result even with adherence to best surgical practices.

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