

Analysis of Outpatient Surgery Center Safety Using an Internet-Based Quality Improvement and Peer Review Program

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Assessing the quality of care delivered in office-based outpatient surgery centers is difficult because formerly there was no central data collection system. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), in its ongoing effort to assess and improve patient care, has developed an Internet-based quality improvement and peer review program to analyze outcomes for surgery centers it accredits. Reporting is mandatory for all surgeons operating in AAAASF-accredited facilities. Each surgeon must report all unanticipated sequelae and at least six random cases reviewed by an accepted peer review group biannually. A total of 411,670 procedures were analyzed during a 2-year period (from 2001 to 2002). There were 2597 sequelae reported during this period. The most common sequela was hematoma formation following breast augmentation. Infection occurred in 388 cases. Deep vein thrombosis, pulmonary embolism, and intraoperative cardiac arrhythmias were found to occur in a frequency consistent with previous reports. Significant complications (hematoma, hypertensive episode, wound infection, sepsis, and hypotension) were infrequent. A total of 1378 significant sequelae were reported for 411,670 procedures. This calculates to one unanticipated sequela in 299 procedures (an incidence of 0.33 percent). Seven deaths were reported. A death occurred in one in 58,810 procedures (0.0017 percent). The overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited office surgery facility or a hospital surgery facility.

This study documents an excellent safety record for surgical procedures performed in accredited office surgery facilities by *board-certified surgeons*. (*Plast. Reconstr. Surg.* 113: 1760, 2004.)

The number of outpatient surgery centers and physician office-based surgery facilities is escalating dramatically.^{1,2} This phenomenon is in direct response to the demand for safe, cost-effective surgical care for procedures that can be performed in an outpatient setting. There

are advantages to performing operations in an outpatient setting for both patients and surgeons, including convenience, patient privacy and comfort, consistency in nursing and support staff, and increased efficiency.³

The American Society of Anesthesiologists predicts that by the year 2005, an estimated 10 million procedures will be performed annually in doctors' offices—twice the number of office-based operations performed in 1995.⁴ This dramatic increase in the number of procedures performed in outpatient surgery centers has focused attention on the need for accreditation as a means of ensuring compliance with standards for their safe operation.^{5,6}

Currently, only 14 states have mandated accreditation of surgery centers. The number of states requiring accreditation or licensure to perform surgery in an outpatient setting will, and should, continue to increase, until accreditation becomes the national standard.

In the spring of 1999, recognizing the importance of accreditation, the American Society of Plastic Surgeons and The American Society for Aesthetic Plastic Surgery passed a joint mandate for all of their members stipulating that members who perform outpatient operations under sedation or general anesthesia do so in an accredited or state-licensed facility.⁷ Accredited or licensed outpatient surgical facilities must meet at least one of the following criteria⁷:

- Be accredited by a nationally recognized or state-recognized accrediting agency or organization, such as the American

Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care, or the Joint Commission on the Accreditation of Healthcare Organizations.

- Be certified to participate in the Medicare program under Title XVII.
- Be licensed by the state in which the facility is located.

MONITORING SURGERY CENTER MANAGEMENT

Design and management of a surgery center require compliance with nationally recognized standards to safeguard patient care. Ongoing monitoring of care delivery is vital to ensure patient safety. However, it is difficult to compile and compare the data documenting care delivery. This difficulty is a consequence of lack of centralization of data collection from the multiple accrediting, licensing, and managing entities of outpatient surgical facilities. As a result, there is little available coordinated information concerning ultimate outcomes of outpatient surgery in nonhospital settings.

Since 1982, AAAASF, the largest organization in the United States that accredits single or multispecialty office-based surgery centers, has been at the forefront of developing safety standards for the operation of outpatient surgery centers and coordinating relevant data. In 1996, AAAASF conducted a voluntary survey of all of their accredited surgery centers to assess outcomes of surgical care. The directors of all the surgery centers were asked to fill out questionnaires about unanticipated sequelae that occurred in their facilities. Of the 418 facilities accredited at that time, 241 (57.7 percent) returned the anonymous questionnaires, a very high response rate. In 1997, Morello, Colon, Fredricks, Iverson, and Singer published a review of this survey, entitled "Patient Safety in Accredited Office Surgical Facilities."⁸

The following findings were of interest:

- 400,675 operative procedures were reported during a 5-year period from January 1, 1989, to December 31, 1993.
- Significant complications (hematoma, hypertensive episode, wound infection, sepsis, and hypotension) were infrequent, numbering 1877, for an occurrence of one in every 213 cases, or 0.47 percent.
- Return to the operating room within 24 hours and precautionary hospitalization were less frequent.

- Seven deaths were reported. A death occurred in one in 58,810 procedures (0.0017 percent). The overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited office-based surgery facility or a hospital surgery facility.^{8,9}

This study documented an excellent safety record for surgical procedures performed in accredited office-based surgery facilities by board-certified surgeons.

QUALITY IMPROVEMENT AND PEER REVIEW

The goal of a surgery facility is to provide the highest level of care delivery. The facility, whether office-based, free-standing, or in a hospital, should provide care with positive outcomes and a reduced incidence of unanticipated sequelae. In an effort to improve quality of patient care, AAAASF designed and adopted the first Internet-based reporting system for quality improvement and peer review. The purpose of the Internet system was twofold: to improve monitoring of random case review and unanticipated sequelae and to facilitate collation and analysis of the data acquired. This system has provided AAAASF with the ability to more precisely evaluate outcomes.

The guidelines for using this new reporting system follow AAAASF standards,⁹ which require facilities to institute an ongoing quality improvement program that (1) monitors and evaluates the quality of patient care, (2) evaluates methods to improve patient care, (3) identifies and corrects deficiencies within the facility, and (4) alerts the medical director to identify and resolve recurring problems.

Peer review must be performed every 6 months and must include reviews of both random cases and unanticipated operative sequelae. If peer review sources external to the facility are used to evaluate delivery of surgical care, the patient consent form is so written as to protect confidentiality of the medical records, consistent with current legal standards. Peer review is performed either by a recognized peer review organization or by a physician other than the operating surgeon.

A minimum of six random cases per surgeon utilizing the facility must be reviewed, and for group practices, 2 percent of all cases performed must be reviewed every 6 months. These random case reviews must include assessment of the following: (1) thoroughness and legibility of the history and physical exam-

ination; (2) adequacy and appropriateness of the surgical consent form; (3) presence of appropriate laboratory, electrocardiographic, and radiographic reports; (4) presence of a dictated operative report or its equivalent; (5) anesthesia record for operations performed with intravenous sedation or general anesthesia; (6) presence of instructions for postoperative and follow-up care; (7) and documentation of unanticipated sequelae.

All unanticipated operative sequelae are reviewed, including, but not limited to the following: (1) unplanned hospital admission; (2) unscheduled return to the operating room for complication of a previous procedure; (3) untoward result of a procedure, such as infection, bleeding, wound dehiscence, or inadvertent injury to another body structure; (4) cardiac or respiratory problems during stay at the facility or within 48 hours of discharge; (5) allergic reaction to medication; (6) incorrect needle or sponge count; (7) patient or family complaint; (8) equipment malfunction leading to injury or potential injury to patient; and (9) death.

Each unanticipated operative sequela chart review includes the following information, in addition to the operative procedure performed: (1) identification of the problem; (2) immediate treatment or disposition of the case; (3) outcome; (4) analysis of reason for problem; and (5) assessment of efficacy of treatment.

The data obtained through the individual surgery center peer review meetings are then entered into the Internet quality improvement and peer review program.

Data obtained from 621 surgery centers from 2001 through 2002 were statistically analyzed. The AAAASF standards require a bound surgical log book be kept that records sequentially all operations performed. The first and last surgical log numbers of all reviewed random cases and unanticipated sequelae from a reporting period are entered into the Internet program with the reported data. This allows for the computation of the total number of cases performed per surgeon per period. In this study, 73 percent of reporting surgeons correctly entered their surgical log numbers. The average number of cases for those surgeons was assigned to the surgeons whose numbers were not correctly entered. The average case consisted of 1.37 procedures. Using this multiple, the total number of procedures reported for this study was 411,670.

A total of 2597 sequelae in 411,670 proce-

dures were reported. The standards for AAAASF require *all* unanticipated sequelae to be reported, including patient complaints, surgery cancellations, and a variety of sequelae deemed less significant than those reported by Morello et al.⁸

When analyzing data in this report comparable to data in the aforementioned article, a total of 1378 significant sequelae were reported in 411,670 procedures over a 2-year period (from 2001 to 2002). This calculates to one unanticipated sequelae in 299 procedures (an incidence of 0.33 percent) compared with one in every 213 cases, or 0.47 percent, for the Morello et al.⁸ article.

Recently, Byrd et al.² reported 35 unanticipated sequelae in 5316 cases. The 0.7 percent incidence of unanticipated sequelae in their study, conducted over a 6-year period, supports the incidence found in the current study.

ANALYSIS OF SEQUELAE

Table I lists the 1378 reported sequelae by type in descending order of frequency.

Hematoma

Hematoma was the most common unanticipated sequela reported in the study. There were a total of 740 hematomas reported, representing 28 percent of all sequelae or 0.18 percent of all procedures. The majority of hematomas ($n = 676$) were managed on an outpatient basis (Fig. 1). Sixty-four patients with hematoma required hospitalization

TABLE I
Sequelae*

Sequelae	No.
Hematoma	740
Infection	388
Necrosis	76
Cardiac events	29
Respiratory distress	20
Pneumothorax	19
Burn	19
Pulmonary embolism	17
Deep vein thrombosis	14
Hypotension/hypertension	16
Pulmonary edema	11
Allergic reaction	6
Cellulitis	6
Death	6
Hypoxia	5
Cardiac arrest	2
Chest pain	2
Hyperthermia	2

*Total number of sequelae = 1378.

676 Hematomas Managed on an Outpatient Basis

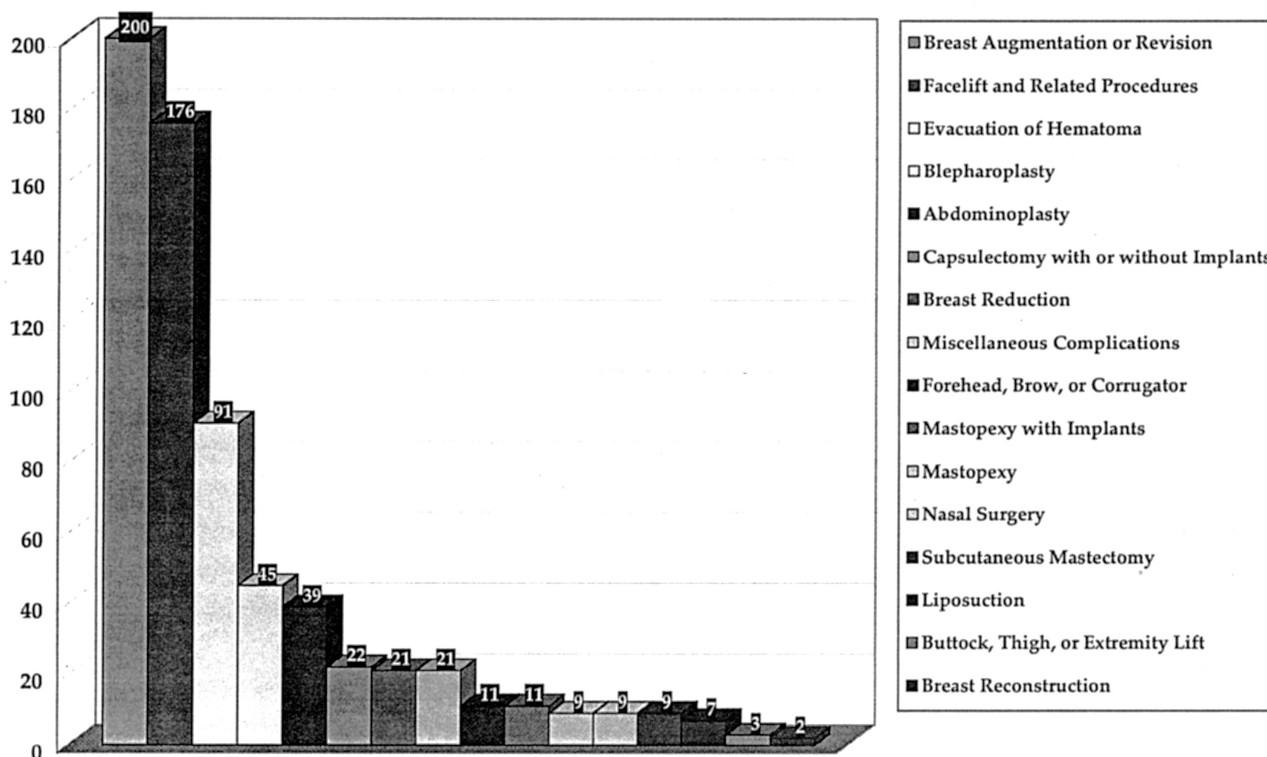


FIG. 1. Hematomas managed on an outpatient basis (n = 676).

64 Hematomas Managed on an Inpatient Basis

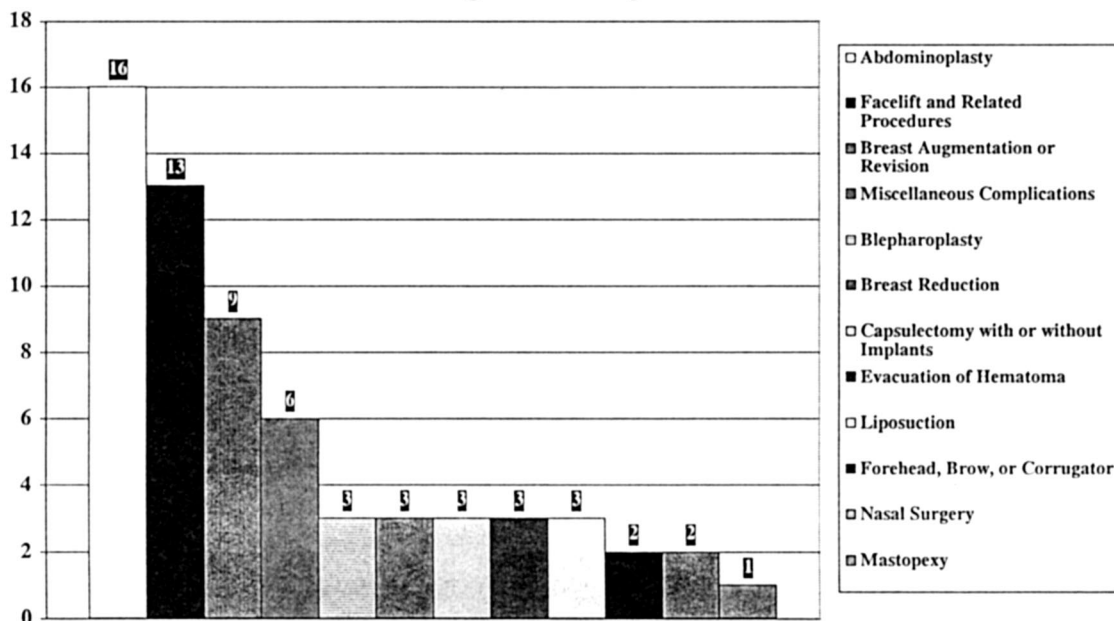


FIG. 2. Hematomas managed on an inpatient basis (n = 64).

(Fig. 2). Of those patients hospitalized, three patients were hospitalized for observation and had no surgical intervention. The aver-

age hospital stay for these patients was 1.38 days (range, 1 to 6 days).

Breast augmentation resulted in the largest

number of hematomas managed as outpatient cases ($n = 200$). Abdominoplasty accounted for the largest number of patients hospitalized with hematomas ($n = 16$). All hematomas were managed successfully without residual sequelae. No deaths were reported as the result of hematomas.

Morello et al.⁸ reported hematoma or bleeding episodes in 965 of the 400,675 operative procedures, or one in every 415 procedures (an incidence of 0.24 percent). Byrd et al.² reported that 77 percent of sequelae were hematomas, an incidence of 0.5 percent or one in 200 procedures. Natof¹⁰ performed a prospective study on 13,433 procedures with a follow-up of 14 days. Bleeding occurred in 74 patients, or one in 182 procedures (0.55 percent).

Infection

There were 388 infections reported, representing an incidence of 0.09 percent or one in 1061 procedures. A total of 348 patients had infections that were managed on an outpatient basis (Fig. 3). Forty of the patients who had

infections required hospitalization (Fig. 4). The average hospital stay for these patients was 5.1 days. The length of stay varied from 1 day to 21 days. All infections resolved with local wound care or a combination of antibiotics and local wound care.

Forty-eight patients had an infection associated with an implant that was eventually removed. Forty-three patients had breast implants removed, and five patients had chin or other facial implants removed. There were no deaths attributable to infection.

Interestingly, Morello et al.⁸ reported the same incidence of infection, 0.09 percent, for a frequency of one in 1145 procedures. Byrd et al.² reported six infections, an incidence of one in 886 procedures, or 0.11 percent. Natof's¹⁰ study reported 10 patients with postoperative infections for an incidence of one in 1343 procedures or 0.074 percent.

Cardiac-Related Sequelae

Cardiac events occurred in 29 patients (incidence of one in 14,196 cases, or 0.007 per-

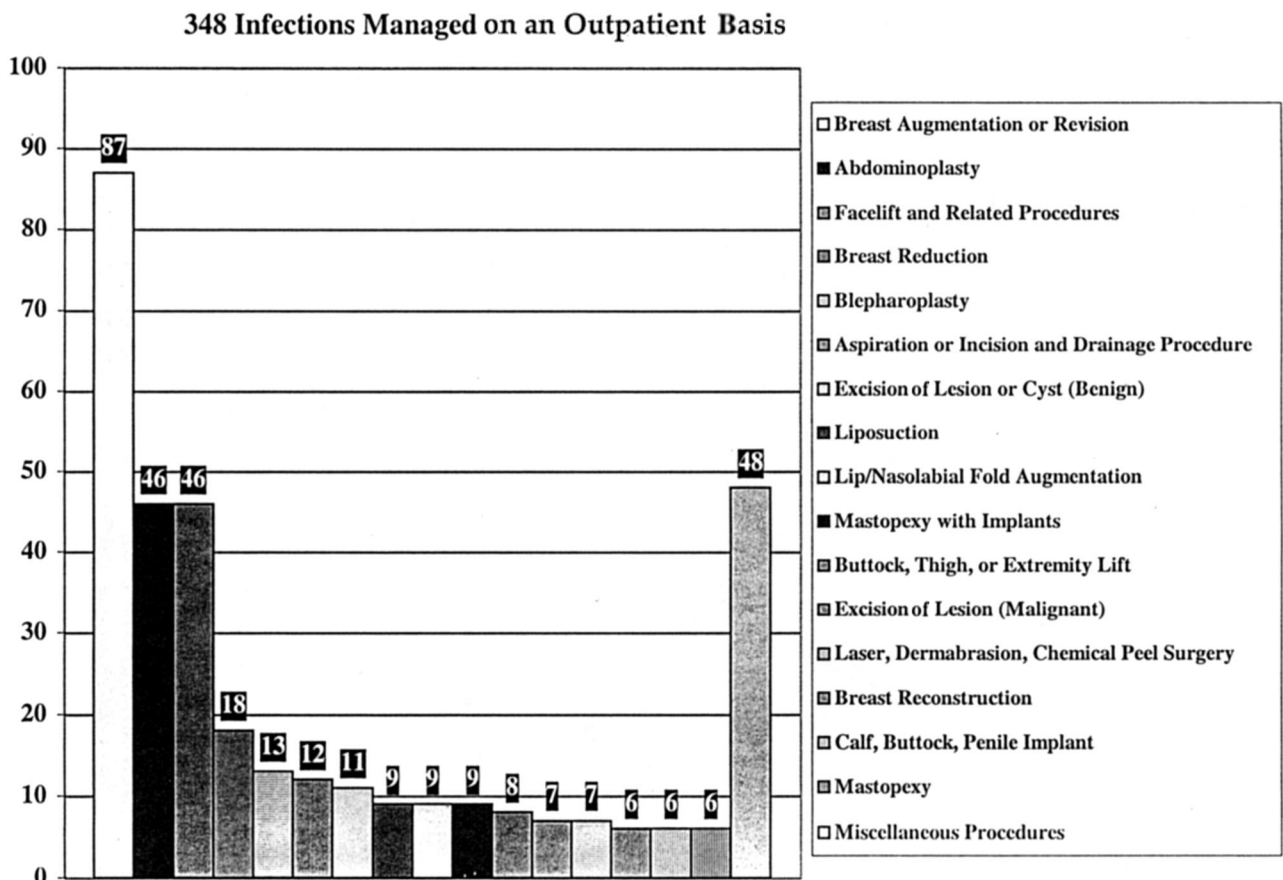


FIG. 3. Infections managed on an outpatient basis ($n = 348$).

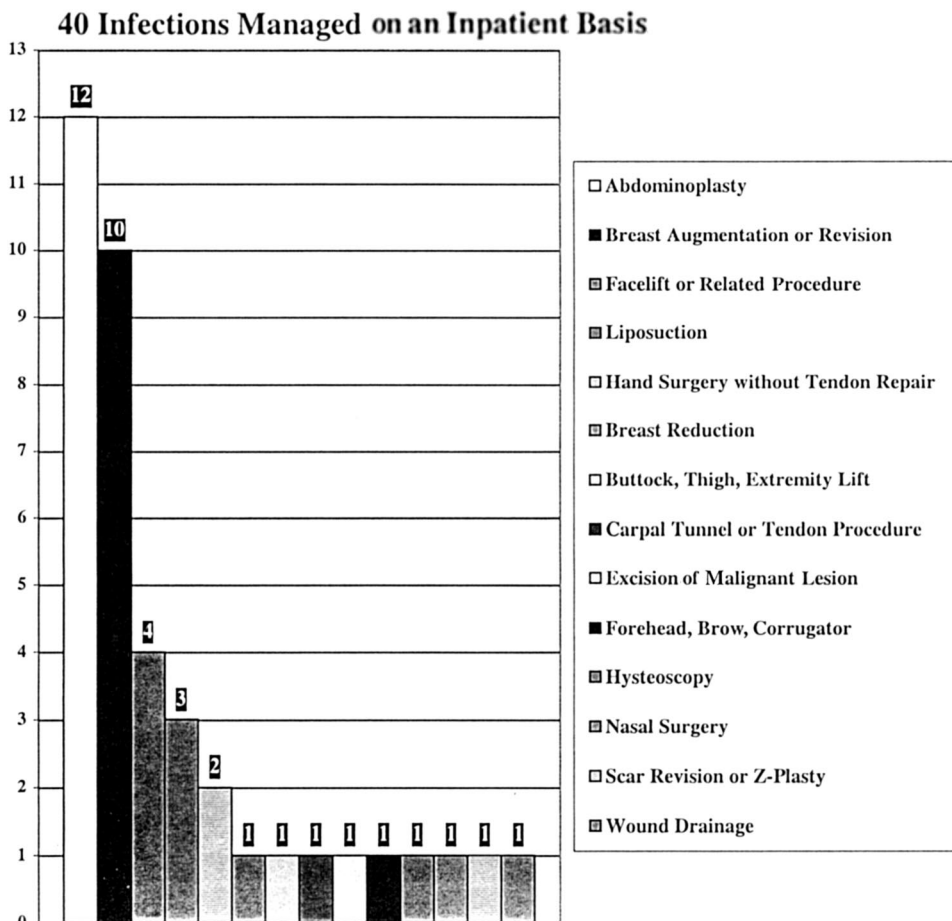


FIG. 4. Infections managed on and inpatient basis (n = 40).

cent). Twenty-seven patients had arrhythmias and two patients had cardiac arrests.

Of the two cardiac arrests, one patient became bradycardic, hypotensive, and unresponsive in the postoperative recovery room. A code was called and cardiopulmonary resuscitation, atropine, and epinephrine were administered. The patient was transferred to a hospital and admitted. Unresponsive and without spontaneous respiration, she was admitted to the cardiac care unit and placed on a respirator. After a 34-day hospital stay, the patient was discharged with some neurologic deficit.

The second patient was undergoing a face lift under intravenous sedation. It is believed that the patient had a myocardial infarction after becoming hypotensive intraoperatively. The patient was resuscitated, but immediately became bradycardic and was admitted to a hospital. She died after a 2-week hospital stay.

Fourteen of the patients with cardiac arrhythmias were hospitalized, with an average length of stay of 4 days (range, 0 to 34 days).

Two patients were reported to have had chest pain in the early postoperative period that was determined to be due to anxiety (Fig. 5).

Blood Pressure Alteration

The current study showed that nine patients developed notable hypertension intraoperatively. All of these patients responded to medical management. Hypertensive episodes occurred in 0.002 percent of cases. One of these patients had their surgery canceled and was referred for medical evaluation.

Seven patients, or 0.002 percent of all cases performed, had notable hypotensive episodes. Five of these patients were hospitalized for an average period of 2.1 days. Two patients received a blood transfusion. All patients recovered without residual sequelae (Fig. 6). In the Morello et al.⁸ article, hypertensive episodes represented 414 cases, or one in 968 procedures (an incidence of 0.1 percent). Intraoperative and postoperative hypotension occurred in 148 cases, or one in

27 Cardiac Arrhythmias

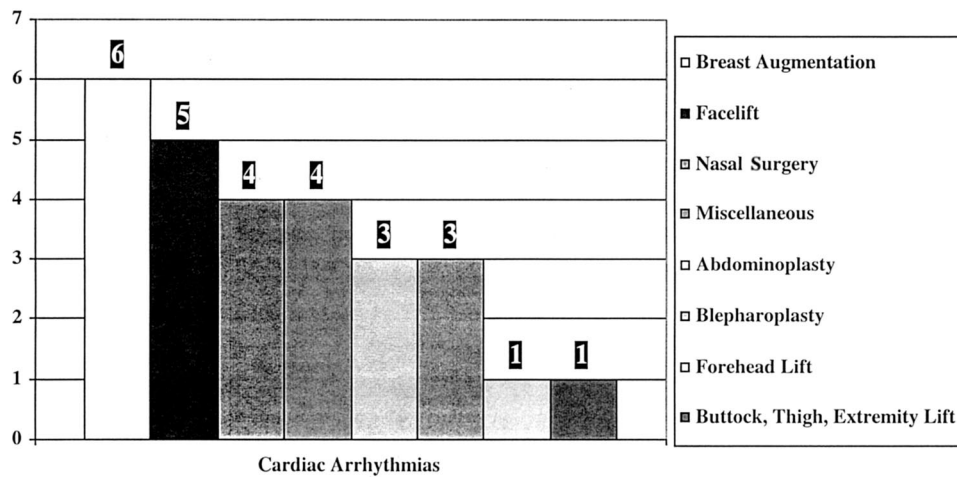


FIG. 5. Cardiac arrhythmias ($n = 27$). There were also two occurrences of cardiac arrest.

Intraoperative Blood Pressure Alterations

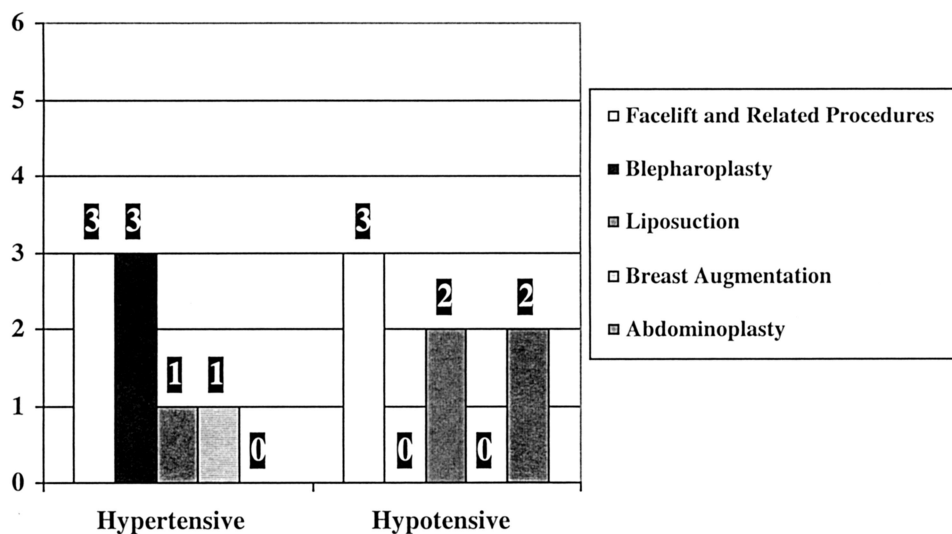


FIG. 6. Intraoperative blood pressure alterations ($n = 15$). One other patient experienced hypertension, but the operation was cancelled.

2707 procedures, an incidence of 0.04 percent.

Deep Vein Thrombosis or Pulmonary Embolism

All surgical patients are at some risk for the development of deep vein thrombosis in the lower extremities. The risk is increased for patients with a previous history of that condition, pulmonary embolism, or chronic venous insufficiency and for those with a family history of thrombotic syndromes. Other contributing factors include obesity, trauma, severe infection, polycythemia, central nervous system disease, malignancy, homocystinemia, history of radia-

tion therapy, especially for pelvic neoplasms, and the use of birth control pills.^{11,12}

There have been few reported studies on the frequency of deep vein thrombosis and pulmonary embolism associated with outpatient surgery. In the 2-year period monitored by the AAAASF quality improvement and peer review program, 31 patients developed deep vein thromboses or pulmonary emboli in 411,670 procedures (Fig. 7). This represents 0.01 percent of procedures performed, consistent with the report by Reinish et al.¹³ As with the study by Morello et al., the Reinish group's study was conducted through a voluntary survey. The

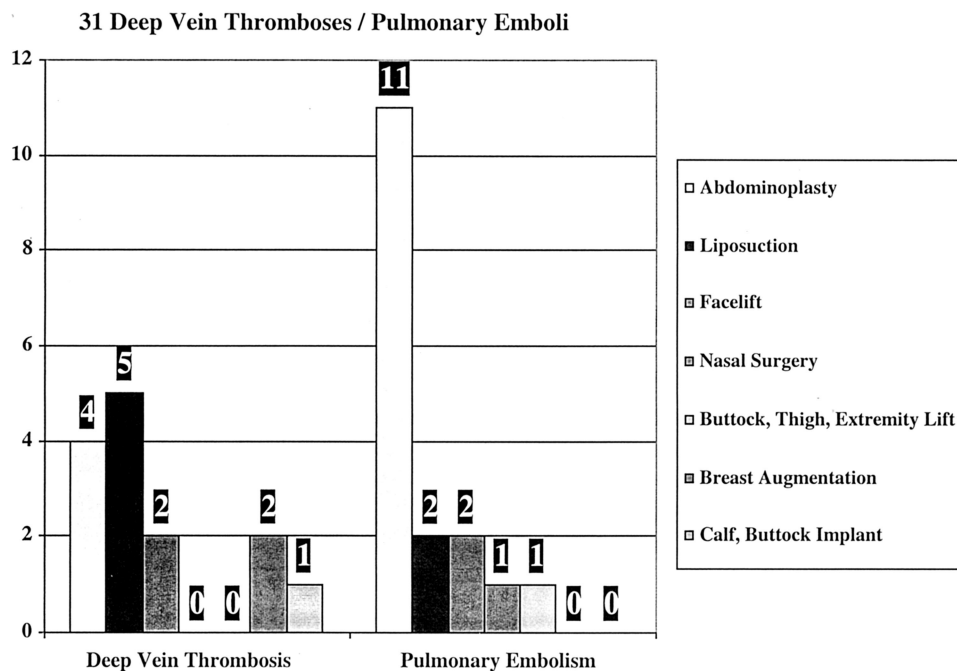


FIG. 7. Deep vein thromboses/pulmonary emboli ($n = 31$).

correlation of statistics with the mandatory AAAASF quality improvement and peer review Internet-based reporting system is significant.

Of these 31 patients with deep vein thromboses or pulmonary emboli, 14 patients had deep vein thromboses, of whom eight were hospitalized for management; six patients were treated on an outpatient basis. The average length of stay for those hospitalized for deep vein thromboses was 5.38 days (range, 2 to 12 days). There were no deaths associated with deep vein thromboses that did not eventuate in pulmonary emboli. All thromboses that did not result in pulmonary embolism resolved without additional sequelae.

The 17 patients who developed pulmonary emboli were hospitalized. The incidence of pulmonary embolism was one in 24,216 procedures, or 0.004 percent. The average length of stay for pulmonary emboli patients was 6.2 days (range, 1 to 11 days). Six deaths were reportedly due to pulmonary embolism. Four of the patients who died of pulmonary embolism had undergone an abdominoplasty. One of the aforementioned patients had undergone multiple procedures. The fifth patient who died had a pulmonary embolus 2 weeks after rhinoplasty. The procedure for the sixth patient who died was suction lipectomy of the abdomen using epidural anesthesia. The total amount of fat removed for the liposuction case was 3700

cc. All fatal pulmonary emboli occurred between postoperative days 2 and 14. In the remaining 11 patients, the pulmonary emboli resolved without residual sequelae.

The incidence of deep vein thrombosis was reported to be 0.3 percent in one large series of patients undergoing hip replacement.¹⁴ Fatal pulmonary emboli occur in 0.1 to 0.8 percent of general surgery patients, 2 to 3 percent of patients undergoing elective hip replacement, and 4 to 7 percent of patients undergoing operative reduction of hip fracture.¹⁴

In a study of patients undergoing face lift surgery, Reinisch et al.¹³ reported an incidence of thrombosis of 0.1 percent based on a survey of selected surgeons from the American Society of Plastic and Reconstructive Surgeons. In that study, 37 of 9493 face lift patients developed deep vein thrombosis (0.39 percent) and 15 patients developed pulmonary embolism (0.16 percent). Byrd et al.² reported no pulmonary emboli in their 5316 elective plastic surgery cases performed in an accredited outpatient plastic surgery facility.

Pneumothorax

Intraoperative pneumothorax has been reported as a complication in major surgical procedures about the chest wall when obtaining rib grafts, mobilizing chest muscle flaps, and performing chest wall reconstruction. In a re-

cent study, Osborn and Stevenson¹⁵ surveyed 363 members of the California Society of Plastic Surgeons, requesting demographic data on each participant regarding the number of years that they were in practice and the number of breast operations performed per year. The remainder of the questions dealt with the incidence of pneumothorax encountered by surgeons when performing breast augmentation. Fifty percent of the surgeons responded ($n = 181$); their responses indicated that a total of 83 cases of pneumothorax had been encountered during breast augmentation in their practices.¹⁵

This study reports 19 cases of pneumothorax (Fig. 8). The incidence of pneumothorax was greatest for breast augmentation and augmentation-related procedures ($n = 17$). The other two cases of pneumothorax were diagnosed during an abdominoplasty and a breast reduction. In 17 patients, the pneumothorax was noted intraoperatively, and in two patients, it was diagnosed between post-operative days 1 and 4. Puncture of the pleura at the time of rib block occurred in seven patients, and an intraoperative pleural tear while cauterizing bleeders was the cause of pneumothorax for 11 patients. In one patient, pneumothorax was attributed to preexisting pulmonary blebs.

Osborn and Stevenson¹⁵ discuss the potential for the occurrence of catamenial pneumothorax caused by endometrial implants on the

lungs. They usually occur between 48 to 72 hours after the onset of menstruation and have been reported to account for 2.8 percent to 5.6 percent of all episodes of spontaneous pneumothorax in women.¹⁵⁻²¹ There were no cases of catamenial pneumothorax reported in this study.

Twelve patients required chest tubes and were hospitalized. The average length of stay was 1.83 days (range, 1 to 7 days). The patient hospitalized for 7 days had bilateral pneumothorax with pulmonary edema that resolved. There were no deaths from pneumothorax in the 411,670 procedures performed.

Hyperthermia

Two cases of hyperthermia were reported. One case was managed with aspirin. The other case was a true malignant hyperthermia; the patient was managed with dantrolene sodium in the surgery center and transported to a hospital. The hospital stay lasted 1 day, and the patient was discharged without residual sequelae.

Deaths

In addition to the six deaths related to pulmonary embolism and the one death related to intraoperative hypoxia, another patient died on the first postoperative day, presumably from hypoxia related to sleep apnea. The patient was obese and had undergone a face lift. She died

19 Pneumothoraces

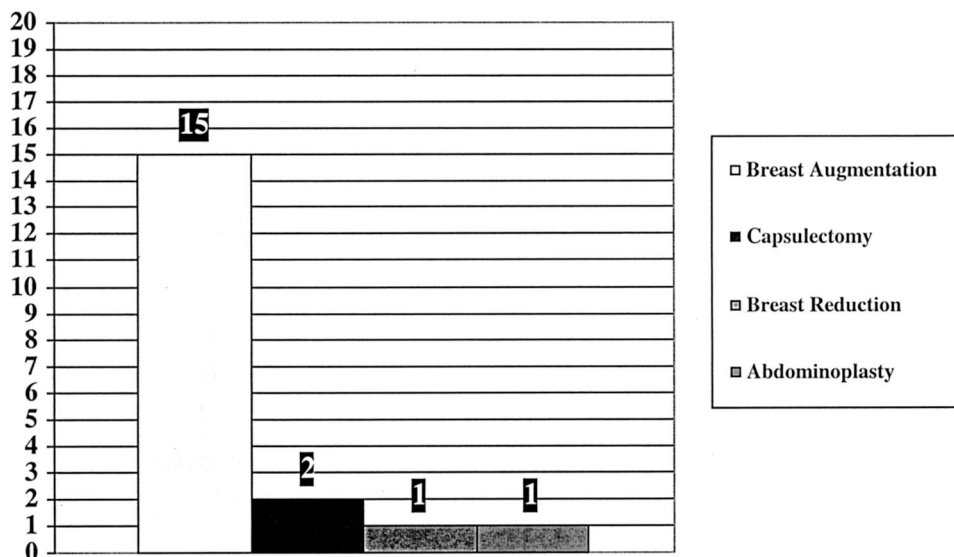


FIG. 8. Pneumothorax ($n = 19$).

in her sleep at home the evening after the operation.

The incidence of a patient dying after having an outpatient procedure was 0.002 percent, or one in 51,459 procedures. This compares favorably to the incidence in Morello et al.'s study,⁸ which reported seven deaths in 400,675 procedures for an incidence of 0.0017 percent, or less than one in 57,000 procedures.

DISCUSSION

Comparison of data obtained through voluntary and mandatory reporting programs demonstrates close correlation in overall incidence of unanticipated sequelae, their occurrence by type, and postoperative deaths. It is important to note that of the eight deaths reported through the Internet reporting program, only two occurred in the intraoperative or immediate postoperative period. Most of the deaths were secondary to the development of pulmonary embolism, which can occur as the result of any surgical procedure, whether it is performed in a multispecialty free-standing outpatient facility, an office-based outpatient facility, or a hospital.

All patients with unanticipated sequelae who required hospitalization as the result of bleeding or infection were managed and discharged from the hospital with the sequelae resolved.

The AAAASF standards for accreditation of a surgery center require all surgeons to be certified by an American Board of Medical Specialties surgical board and to have core credentials in a hospital for all procedures that they perform in their surgery centers. It may be assumed that the surgical technique for any given procedure performed by a certified surgeon would be the same whether the procedure is performed in a hospital or a surgery center. The low incidence of intraoperative sequelae in this report demonstrates conclusively the safety of operation of outpatient surgery centers that are accredited by a recognized accrediting organization and staffed by American Board of Medical Specialties board-certified surgeons.

Additional broad based studies are being designed to identify areas to improve the delivery of outpatient surgical care. The first Internet model for collecting data on outpatient surgical outcomes, designed by the AAAASF, has added a new dimension to monitoring and evaluating patient care. Its current use and expansion will provide the needed data for

further analysis of surgical outcomes. It is important to note that the analysis of outcomes will be more meaningful when reviewed in conjunction with a surgery center's compliance with accepted standards for operation.^[22-24]

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