

# Comparative Outcomes Analysis of Procedures Performed in Physician Offices and Ambulatory Surgery Centers

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**Hypothesis:** This study compared outcomes to determine whether patient safety is similar in Florida ambulatory surgery centers and offices.

**Data Sources:** All adverse incident reports to the Florida Board of Medicine for procedure dates April 1, 2000, to April 1, 2002 were reviewed. The numbers of office procedures performed during a 4-month period were used to estimate the total number of procedures. Ambulatory surgery death summaries, adverse incident data, and volumes of procedures for 2000 were procured from the Florida Agency for Health Care Administration.

**Study Selection/Data Extraction:** Adverse incident reports were reviewed by multiple parties; only reports that involved an office surgical procedure and resulted in injury or death were included in the outcomes calculation. Reports were extracted independently by multiple reviewers.

**Data Synthesis:** Adverse incidents occurred at a rate of 66 and 5.3 per 100 000 procedures in offices and ambulatory surgery centers, respectively. The death rate per 100 000 procedures performed was 9.2 in offices and 0.78 in ambulatory surgery centers. The relative risks for injuries and deaths for office procedures vs ambulatory surgery centers were 12.4 (95% confidence interval, 9.5-16.2) and 11.8 (95% confidence interval, 5.8-24.1), respectively.

**Conclusions:** In this review of surgical procedures performed in offices and ambulatory surgery centers in Florida during a recent 2-year period, there was an approximately 10-fold increased risk of adverse incidents and death in the office setting. If all office procedures had been performed in ambulatory surgery centers, approximately 43 injuries and 6 deaths per year could have been prevented.

*Arch Surg.* 2003;138:991-995

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**D**URING THE 1980s, many surgical procedures previously performed in hospitals began to be performed in freestanding ambulatory surgery centers (ASCs). By the 1990s, more than 50% of all surgeries were performed in the ambulatory setting. While many initially questioned whether these procedures could be safely done outside the hospital, the safety of surgeries performed in licensed ASCs is now accepted.<sup>1</sup> Beginning in the 1990s there was another shift, with greater numbers of surgical procedures being performed in physician offices that had previously been performed in ASCs. Although there are few data on the actual numbers of office surgeries, it has been estimated that up to 1.2 million procedures nationwide per year are currently being performed.<sup>2</sup> Unlike ASCs, which are highly regulated by governmental agencies, the physician office is usually not. One article went so far as to describe

surgery in the physician office as the "wild, wild west of health care."<sup>3</sup>

State medical boards are slowly moving toward enhanced office-based surgery regulation.<sup>4</sup> However, to date, only 10 states (Arizona, California, Connecticut, Florida, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, and Texas) have placed regulations on office-based procedures, and only a few states require any reporting of adverse events that occur in offices. In April 2001, the Federation of State Medical Boards formed a special committee on outpatient (office-based) surgery. The Federation House of Delegates adopted the committee recommendations as policy in April 2002. The 16-page model guidelines include recommendations on administration, personnel, patient evaluation, anesthesia, accident reporting, facilities accreditation, and liposuction procedures.<sup>5</sup>

The Florida Board of Medicine first instituted a standard of care for office-based procedures in 1994. Following a

number of deaths in the subsequent 5 years, the board sought to strengthen the standards. After almost 2 years of extensive debate, the board issued a new standard of care for office surgery in March 2000. The new rules included requirements for limiting the types and length of procedures, accrediting the office facilities, credentialing the surgeons, determining the appropriate level of training for anesthesia personnel, and mandatory reporting of adverse incidents.<sup>6</sup> Before this, there had been no central source of data regarding adverse incidents in physician offices in Florida. In the first 5 months under these new regulations, 6 deaths were reported, a number that seemed very high to the board. This led the Florida Board of Medicine, in August 2000, to impose an unprecedented moratorium on level III office surgery. (Level III surgery includes procedures performed with the patient under general anesthesia, major conduction anesthesia, and deep levels of intravenous sedation.) The moratorium expired 90 days later, but with the following continuing restrictions: the board rules prohibit level III surgery for high-risk (American Society of Anesthesiologists class 3) patients, prohibit the combination of liposuction and abdominoplasty, limit the length of surgery to 8 hours, and required the reporting of all surgical procedures. The original March 2000 rule also required the presence of an anesthesiologist for all level III procedures. Legal challenges to this portion of the ruling were dismissed, and this rule took effect on April 15, 2002.

As mentioned, mandatory reporting of adverse incidents occurring in physician offices began in March 2000. An office adverse incident is defined in Florida Statutes section 458.351 as an event over which the physician could exercise control, that is associated in whole or in part with a medical intervention, and that results in patient death, injury, or any condition that requires transfer of the patient to a hospital. The physician is required to submit a form to the Board of Medicine within 15 calendar days after the occurrence of the adverse incident. (A copy of the physician adverse incident form is available from the authors.) Licensed ambulatory surgical facilities are required to report adverse incidents under Florida Statutes section 395.1097(8); these incidents include death, brain or spinal damage, wrong procedure, and surgical repair of unexpected complication.

Unlike adverse incident reports for hospitals and ASCs, which are confidential under Florida law, the physician office adverse incident reports are public records under Chapter 119, Florida Statutes; therefore, every office adverse incident report was available for public review.

## METHODS

In May 2002, copies of all adverse incident reports filed to the Florida Board of Medicine were obtained by special request from the Florida Board of Medicine (4052 Bald Cypress Way, Bin #C03, Tallahassee, FL 32399). Each of the incident reports was individually evaluated and placed into one of the following categories: cosmetic, gynecologic, general surgery, otolaryngologic, endoscopy, chemotherapy-radiology, or other. Only reports with procedure dates from April 1, 2000, to April 1, 2002, were reviewed. The number of adverse incidents that involved a surgical procedure and resulted in injury or death were summarized.

Each Florida office performing surgery is required to register with the Florida Board of Medicine. These offices were also required to report surgical logs of all procedures performed in the office each month during the period from November 1, 2000, to February 28, 2001. This information was obtained from Florida Board of Medicine materials presented at the Florida Board's Surgical Care Subcommittee meeting in Tampa, Fla, in May 2002. To adequately estimate the number of office procedures during the 2-year study period, we chose the month with the largest number of procedures and multiplied by 24. Also, during this mandatory reporting period there were 230 offices reporting. By May 2002, the number of registered offices had risen to 315. Therefore, the reported volume of surgeries was multiplied by 315/230 (1.36956) to adjust for the increased number of offices during the study investigation period. This calculation certainly overestimates the number of actual procedures and yields a calculated total volume of 141 404 procedures during the 2-year period.

For each surgical death report, additional information was acquired. Board certification and active hospital privilege information was obtained from the Florida Department of Health Web site.<sup>7</sup> The facility accreditation status was determined from a listing of all registered Florida office surgery facilities obtained by special request in July 2002 from the Florida Board of Medicine. The presence or absence of an anesthesiologist was determined by review of the adverse incident report for each death.

Data from Florida ASCs were obtained to compare the adverse incident and mortality rates with those associated with office procedures. For ASCs, precise data on the number of procedures performed was obtained from the Florida Agency for Health Care Administration Web site.<sup>8</sup> During the 2000 calendar year, 2316249 procedures were performed in Florida ASCs. This number was corrected to exclude cardiac catheterization and radiation therapy visits that were included in the total number of records submitted to the state by some of the centers. Unfortunately, as of September 2002, data on the number of 2001 ambulatory surgery procedures had not yet been posted on this Web site. Therefore, only data from 2000 were used in the adverse incident and mortality calculations. *International Classification of Diseases, Ninth Revision*, procedure and injury codes for each reported 2000 ASC death were obtained by special request from the Florida Agency for Health Care Administration on August 29, 2002. Similar data for 2001 were also obtained; however, the 2001 data were not used in the calculation of morbidity and mortality because the precise number of procedures was not available.

## RESULTS

A total of 182 office surgery incident reports from the 24-month study period were reviewed. Seventeen of these reports indicated patient death. Of these 17 deaths, 4 were not associated with an office surgical intervention. Two of these deaths occurred in radiology suites; one was caused by an anaphylactic reaction to contrast medium, and 1 was due to a severe asthmatic exacerbation. The third was an incorrect report of death after a tonsillectomy performed in a hospital. The fourth was the death of a terminally ill cancer patient in an office waiting room. The other 13 deaths are listed in **Table 1** and include 5 that were associated with cosmetic surgery procedures. Eighty-nine incidents were related to chemotherapy administration or some other nonsurgical intervention that would not have occurred in an ambulatory surgical facility, and thus were excluded. The remaining 93 inci-

**Table 1. April 2000 to April 2002 Florida Office Surgery Deaths (n = 13)**

Category	Procedure	Reported Cause	Anesthesiologist Present*	Accredited Office Facility†	Hospital Privileges and Board Certified‡
Endoscopy	Esophagogastroduodenoscopy	Esophageal perforation	No	No	Yes
Endoscopy	Colonoscopy	Cardiac arrest	No	No	Yes
General surgery	Insertion of vascular device	Cardiac arrest	No	Yes	No
General surgery	Removal of catheter	Respiratory arrest	No	No	Yes
Pain	Spinal injection	Cardiac arrest	Yes	No	Yes
Gynecologic	Termination of pregnancy	Local anesthetic toxicity	No	No	No
Cosmetic	Abdominoplasty/liposuction	Pulmonary embolus	No	Yes	Yes
Cosmetic	Abdominoplasty/liposuction	Pulmonary embolus	No	Yes	Yes
Cosmetic	Rhinoplasty	Respiratory/cardiac arrest	No	No	Yes
Cosmetic	Reduction mammoplasty	Bronchospasm	Yes	Yes	Yes
Cosmetic	Abdominoplasty	Cardiac arrest	No	Yes	Yes
Otolaryngologic	Tonsillectomy	Hemorrhage	No	No	Yes
Radiology	Liver biopsy	Hemorrhage	No	No	Yes

\*Yes in 2 (15%).

†Yes in 5 (38%).

‡Yes in 11 (85%).

dents were judged to be related to a procedure that would likely be performed in an ASC and are compared in **Table 2**. As shown in Table 1, of the office death cases, 11 (85%) of the physicians were board certified and held active hospital privileges. Five (38%) of the facilities were accredited, and 2 (15%) had an anesthesiologist present.

The reported deaths from Florida ASCs are summarized in **Table 3**. Also listed are the *International Classification of Diseases, Ninth Revision*, procedure codes and injury codes, each followed by its description. There were 18 deaths and 123 adverse surgical incidents in 2000. Many of the types of procedures that resulted in office deaths were also performed in ASCs. These included endoscopy, tonsillectomy, liver biopsy, dilation and curettage, and pain procedures. Of the estimated 141 404 procedures performed in offices between April 1, 2000, and April 1, 2002, there were 13 surgery-related deaths, as summarized in Table 2. There were 2316249 reported procedures performed in ASCs during 2000, of which 18 resulted in death. Thus, adverse incidents occurred at a rate of 66 per 100 000 procedures in offices and 5.3 per 100 000 procedures in ASCs. The death rate per 100 000 procedures performed was 9.2 in offices and 0.78 in ASCs. The relative risks for injuries and deaths for office procedures vs ASCs were 12.4 (95% confidence interval, 9.5-16.2) and 11.8 (95% confidence interval, 5.8-24.1), respectively.

#### COMMENT

In this review of surgical procedures performed in offices and ASCs in Florida during a recent 2-year period, there was a significantly increased risk of adverse incidents and death in the office setting. The nationwide trend toward more office-based procedures combined with the increasing degree of surgical complexity in this setting is cause for considerable concern. The Florida Board of Medicine has taken a leadership position during the past decade in improving safety standards for the office surgical setting because of concerns about patient morbidity and mortality. Florida's government agencies have also been cooperative in providing data needed to evaluate

**Table 2. Surgical Outcomes in Florida Offices and Ambulatory Surgery Centers (ASCs)**

	Injury/Incident		Deaths	
	Offices	ASCs	Offices	ASCs
No. reported	93	123	13	18
Procedures	141 404	2 316 249	141 404	2 316 249
Rate per 100 000 procedures	65.8	5.3	9.2	0.8
Relative risk (95% confidence interval)	12.4 (9.5-16.2)		11.8 (5.8-24.1)	

the effect of regulations. Several changes have been made in attempts to improve patient safety. Surgeons performing procedures are required to maintain board certification and hospital admitting privileges; offices are required to maintain accreditation; and anesthesiologists are required to supervise anesthesia performed on all patients undergoing level III procedures.

Despite these requirements, data from the study period suggest that adverse incidents and deaths are each 10 times more likely to occur in an office than in an ASC in Florida. If all of the procedures performed in offices had instead been performed in ASCs, an estimated 43 injuries and 6 deaths per year could have been prevented. If this mortality rate were extrapolated nationally, approximately 96 additional deaths could occur each year. It is interesting to note that the recent billion-dollar Firestone tire recall resulted from 123 nationwide fatalities during several years.<sup>9</sup>

Previous reviews of morbidity and mortality data have shown mixed results, illustrating the difficulty in obtaining and comparing this information (**Table 4**). Obtaining adverse incident and death information for both offices and ASCs as well as total cases performed in both settings is exceedingly difficult. In most states this information simply does not exist. The studies included in

**Table 3. 2000 Florida Ambulatory Surgery Center Deaths (n = 18)**

Category	Surgical Procedure Code	Reported Injury Code
Ophthalmology	13.59 Extracapsular lens extraction, NEC	441.5 Aortic aneurysm—ruptured
Ophthalmology	13.59 Extracapsular lens extraction, NEC	427.5 Cardiac arrest
Otolaryngologic	28.3 Tonsillectomy/adenoidectomy	798 Sudden death, cause unknown
Endoscopy	42.92 Esophageal dilation	998.2 Accidental puncture or laceration
Endoscopy	43.11 Percutaneous endoscopic gastrostomy	998.89 Unspecified complication of procedure, NEC
Endoscopy	45.13 Small-bowel endoscopy, NEC	798.2 Death occurring in less than 24 h
Endoscopy	45.23 Flexible fiberoptic colonoscopy	799.1 Respiratory arrest
Endoscopy	45.23 Flexible fiberoptic colonoscopy	959.9 Unspecified site
Endoscopy	45.23 Flexible fiberoptic colonoscopy	998.9 Unspecified complication of procedure, NEC
Endoscopy	45.23 Flexible fiberoptic colonoscopy	959.9 Unspecified site
Endoscopy	45.25 Endoscopic biopsy of large intestine	997.1 Cardiac complications
Radiology	50.11 Percutaneous needle biopsy, liver	864.0 Injury of liver
General surgery	54.91 Percutaneous abdominal drainage	798.2 Death occurring in less than 24 h
Urology	62.3 Unilateral orchiectomy	798.2 Death occurring in less than 24 h
Gynecologic	69.02 D&C post delivery	998.2 Accidental puncture or laceration
Orthopedics	82.21 Excision lesion, tendon sheath, hand	425.4 Other primary cardiomyopathies
Plastic surgery	86.83 Size reduction plastic operation	998.9 Unspecified complication of procedure, NEC
Pain	99.99 Nonoperative procedure, NEC	427.5 Cardiac arrest

Abbreviations: D&C, dilation and curettage; NEC, not elsewhere classified.

**Table 4. Summary of Published Mortality Rates per 100 000 Patients**

Ambulatory Surgery Centers			Physician Office		
Source	No. of Patients	Mortality	Source	No. of Patients	Mortality
Natof, <sup>13</sup> 1980	13 433	0	Morello et al, <sup>10</sup> 1997	400 695	1.7
Warner et al, <sup>1</sup> 1993	35 598	4.4	Grazer and de Jong, <sup>16</sup> 2000 (liposuction)*	496 245	19
Mezei and Chung, <sup>14</sup> 1999	17 638	0	Hoefflin et al, <sup>11</sup> 2001	23 260	0
Letts et al, <sup>15</sup> 2001	4899	0	Fleisher et al, <sup>12</sup> 2002 (Medicare)	28 199	35
Fleisher et al, <sup>12</sup> 2002 (Medicare)	175 288	25	Present study	141 404	9.2
Present study	2 316 249	0.78			

\*A total of 47.7% of deaths were from office procedures.

Table 4 represent the most thorough review to date, with the largest, most complete sample size, representing both the numerator and denominator for both ASC and office procedures in Florida.

The office mortality rate of 9.2 deaths per 100 000 patients found in this study is comparable with that previously reported. Morello et al<sup>10</sup> relied on voluntary reporting, leaving the possibility that physicians who did not respond to the survey may have had a higher proportion of deaths. Hoefflin et al<sup>11</sup> reported no office deaths in more than 23 000 cases; however, their data are from 1 accredited office with board-certified anesthesiologists and surgeons. This is a different level of care than is provided in any of the other comparison reports. The data from Fleisher et al<sup>12</sup> are for Medicare patients, which is a uniformly older population and expected to have a higher morbidity.

There are possible explanations for the higher rates of adverse incidents and deaths in offices. It is possible, although doubtful, that the acuity of the patients' conditions in offices was higher. Instead, it is more likely that the sicker patients would be taken to an ASC or hospital facility because regulations prohibit level III surgery on these patients. Also, we would assume that the less complicated surgical procedures would be performed in the office and the more complicated ones in the ASC. How-

ever, the lack of peer oversight in the office may allow some physicians to use poor judgment in performing riskier procedures on sicker patients. This becomes more plausible in areas with intense competition for cosmetic surgery patients, such as exists in many metropolitan Florida communities. A recent news article detailed several office deaths that were not reported to the Florida Board of Medicine.<sup>17</sup> Additional unreported deaths would make the office mortality rate even higher.

A statistical analysis of the impact of requirements for surgeon credentialing, office accreditation, and the presence of an anesthesiologist could not be determined because of insufficient data on the patients who did not experience adverse incidents. Information from the incident reports for the patients who died in offices did indicate good compliance with requirements for surgeon board certification and hospital privileges. Unfortunately, the accreditation requirement was poorly met, with less than half of the offices being in compliance. This finding is identical to that contained in a recent report by Coldiron,<sup>18</sup> who looked at only 19 months of Florida data. An anesthesiologist was present in only 15% of the cases resulting in death; however, Florida only recently enforced the rule requiring the presence of an anesthesiologist for level III anesthetics, and it is not clear whether

the circumstances warranted this level of anesthesia for the procedures performed. However, anesthesiologists are present in nearly all ASCs and were present in the study reported by Hoefflin et al<sup>11</sup> in which there were no deaths in more than 23 000 office procedures. This suggests that their presence may be a factor in more favorable outcomes.

More study is needed to determine whether the new office surgery policies instituted by the Florida Board of Medicine have made any difference. This evaluation should include the effect of comorbid conditions, type and length of procedures, and patient age. Single-operating-room facilities should be compared with facilities with 3 or more rooms. The single-room facilities are more likely to have little or no peer review and no backup personnel, and may have less and poorer-quality equipment because the cost is borne by only 1 physician.

A potential solution to the problem of data collection is for the government, perhaps in conjunction with the American Medical Association, to create a mandatory national computerized database that tracks and reports the numbers of cases, adverse incident reports, and deaths in ASCs and office-based procedures. With a massive database of accurate information, risk factors that predispose patients to adverse incidents can be properly identified so that patient safety and outcomes may be improved.

Accepted for publication February 22, 2003.

This study was presented in part as an abstract at the International Anesthesia Research Society 77th Clinical and Scientific Congress; March 21-25 (poster) and 22 (oral presentation), 2003; New Orleans, La; and as a poster at the 5th International Congress on Ambulatory Surgery; May 8-11, 2003; Boston, Mass.

We thank Rebecca Twersky, MD, and Rafael Miguel, MD, for their assistance.

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