

Determining the Safety of Office-Based Surgery: What 10 Years of Florida Data and 6 Years of Alabama Data Reveal

JOHN STARLING III, MD,* MAYA K. THOSANI, MD,* AND BRETT M. COLDIRON, MD, FACP**†

BACKGROUND This is a continued examination of 10 years of prospectively collected Florida in-office adverse event data and new comparable data from mandatory Alabama in-office adverse event data reporting.

OBJECTIVE To determine which office surgical procedures have resulted in reported complications.

METHODS This study is a compilation of mandatory reporting of office surgical complications by Florida and Alabama physicians to a central agency. Reports resulting in death or a hospital transfer were further investigated over the telephone or on-line to determine the reporting physician's board certification status, hospital privilege status, and office accreditation status.

RESULTS In 10 years in Florida, there were 46 deaths and 263 procedure-related complications and hospital transfers; 56.5% (26/46) of deaths and 49.8% (131/263) of hospital transfers were associated with non-medically necessary (cosmetic) procedures. The majority of deaths (67%) and hospital transfers (74%) related to non-medically necessary (cosmetic) procedures were from procedures performed on patients under general anesthesia. Liposuction and liposuction with abdominoplasty or other cosmetic procedure resulted in 10 deaths and 34 hospital transfers. Thirty-eight percent of offices reporting adverse events were accredited by an independent accrediting agency, 93% of physicians were board certified, and 98% of physicians had hospital privileges. The most common specialty of physicians reporting adverse events was plastic surgery (45% of all reported complications). Dermatologists reported four total complications (no deaths) and accounted for 1.3% of all complications over the 10-year period. In 6 years in Alabama, there were three deaths and 49 procedure-related complications and hospital transfers; 42% (22/52) of hospital transfers and no deaths were associated with non-medically necessary (cosmetic) procedures. The majority of hospital transfers related to cosmetic procedures (86%) were from procedures performed on patients under general anesthesia. Liposuction accounted for no deaths and two hospital transfers. Seventy-one percent of offices reporting adverse events were accredited by an independent accrediting agency, and 100% of physicians were board-certified. Plastic surgery was the most common specialty represented in adverse event reporting (42.3% of all reported complications). Dermatologists reported one complication (no deaths) and accounted for 1.9% of all complications over the 6-year period.

CONCLUSIONS Continued analysis reveals that medically necessary office surgery does not represent an emergent hazard to patients. The data obtained from 10 and 6 years of adverse event reporting in Florida and Alabama, respectively, are comparable and consistent. Medically necessary surgical procedures performed in the office setting by dermatologists have an exceedingly low complication rate, and complications that arose were largely unexpected, isolated, and possibly unpreventable. Cosmetic procedures performed in offices by dermatologists under local and dilute local anesthesia yielded no reported complications. Complications from cosmetic procedures accounted for nearly half of all reported incidents in Florida and Alabama, and in both states, plastic surgeons were most represented in adverse event reports. Liposuction performed under general anesthesia requires further investigation because deaths from this procedure continue to occur despite the ability to use dilute local anesthesia for this procedure. Requiring physician board certification and physician hospital privileges does not seem to increase safety of patients undergoing surgical procedures in the office setting. Mandatory reporting of adverse events in the office setting should continue to be championed. Reporting of delayed deaths after hospital outpatient and ambulatory surgery center procedures should be implemented. All data should be made available for scientific analysis after protecting patient confidentiality.

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*Skin Cancer Center, Cincinnati, Ohio; †Department of Dermatology, University of Cincinnati, Cincinnati, Ohio

Increased media attention on human error in medicine has continued to bring patient safety issues to the forefront of a national debate, and in response, numerous state medical boards have drafted, and will continue to draft, regulations designed to protect patients undergoing procedures in the office setting. As legislative bodies move to protect patient safety, regulations should be drafted based on sound data and the best available evidence. We have previously reported examinations of the data collected by the state of Florida over 1 year, 19 months, 3 years, 4 years, 5 years, and 7 years.¹⁻⁷ Since the last report, Florida data collection has continued, but 6 years of office surgery incident reports from the Alabama State Board of Medical Examiners have also been obtained (via special request).

Materials and Methods

The state of Florida instituted mandatory physician office adverse event reporting in February 2000. These reports are public domain and are reported to the Agency for Health Care Administration (AHCA, Tallahassee, FL). Reportable events include the death or hospital transfer of a patient, brain or spinal damage, procedure performed on the wrong patient or surgical site, other damages not included in the informed consent, and the removal of unplanned foreign objects remaining from a surgical procedure. Because underreporting is a recognized potential problem, the AHCA crosschecks these reports with malpractice claims and spontaneous complaints. Any physician with a discrepancy in adverse event reporting is required to submit a report and is investigated and sanctioned. The Florida reports are the only source to list the reporting physician's identity, which allows for investigation of credentials, office accreditation, and hospital privileges.

Alabama instituted mandatory physician office adverse event reporting in December 2003. Any

procedure in an office that results in death, patient transfer to the hospital, anesthetic or surgical events requiring CPR, unscheduled hospitalization related to the surgery, and surgical site deep wound infection must be reported.

Although these reports are not currently in the public domain, we petitioned the Alabama Board of Medical Examiners to obtain these data. The reports were obtained from the board with supplemental information on physician board certification and office accreditation to match the comparative data set from Florida.

State law requires that these adverse events be reported, and there was no intervention on human subjects. Therefore, approval by an Institutional Review Board was not sought for this study.

All incidents in Florida from March 2000 to January 2010 and in Alabama from December 2003 to December 2009 filed with the Florida AHCA and Alabama Board of Medical Examiners, respectively, were collected and analyzed. These reports and summary spreadsheets are available and can be downloaded from <http://www.theskincancercenter.net/reports>. Physician hospital privileges were determined over the Internet at the Florida Department of Health Healthcare Practitioner License Search (<https://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP>). This information was then verified with the respective hospitals. Physician board certification was determined by Internet verification at <https://www.abms.org/WC/login.aspx>. Office accreditation was determined over the internet at Accreditation Association for Ambulatory Health Care (AAAHC) at http://www.aaahc.org/eweb/dynamicpage.aspx?site=aaahc_site&webcode=find_orgs, the American Association of Accreditation of Ambulatory Surgery Facilities (AAAASF) at <http://www.aaaasf.org>, and The Joint Commission at <http://www.qualitycheck.org/consumer/searchQCR.aspx>.

Results

Data collected from each state are presented in Tables 1–5.

Florida

In 10 years of Florida data, there were 309 reported adverse incidents arising from an office-based surgical procedure. Of these, 46 resulted in death and 263 in reportable complications or hospital transfers. Cosmetic procedures accounted for 56.5% (26/46) of deaths and 49.8% (131/263) of hospital transfers. The overwhelming majority of cosmetic cases resulting in hospital transfer (79%) or death (67%) were performed under general anesthesia. The most common cosmetic procedures resulting in hospital transfer or death were liposuction and abdominoplasty. Liposuction resulted in 28% of all cosmetic complications (14% of total complications) and 32% of the cosmetic deaths (22% of total deaths). All but five cases of liposuction were performed under general anesthesia. Many of the deaths reported after liposuction were delayed by several hours to days and were most frequently due to pulmonary emboli, fat emboli, respiratory failure, or cardiorespiratory arrest.

There were four adverse event reports from dermatologists in 10 years in Florida; none resulted in death. One report involved a vasovagal episode that occurred after liposuction performed under general anesthesia. There was a brief episode of atrial fibrillation that occurred 2 hours after an excision performed with a minimal amount of local anesthesia. Another report involved a wrong surgical site during a Mohs procedure performed with local anesthesia. One mentally impaired patient on home oxygen therapy suffered a second-degree burn to the face during an excision under intravenous sedation when an electrocautery spark ignited the oxygen supply.

Alabama

In 6 years of Alabama data, there were 52 adverse surgical incident reports. Three resulted in death and 49 in reportable complications or hospital transfers. There were no deaths from cosmetic procedures. Forty-two percent of all reported incidents were from cosmetic procedures, and 89% of these procedures were performed under general anesthesia. Liposuction performed under general anesthesia was responsible for two hospital transfers over this 6-year period, but there were no reported deaths. These two hospital transfers were because of pulmonary edema.

TABLE 1. Subspecialty Comparison of Complication Rates According to State

Specialty	Florida		Alabama	
	Complications	Physicians in State	Complications	Physicians in State
	%			
Plastic surgery	44.9	0.55	42.3	0.53
Gastroenterology	11.0	1.4	1.9	1.3
Nephrology and interventional nephrology	1.3	0.8	51.9	1.2
Obstetrics and gynecology	6.4	2.6	0	3.5
Radiology and interventional radiology	10.4	6.0	0	5.8
Cardiology	9.1	2.6	0	3.0
Otorhinolaryngology and facial plastic surgery	4.2	0.66	0	0.91
Vascular surgery	3.2	0.23	0	0.62
Dermatology and dermatologic surgery	1.3	1.2	1.9	0.78

TABLE 2. Ten Years of Florida Data

Data	Value
Physicians in state, <i>n</i>	54,923
Complications, <i>n</i>	309
All-cause deaths, <i>n</i> (%)	46 (14.9)
Hospital deaths or complications, <i>n</i> (%)	263 (85.1)
Anesthesia complications, <i>n</i> (%)	39 (12.6)
Deaths caused by anesthesia, <i>n</i> (%)	8 (17.4)
Complications caused by tumescent anesthesia, <i>n</i> (%)	2 (0.76)
Complications per physician, %	0.56
Complications per year, <i>n</i>	31

TABLE 4. Six Years of Alabama Data

Data	Value
Physicians in state, <i>n</i>	9,210
Complications, <i>n</i>	52
All-cause deaths, <i>n</i> (%)	3 (5.7)
Hospital transfers or complications, <i>n</i> (%)	49 (94.2)
Anesthesia complications, <i>n</i> (%)	2 (3.8)
Deaths caused by anesthesia, <i>n</i> (%)	0
Complications caused by tumescent anesthesia, <i>n</i> (%)	0
Complications per physician, %	0.56
Complications per year, <i>n</i>	8.6

TABLE 3. Florida Physician Breakdown According to Specialty

Specialty	Physicians in State	
	Complications	<i>n</i> (%)
Plastic surgery	139 (44.9)	303 (0.55)
Gastroenterology	34 (11)	759 (1.4)
Nephrology and interventional nephrology	4 (1.3)	442 (0.80)
Obstetrics and gynecology	20 (6.4)	1,447 (2.6)
Radiology and interventional radiology	32 (10.4)	3,281 (5.97)
Otorhinolaryngology	15 (4.2)	365 (0.66)
Urology	11 (3.6)	657 (1.2)
Cardiology	28 (9.1)	1,443 (2.6)
Orthopedics	1 (0.3)	927 (1.7)
Dermatology	4 (1.3)	651 (1.2)
Oral and maxillofacial surgery	2 (0.7)	144 (0.26)
Vascular surgery	10 (3.2)	129 (0.23)
Anesthesiology	5 (1.6)	2,810 (5.1)
Colorectal surgery	0 (0)	81 (0.15)

TABLE 5. Alabama Physician Breakdown According to Specialty

Specialty	Physicians in State	
	Complications	<i>n</i> (%)
Plastic surgery	22 (42.3)	49 (0.53)
Gastroenterology	1 (1.9)	123 (1.3)
Nephrology and interventional nephrology	27 (51.9)	108 (1.2)
Obstetrics and gynecology	0 (0)	320 (3.5)
Radiology and interventional radiology	0 (0)	531 (5.77)
Otorhinolaryngology	0 (0)	84 (0.91)
Urology	0 (0)	88 (0.96)
Cardiology	0 (0)	275 (3.0)
Orthopedics	0 (0)	346 (3.8)
Dermatology	1 (1.9)	72 (0.78)
Oral surgery	0 (0)	47 (0.51)
Vascular surgery	0 (0)	57 (0.62)
Anesthesiology	0 (0)	349 (3.8)
Colorectal surgery	1 (1.9)	10 (0.11)

Over the 6 years of Alabama data examined, there were no deaths and only one hospital transfer reported by a dermatologist. This was for a documented methicillin-resistant *Staphylococcus aureus* infection and seroma development subsequent to a melanoma excision under local anesthesia.

Physician Specialty

Data collected from each state are presented in Tables 1–5.

Analysis of the adverse event reports according to physician specialty revealed that plastic surgeons were responsible for 44.9% of all reported complications over a 10-year period in Florida and

42.3% of all complications over a 6-year period in Alabama. Plastic surgeons represent 0.55% and 0.53% of the total number of physicians in the states of Florida and Alabama, respectively.

Table 1 highlights the complications according to physician subspecialty in both states. According to Medicare physician registration information, there are approximately 55,000 practicing physicians in Florida and 9,200 in Alabama total. Based on the number of complications reported in each state over the compiled 16 years, both reveal a rate of complications per physician of less than 0.5%.

Office Accreditation

The Alabama Board of Medical Examiners encourages all surgical offices registered with the board to maintain accreditation by an independent organization; 71% of reporting offices in this analysis were accredited. Florida's Department of Health has begun an annual inspection of all surgical offices not otherwise accredited by AAAHC, AAAASF, or JCAHO in an effort to have 100% of offices accredited by an independent organization, but at the time of initial data collection of each incident, only 38% of offices reported independent accreditation. The data reveal no clear pattern that suggests that independent accreditation is particularly effective in preventing complications leading to death and hospital transfers after office procedures.

Physician Board Certification and Hospital Privileges

The overwhelming majority of physicians (93% of Florida and 100% of Alabama) reporting adverse events were board certified. In Florida, 98% of reporting physicians had hospital privileges. We were unable to assess hospital privileges from the data collected from Alabama. There was no pattern of more adverse events in those who were not board certified or had no hospital privileges although the sample sizes of non-board certified physicians and physicians without hospital privileges were too small to analyze. Therefore, no conclusions can be drawn regarding effect of physician

hospital privileges or board certification on overall safety of patients undergoing surgical procedures in the office setting.

Discussion

Patient safety concerns, especially protection of patients undergoing surgical procedures in the office setting, have moved to the forefront of a national debate and therefore have become an important topic for legislative leaders and health care providers. This analysis of adverse event reporting from two states confirms trends that have been previously identified in earlier analyses of this data.¹⁻⁶ Analysis now includes 10 years of Florida adverse event reporting data, and the pattern of deaths and injuries has remained remarkably consistent with the first year of reports, that just over half of complications arose from cosmetic procedures. The addition of 6 years of Alabama adverse event reporting data strengthens the significance of these trends. These support the trends seen in the data collected from Florida, with 42% of all reports arising from cosmetic procedures.

The pattern of deaths and injuries specifically from liposuction performed under general anesthesia in Florida continues to be remarkable. Liposuction under general anesthesia accounted for 22% of total procedure-related deaths and 14% of total procedure-related complications. Liposuction under general anesthesia accounted for 32% of cosmetic procedure-related deaths and 22% of all cosmetic procedure-related complications. Review of the Florida data shows that deaths and adverse events associated with liposuction under general anesthesia have trended lower. This is presumed to be secondary to the Florida Board of Medicine's restriction of the number of cosmetic procedures that can occur at once when liposuction is being performed.⁸ Although Florida requires physicians operating under general and intravenous sedation to keep case logs, these logs are not public domain, and the number of liposuction cases performed in each state under general anesthesia could not be

obtained, preventing calculation of an accurate fatality rate. Nevertheless, a recent report estimated a fatality rate as high as 1 in 5,224 for liposuction under general anesthesia.⁹

Although the exact number of liposuction cases performed in each state under general anesthesia are not obtainable, we sought context from 2010 national statistics regarding liposuction procedure volume. National statistics compiled separately by the American Society for Aesthetic Plastic Surgery (ASAPS)¹⁰ and the American Society for Plastic Surgeons (ASPS)¹¹ demonstrated that liposuction was one of the top five invasive cosmetic surgical procedures performed in 2010, with 289,016 and 203,106 cases listed, respectively. The 2010 ASPS report further stratifies procedure volume according to region. Data on specific states are not available at this time. Region 4 (Florida, Delaware, District of Columbia, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia, and Puerto Rico) accounted for 44,075 (22%) of all liposuction cases performed. Region 3 (Alabama, Kentucky, Mississippi, Tennessee, Arkansas, Louisiana, Oklahoma, and Texas) accounted for 29,101 (14%) of total liposuction cases performed.

This analysis shows that, in 16 years of adverse event reporting data combined from two states, there were no reports arising from liposuction performed under dilute local (tumescent) anesthesia; this is in agreement with recent reports of the safety of liposuction using only tumescent local anesthesia.^{12,13} Liposuction performed under general anesthesia requires further investigation because deaths from this procedure continue to occur despite the ability to use dilute local anesthesia for this procedure. Because liposuction remains one of the most commonly performed cosmetic surgical procedures in the United States,^{10,11} and a recent report estimates that one-third of all liposuction in the United States is performed using tumescent anesthesia,¹⁴ we contend that continued use of general anesthesia for liposuction must be questioned and investigated rigorously.

The majority of patient deaths occurring in the context of general anesthesia (especially when used for liposuction) were delayed. Two patient deaths were reported that appear to have been caused directly by general anesthesia: one from malignant hyperthermia and one due to an allergic reaction. The remaining deaths occurring in this context were associated with, but not caused by, general anesthesia. Mandatory reporting of delayed deaths by ambulatory surgery center and hospital outpatient facilities, which is not currently done, would be beneficial.

The data show that the requirement for physicians to be board certified has little to no effect on patient safety with 93% of Florida and 100% of Alabama reporting physicians being board certified in their respective specialties. Similarly, office accreditation does not seem to offer significant patient safety advantages, with 38% of Florida and 71% of Alabama reporting facilities being accredited by an independent organization. There is no clear pattern that suggests that board certification or accreditation are effective in preventing deaths, complications, or hospital transfers after office-based surgical procedures.

We again have found that most of the incidents due to medically necessary procedures presented here were isolated, unexpected, and possibly unpreventable. With continued legislation regarding regulation for office-based surgical procedures, we again call for consideration of the balance between prevention of loss of life by more regulations and loss of life created by less access to medically necessary care. Such regulations will only be effective if based on objective analysis of sound, complete data.

The benefit of a national discussion between patients, providers, and patient safety advocates regarding the prevalence of deaths and injuries due to cosmetic surgical procedures cannot be underestimated. Mandatory reporting of adverse events in the office setting should continue to be champi-

oned. Reporting of delayed deaths after hospital outpatient and ambulatory surgery center procedures should be implemented. All data should be made available for scientific analysis after protecting patient confidentiality. As physicians strive to practice evidence-based medicine, we welcome evidence-based regulations that continue to forward patient safety measures and the reduction of medical errors while avoiding severely restricted access to medically necessary care.

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Address correspondence and reprint requests to:
John Starling, III, MD, The Skin Cancer Center,
Cincinnati, Ohio, or e-mail: johnthree@gmail.com.