Safety and Efficacy of Office-Based Surgery with Monitored Anesthesia Care/Sedation in 4778 Consecutive Plastic Surgery Procedures

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Office-based surgery has several potential benefits over hospital-based surgery, including cost containment, ease of scheduling, and convenience to both patients and surgeons. Scrutiny of office-based surgery by regulators and state-licensing agencies has increased and must be addressed by improved documentation of safety and efficacy. To evaluate the safety and efficacy of the authors' office-based plastic surgery, a review was undertaken of 3615 consecutive patients undergoing 4778 outpatient plastic surgery procedures under monitored anesthesia care/sedation in a single office.

The charts of 3615 consecutive patients who had undergone office-based surgery with monitored anesthesia care/sedation between May of 1995 and May of 2000 were reviewed. In all cases, the anesthesia protocol used included sedation with midazolam, propofol, and a narcotic administered by a board-certified registered nurse anesthetist with local anesthesia provided by the surgeon. Charts were reviewed for patient profile, types of procedures, multiple procedures, duration of anesthesia, American Society of Anesthesiologists class, and complications related to anesthesia. Outcomes measured included death, airway compromise, dyspnea, hypotension, venous thrombosis, pulmonary emboli, protracted nausea and vomiting lasting more than 24 hours, and unplanned hospital admissions. Statistical analyses were performed using the Microsoft Excel program and the SAS package. Results were as follows: 92.3 percent of the patients were female and 7.7 percent were male, with a mean age of 42.7 years (range, 3 to 83 years). Patients underwent aesthetic (95.6 percent) and reconstructive (4.4 percent) plastic surgery procedures. Same-session multiple procedures occurred in 24.8 percent of patients. The vast majority of patients were healthy: 84.3 percent of patients were American Society of Anesthesiologists class I, 15.6 percent were class II, and 0.1 percent were class III. The operations required a mean of 111 minutes. There were no deaths, ventilator requirements, deep venous thromboses, or pulmonary emboli. Complications were as follows: 0.05 percent ($n = 2$) of patients had dyspnea that resolved, 0.2 percent ($n = 6$) of patients had protracted nausea and vomiting, and 0.05 percent ($n = 2$) of patients had unplanned hospital admissions (<24 hours). One patient had an emergent intubation. No prolonged adverse effects were noted. There was a 30-day follow-up minimum.

Outpatient surgery is an important aspect of plastic surgery. It was shown that office-based surgery with intravenous sedation, performed by board-certified plastic surgeons and nurse anesthetists, is safe. Appropriate accreditation, safe anesthesia protocols, and proper patient selection constitute the basis for safe and efficacious office-based outpatient plastic surgery. (*Plast. Reconstr. Surg.* 111: 150, 2003.)

Office-based surgery has several potential benefits over hospital-based surgery, including cost containment, ease of scheduling, more personalized attention, convenience, and avoidance of hospital-based infections. Although costs are usually lower in office-based surgery, high-quality care, including safety and efficacy, should be the determining factor in choice of facilities. Between 1989 and 1990 alone, office-based surgical procedures increased threefold, to 1.2 million according to estimates by SMG Marketing (Chicago, Ill.), a health-care consulting and research group. In previous studies, the estimated 3 to 5 percent of all surgical procedures performed in the office setting was anticipated to increase to 15 percent by the

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year 2000.[1] Furthermore, outpatient surgery will account for more than four of five surgical procedures performed by 2005.[2] Of those operations, a quarter, almost 10 million, will be performed in doctors' offices, up 25 percent since 1998.[2]

Scrutiny of office-based surgery by regulators and state-licensing agencies has increased and must be addressed by improved documentation of safety and efficacy.[3] Published data confirm that the overall risk of office-based surgical procedures performed at facilities accredited by organizations such as the American Association for Accreditation of Ambulatory Surgery Facilities is comparable with the risk of surgery performed in free-standing or hospital ambulatory surgical facilities such as the Mayo Clinic.[4] The rate of complications for plastic surgery performed by American Board of Plastic Surgery–certified surgeons in accredited office-based facilities was 0.47 percent (<1 percent). The data covered more than 400,000 operations performed over 5 years by nearly 250 accredited facilities.[2,4]

Our interest is the safety of the patients. To satisfy patient demands, it is common to perform multiple aesthetic procedures with a single anesthetic. High patient expectations make it imperative to administer safe, reliable anesthesia with minimal adverse effects or complications. The experience with the cosmetic patient has increased, anesthetic agents have improved, and more sophisticated means of monitoring exist.

The debate of choosing general endotracheal anesthesia versus intravenous sedation is ongoing. There are advantages and disadvantages with each method. In one questionnaire to active members of the American Society for Aesthetic Plastic Surgery, 92 percent of respondents used intravenous sedation and local anesthesia; 54 percent of respondents reported also using general endotracheal anesthesia.[5] Both should be safe if given by a board-certified anesthetist or anesthesiologist, and the choice should be made according to the patient's desires and the surgeon's level of comfort. To evaluate the safety and efficacy of office-based plastic surgery, we present here our experience with monitored anesthesia care/sedation over the 5 years since we started using the current anesthesia protocol.

PATIENTS AND METHODS

Background

A retrospective chart review was performed on 3615 consecutive patients who had undergone 4778 office-based operations with monitored anesthesia care/sedation between May of 1995 and May of 2000 at the Charlotte Plastic Surgery Center. All surgeons who performed the operations are board certified in plastic surgery with privileges to perform the same surgical operations in an accredited hospital. Board-certified registered nurse anesthetists dedicated to our center administered the anesthesia. Of the 3625 charts reviewed, 10 were excluded because of incomplete information. There were no exclusion criteria. Charts were reviewed for patient demographics, procedure types, duration of anesthesia, American Society of Anesthesiologists status classification, and complications related to anesthesia. Follow-up information was obtained by office visits and communications with patients. The follow-up period was 30 days.

Outcomes measured included death, airway compromise, dyspnea, hypotension, deep venous thrombosis, pulmonary emboli, protracted nausea and vomiting, and unplanned hospital admissions. The purpose of this study was to evaluate safety and efficacy of monitored anesthesia care/sedation anesthesia in an office-based practice. Surgically related complications (e.g., hematoma, wound dehiscence) are not discussed. When a patient returned for an operation on a different day for a different procedure, he or she was considered a new patient.

Monitored Anesthesia Care/Sedation Anesthesia Protocol

Our facility is certified by the American Association for Accreditation of Ambulatory Surgery Facilities as a Level C center (patients may receive general anesthesia by means of endotracheal tube, laryngeal mask intubation, or inhalation anesthesia).[6] The center has advanced monitoring equipment, including noninvasive blood pressure monitoring, electrocardiography, oxygen saturation monitoring, end-tidal carbon dioxide monitoring, temperature monitoring, and bispectral index monitoring (Bis; Aspect Medical Systems, Natick, Mass.). The Bis monitoring device allows for deeper levels of anesthesia to be reached without the use of inhalation agents.[7] The device provides

an excellent pharmacodynamic measure of the individual's brain response to drug concentration. This action improves drug management during anesthesia specific for the level of sedation, and consciousness. Bis monitor application can reduce drug use and shorten recovery time. A cardiac defibrillator and equipped crash cart are available inside and outside the operating room. The center abides by the American Association of Nurse Anesthetists recommendations of having a health care provider (i.e., nurse or surgeon) who is certified in cardiac life support in the facility until the patient in discharged.[8] Registered nurses are assigned exclusively to a single postoperative patient during the recovery period.

Preoperatively, the patient received an evaluation by both the surgeon and the certified registered nurse anesthetist, at which time questions relating to both surgery and anesthesia are addressed. Initially, intravenous antibiotics were given, along with 0.1 to 0.2 mg of glycopyrrolate (Robinul; Wyeth-Ayerst Laboratories, Princeton, N.J.), an anticholinergic to dry secretions. For patients with a history of reflux disease, metoclopramide (Reglan; A.H. Robbins, Richland, Va.) 10 mg intravenously was used. Clonidine (Catapres; Boehringer Ingelheim Pharmaceuticals, Ridgefield, Conn.) was administered at a dose of 0.1 to 0.2 mg orally for patients undergoing brow lifts or face lifts for optimizing blood pressure control.

Before sedation, all monitors and supplemental oxygen were applied. Patients then received a titrated dose of meperidine (Demerol; Abbott Laboratories, Abbott Park, Ill.) and midazolam (Versed; Roche, Nutley, N.J.). Propofol (Diprivan; Zeneca Pharmaceuticals, Wilmington, Del.), ranging from 25 to 100 μg/kg/min, started intravenously has well-documented antiemetic properties, euphorigenic qualities, and a lessened hangover effect.[9] Versed and fentanyl (Sublimaze; Akron, Abita Springs, La.) were also given in all cases. A recent meta-analysis by Sneyd et al. demonstrated that patients who received maintenance of anesthesia with propofol had a significantly lower incidence of postoperative nausea and vomiting in comparison with inhalation agents.[10] Ketamine was added to the intravenous drip in a few cases based on the preference of the certified registered nurse anesthetist. Malignant hyperthermia, which can be life threatening, is not triggered by the use of these medications.[9] The surgeon administered local anesthesia when necessary, typically 0.25% lidocaine with epinephrine 1:200,000 (Xylocaine; Astra Pharmaceuticals, Westborough, Mass.). Our tumescent solution for liposuction is the following: 1 liter of lactated Ringer's solution plus 50 cc lidocaine 1% plus one ampule of epinephrine 1:1000. All surgeons at our center use the wet technique of liposuction.

Postoperatively, electrocardiograph, blood pressure, and pulse oxymetry monitoring are all mandatory. All patients remain for a minimum of 1 hour in the recovery room with a registered nurse specifically designated to each patient. The operating surgeon is on the premises at all times during recovery. We follow the guidelines set forth by the Task Force on Sedation and Analgesia in Ambulatory Settings recommended in October of 1998, summarized by their statement, "When a patient is discharged, one must assume there will be no medical supervision once the patient leaves the facility."[11] A protocol for dealing with emergent hospital transfers is in effect with two of the nearby hospitals.

Statistical Analysis

Data were compiled on an Excel file (Microsoft Excel, Version 5.0a; Microsoft, Redmond, Wash.) and converted to an SAS data set (SAS Institute, Cary, N.C.).[12] Standard statistical tests were used. Descriptive statistics included means and standard deviations or counts and percentages. The t test was used to compare the mean age of patients with hypertension and those without hypertension. Data measured on the nominal scale (i.e., gender) were compared between the two groups using a chi-square test. A value of $p < 0.05$ was considered statistically significant. An individual at the Department of Biostatistics at the Carolinas Medical Center (Charlotte, N.C.) assisted in the statistical analyses.

Results

Patient Profile

Female patients were the expected majority (92.3 percent female; 7.7 percent male). The mean age was 42.7 years (range, 3 to 83 years) (Fig. 1). Patients were classified as I, II, or III according to the criteria set forth by the American Society of Anesthesiologists. The vast majority of patients were healthy, with no significant medical problems (84.3 percent were class

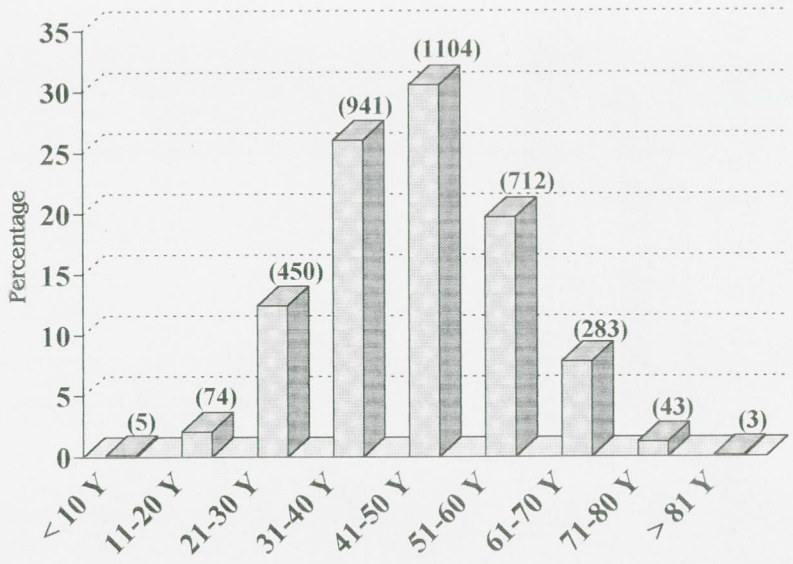

FIG. 1. Age distribution of patients (years). Numbers in parentheses indicate the number of patients in each group.

I, 15.6 percent were class II, and 0.1 percent were class III) (Table I). The significant medical comorbidities that existed were diabetes mellitus (21 patients), coronary artery disease (three), asthma (three), and smoking (456 patients) (Table I).

An important finding was that 92 (2.5 percent) of the 3615 patients had hypertension. There was no statistically significant difference between the hypertension rates of male and female patients ($p = 0.452$). The patients with hypertension had a mean age of 55.4 ± 11.6 years versus the rest, who were normotensive with a mean age of 42.4 ± 11.9 years; that difference was statistically significant ($p < 0.0001$). The rates of hypertension in the group older than 70 years were statistically significantly higher than the other two age categories (i.e., <50 years and 50 to 70 years; $p < 0.001$).

TABLE I
Patient Information

	n	%
Male patients	278	7.7
Female patients	3337	92.3
Age		
Average	42.7	
Range	3–83	
Coronary artery disease	3	<1
Hypertension	92	2.5
Asthma	16	<1
Smokers	456	13
Diabetes mellitus	21	<1
Class I patients	3047	84.3
Class II patients	564	15.6
Class III patients	4	0.1
Duration of operation (min)		
Average	111	
Range	5–720	
No. of patients undergoing multiple procedures simultaneously	897	24.8
Average number of operations per patient	1.3	

Patients underwent a variety of aesthetic (95.6 percent) and reconstructive (4.4 percent) plastic surgery procedures. In total, 4778 procedures were performed on 3615 patients; 897 patients (24.8 percent) underwent multiple procedures during the same surgery. The procedures required on average 111 minutes of anesthesia time (range, 20 to 350 minutes) (Fig. 2). Less than 1 percent of the operations lasted for more than 6 hours.

Complications

There were no deaths, surgical airway requirements, ventilatory requirements, deep venous thromboses, or pulmonary emboli (Table II). Two patients (0.05 percent) had dyspnea that resolved with simple measures. One patient (0.03 percent) had severe intraoperative hypotension that resolved with medical treatment and did not require modification in the operative plan. Six patients (0.2 percent) having protracted nausea and vomiting that lasted for more than 24 hours were treated as outpatients successfully with Tigan suppositories. Two patients (0.05 percent) had unplanned hospital admissions (<24 hours) related to anesthesia. No complications occurred in class III patients. Two complications occurred in class

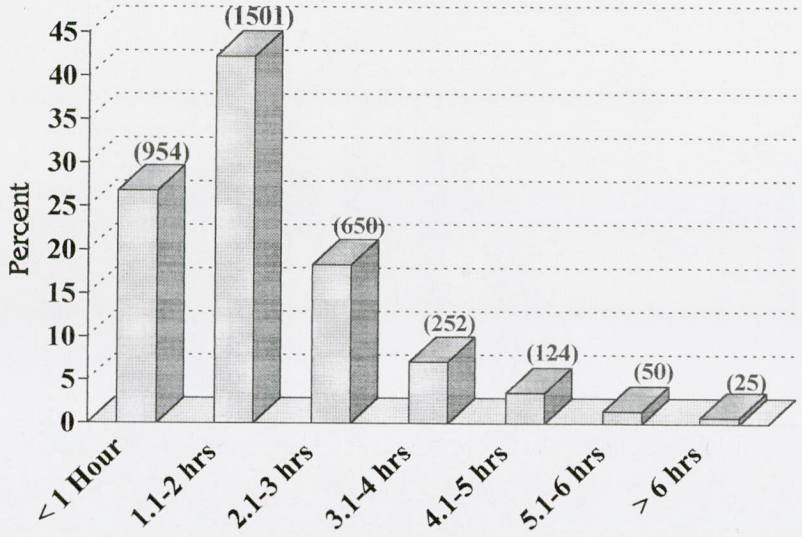

FIG. 2. Duration of procedures. Numbers in parentheses indicate the number of patients in each group.

TABLE II
Anesthetic Complications

Complication	No. of Patients	
	n	%
Nausea and vomiting	6	0.2
Hospital admission	2	0.05
Dyspnea	2	0.05
Hypotension	1	0.03
Emergent intubation	1	0.03
Death		0
Ventilator requirements		0
Deep venous thrombosis		0
Pulmonary embolism		0

II patients: the first had protracted nausea and vomiting; the second patient had laryngospasm, which led to emergent intubation, during extensive tip rhinoplasty. She was extubated at the end of the case and recovered uneventfully. The two cases are described below.

CASE REPORTS

Case 1

A 45-year-old woman underwent high-volume liposuction (10,500 cc) and became hypothermic. The patient was admitted to the hospital for overnight observation. The next morning, her hemoglobin level was within the normal range. She was discharged home and recovered uneventfully.

Case 2

A 37-year-old woman underwent an abdominoplasty and 800 cc of liposuction from the back and flanks. She had severe nausea and vomiting in the recovery room. The patient was admitted to the hospital on the night of surgery for intravenous hydration and antiemetic treatment. She was discharged the following day without additional concerns.

DISCUSSION

The demand for cosmetic surgery has risen to new highs in the past few years. According to the American Society of Plastic Surgeons, liposuction procedures performed by board-certified plastic surgeons in the United States have increased from 47,212 in 1992 to 230,865 in 1999 (389 percent increase). Breast augmentation increased 26 percent in the same period despite the moratorium on silicone breast implants, and eyelid surgery increased 18 percent. The plastic surgery profession must provide cosmetic procedures that are safe and yield good results.

We have presented a series of 3615 patients undergoing 4778 outpatient procedures that are varied in complexity with monitored anesthesia care/sedation. Patients were of all ages, and only a few operations lasted more than 6 hours, so they were very comparable with cases treated using general anesthesia. The operations occurred in an American Association for Accreditation of Ambulatory Surgery Facilities-accredited facility, with board-certified plastic surgeons, board-certified nurse anesthetists, and protocols for patient safety. We excluded 10 patients because of incomplete chart information. We attribute our good follow-up record to the stability of the practice, which was established in 1951, the standardized record keeping followed by all of the physicians, and the diligent efforts of the office staff. There were no deaths and the few complications included two unexpected hospital admissions and one emergent intubation. The hospital

TABLE III
Aesthetic Procedures Performed

Procedure	No. of Procedures
Liposuction	1212
Breast augmentations	680
Blepharoplasties	674
Face lifts (including malar lifts and neck lifts)	499
Carbon dioxide laser	349
Capsulectomies and breast revision	307
Endobrow lifts	207
Rhinoplasties	156
Abdominoplasties	99
Mastopexies	90
Fat grafting	53
Dermabrasion	46
Brow lifts	40
Otoplasties	34
Facial peels	16
Genioplasties	14
Brachyplasties	11
Breast reductions	8
Hair transplants	6
Thigh lifts	4
Lip augmentation	2
Other	63
Total	4570

admissions proceeded in accordance with an arrangement with two nearby hospitals, so no problems were encountered. All patients recovered well, with no long-term complications.

Monitored anesthesia care/sedation has been criticized for not having the same safety profile as general anesthesia. A survey among 304 office-based certified registered nurse anesthetists revealed that 88 percent use conscious sedation as the most common technique in their office setting, and 66 percent of them use general anesthesia as the next most common technique.[6] Our experience is that a board-certified anesthetist can provide safe and effective monitored anesthesia care/sedation and a smooth emergence from anesthesia. One patient needed emergency intubation because of laryngospasm and subsequently was extubated without a problem. That case highlights the need for the anesthetist to be comfortable in emergent intubation and in rendering general anesthesia if the need arises.

TABLE IV
Reconstructive Procedures Performed

Procedure	No. of Procedures
Scar revisions	125
Skin lesion excisions	32
Nipple reconstruction	17
Skin and bone grafts	14
Local flaps	4
Other	16
Total	208

General anesthesia may be preferred over intravenous sedation to paralyze the patient's movement during the procedure and avoid distracting the surgeon. Monitored anesthesia care/sedation, if properly administered, may render the patient comfortable and motionless. An added advantage of monitored anesthesia care/sedation versus general anesthesia is the lower rate of deep venous thromboses and pulmonary emboli in procedures lasting longer than 3 to 4 hours.[7] Our patients' rate of protracted nausea and vomiting (0.2 percent) is comparable with that of ambulatory centers and hospitals (0.18 percent).[13] A benefit of deep sedation is the lack of an endotracheal tube, thus eliminating a sore throat, the possibility of chipped teeth, and the stress of difficult or impossible intubations.[9] Our results support the data presented by Hoefflin et al. in a recent article about the safety of office-based anesthesia in 23,000 consecutive procedures performed using general anesthesia.[14]

In 1997, nonplastic surgeons performed 50 percent of 250,000 liposuction procedures. Many of these practitioners have had limited training in cosmetic surgical techniques.[15] In 2000, in light of recent deaths caused by liposuction, legislatures stepped in and issued a temporary moratorium on office-based surgery in Florida that lasted for 90 days and was later lifted. It is the duty of the plastic surgery profession to ensure the safety of our patients while providing quality care. Complications are inevitable; however, we have shown that office-based surgery with monitored anesthesia care/sedation, performed by board-certified plastic surgeons and board-certified nurse anesthetists, was safe for pediatric and adult patients in all cases listed in Tables III and IV.

Appropriate accreditation, safe anesthesia protocols, and proper patient selection constitute the basis for safe and efficacious office-based outpatient plastic surgery.

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