Determining the Safety of Office Based Surgery:

What Ten Years of Florida Data and Six Years of Alabama Data Reveal

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Note: The authors have no interest(s) with commercial supporters.

Background: This report is a continued examination of ten 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 via telephone or internet follow-up to determine the reporting physician's board certification status, hospital privilege status, and office accreditation status.

Results: In ten years in Florida there were 46 deaths and 263 procedure-related complications and hospital transfers. A total of 57\% (26/46) of the deaths and 49.8\% (131/263) of hospital transfers were associated with non-medically necessary (cosmetic) procedures. The majority of non-medically necessary (cosmetic) procedure related deaths (67\%) and hospital transfers (74\%) 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. Of the offices reporting adverse events, 38% of offices 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 4 total complications (no deaths), and accounted for 1.3% of all complications over this 10 year period.

In six years in Alabama there were 3 deaths and 49 procedure related complications and hospital transfers. A total of 42% (22/52) of hospital transfers and zero deaths were associated with non-medically necessary (cosmetic) procedures. The majority of cosmetic procedure related hospital transfers (86%) were from procedures performed on patients under general anesthesia.

Liposuction accounted for no deaths and 2 hospital transfers. Of the offices reporting adverse events, 71% of offices 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 1 complication (no deaths), and accounted for 1.9% of all complications over this 6 year period.

**Conclusion:** Continued analysis reveals that medically necessary office surgery does not represent an emergent hazard to patients. The data obtained from 10 years of Florida and 6 years of Alabama adverse event reporting are both comparable and consistent. Medically necessary surgical procedures performed in the office setting by dermatologists have an exceedingly low complication rate, and complications that did arise 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 both Florida and Alabama, and in both states plastic surgeons were most represented.
in adverse event reports. Liposuction performed under general anesthesia requires further investigation as deaths from this procedure continue to occur despite the possibility of using 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 (ASC) procedures should be implemented. All data should be made available for scientific analysis after protecting patient confidentiality.

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 from 1 year, 19 months, 3 years, 4 years, 5 years, and 7 years.1,2,3,4,5,6,7 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 of 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. As 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.

The state of Alabama instituted mandatory physician office adverse event reporting in
December of 2003. Any procedure in an office that results in death, patient transfer to hospital,
anesthetic or surgical events requiring CPR, unscheduled hospitalization related to the surgery,
and surgical site deep wound infection must be reported.

While these reports are currently not 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.

As these adverse events are required to be reported by state law and there was no
intervention on human subjects, approval by an Institutional Review Board (IRB) was not sought
for this study.

All incidents in Florida from 3/2000-1/2010 and Alabama from 12/03-12/09 filed with
the Florida AHCA and Alabama Board of Medical Examiners, respectively have been collected
and analyzed. These reports and summary spreadsheets are available and can be downloaded at
http://www.theskinancercenter.net/reports. Physician hospital privileges were determined via
internet at the Florida Department of Health Healthcare Practitioner License Search at
https://www.doh.state.fl.us/IRM00PRAFS/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 via
internet at Accreditation Association for Ambulatory Health Care (AAAHC) at
http://www.aaahc.org/cweb/dynamicpage.aspx?site=aaahc_site&webcode=find_orgs, the
American Association of Accreditation of Ambulatory Surgery Facilities (AAASF) at
http://www.aaaasf.org, and The Joint Commission at

Results:

Data collected from each state are presented in Table 1, 2, and 3.

Florida:

In 10 years of Florida data there were a total of 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 57% (26/46) of deaths
and 49.8% (131/263) of hospital transfers. The overwhelming majority of cosmetic cases
resulting in hospital transfer or death (79% and 67%, respectively) were performed under general
anesthesia. The most common cosmetic procedures resulting in hospital transfer and/or death
were liposuction and abdominoplasty. Liposuction resulted in 28% of all cosmetic
complications (14% of total complications), and resulted in 32% of the cosmetic deaths (22% of
total deaths). All but 5 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, and cardiorespiratory arrest.
There were 4 adverse event reports from dermatologists in 10 years in Florida, and none resulted in death. One report involved a vasovagal episode which occurred after liposuction performed under general anesthesia. Next, there was a brief episode of atrial fibrillation which 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 2nd degree burn to the face during an excision under IV sedation when an electrocautery spark ignited the oxygen supply.

Alabama:

In 6 years of Alabama data there were a total of 52 adverse surgical incident reports. Three resulted in death, and 49 in reportable complications, or hospital transfers. There were no deaths from cosmetic procedures. Nearly half of all reported incidents (42%) were from cosmetic procedures, and 89% of these procedures were performed under general anesthesia. Liposuction performed under general anesthesia was responsible for 2 hospital transfers over this 6 year period, but there were no reported deaths. These 2 hospital transfers were due to pulmonary edema.

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 (MRSA) infection and seroma development subsequent to a melanoma excision under local anesthesia.

Physician Specialty:

Data collected from each state are presented in Tables 1, 2, and 3.
Analysis of the adverse event reports by 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 in 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 2 highlights the complications by physician subspecialty in both states. According to the Medicare physician registration information, the number of practicing physicians in Florida total about 55,000, while those for Alabama total about 9,200. Based on the number of complications reported in each state over the compiled 16 years, both reveal a minimal rate of percent complication per physician 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, and indeed 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 being accredited by an independent organization. However, 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 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. Of those who were not board certified and/or had no hospital privileges, there was no
increase or pattern of increased adverse events noted. However, the sample sizes of both non
board certified physicians and physicians without hospital privileges were both extremely small
and thus too small to analyze. Therefore, no conclusions can be drawn regarding impact of
physician hospital privileges and/or board certification on overall safety of patients undergoing
surgical procedures in the office setting.

Discussion:

Patient safety issues, 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 continue to solidify trends which have been previously identified in
earlier analyses of this data. Analysis now includes 10 years of Florida adverse event
reporting data, and remarkably the pattern of deaths and injuries has remained consistent with the
first year of reports, that just over half of complications arose from cosmetic procedures. The
significance of these trends are strengthened by the addition of 6 years of Alabama adverse event
reporting data. These support the trends seen in the data collected from Florida, with nearly half
(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. Although Florida requires physicians operating under general and intravenous sedation to keep case logs, these logs are not public domain, and the total number of liposuction cases performed in each state under general anesthesia could not be obtained, preventing calculation of an accurate fatality rate. However, a recent report estimated that a fatality rate as high as 1 in 5224 for liposuction under general anesthesia. Although the exact number of liposuction cases performed in each state under general anesthesia are not obtainable currently, we sought context from 2010 national statistics regarding liposuction procedure volume. National statistics compiled separately by The American Society for Aesthetic Plastic Surgery (ASAPS) and The American Society for Plastic Surgeons (ASPS) 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 further stratifies procedure volume by region. Data on specific states are not available at this time. "Region 4", i.e. 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", i.e. 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, and this is compatible with recent reports of the high safety of liposuction using
exclusively tumescent local anesthesia. Liposuction performed under general anesthesia requires further investigation as deaths from this procedure continue to occur despite the possibility of using dilute local anesthesia for this procedure. As liposuction remains one of the most commonly performed cosmetic surgical procedure in the United States and a recent report estimates that one-third of all liposuction in the United States is performed with tumescent anesthesia, we contend that continued use of general anesthesia for liposuction must be called into question and investigated rigorously.

The majority of patient deaths occurring in the context of general anesthesia (especially when used for liposuction) were delayed. There were two patient deaths reported that appear to be caused directly by general anesthesia—one death from malignant hyperthermia, and one death 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 (ASC) 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 impact on patient safety as 93% of Florida and 100% of Alabama reporting physicians were board-certified in their respective specialties. Similarly, office accreditation does not seem to offer significant patient safety advantages as 38% of Florida and 71% of Alabama reporting facilities were accredited by an independent organization. There is no clear pattern that suggests that board certification or accreditation are effective in preventing deaths, complications, and 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
ongoing regarding regulation for office based surgical procedures, we again call for 
consideration of the balance between prevention of loss of life by increased regulations vs. loss 
of life created by decreased 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 among 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 championed. Reporting of delayed deaths after hospital outpatient and 
ambulatory surgery center (ASC) 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 can 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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<th>Specialty</th>
<th>Florida</th>
<th>Alabama</th>
</tr>
</thead>
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<tr>
<td></td>
<td>% of complications</td>
<td>% of physicians in state</td>
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<tr>
<td>Plastic surgery</td>
<td>44.9%</td>
<td>0.55%</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>11.0%</td>
<td>1.4%</td>
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<tr>
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<td>1.3%</td>
<td>0.8%</td>
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<td>Ob-Gyn</td>
<td>6.4%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Radiology/Interventional Radiology</td>
<td>10.4%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>9.1%</td>
<td>2.6%</td>
</tr>
<tr>
<td>ENT/Facial plastic surgery</td>
<td>4.2%</td>
<td>0.66%</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>3.2%</td>
<td>0.23%</td>
</tr>
<tr>
<td>Dermatology/Dermatologic surgery</td>
<td>1.3%</td>
<td>1.2%</td>
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</tbody>
</table>
Table 2: 10 years of Florida Data

Florida data breakdown: Ten years total
- Total number of physicians in state = 54, 923
- Total number of complications = 309
- Total number of deaths (all cause) = 46 (14.5%)
- Total number of hospital transfers/complications = 263 (85.1%)
- Total number of anesthesia complications = 39 (12.6%)
- Total number deaths (due to anesthesia) = 8 (17.4%)
- Total number of complications due to tumescent anesthesia = 2 (0.76%)
- % complication per physician in Florida = 0.56%
- # of complications per year in Florida = 31

Physician breakdown by specialty:

<table>
<thead>
<tr>
<th>Specialty</th>
<th># of complications</th>
<th>% of complications</th>
<th># of physicians in state</th>
<th>% of physicians in state</th>
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<tbody>
<tr>
<td>Plastic surgery</td>
<td>139</td>
<td>44.9%</td>
<td>303</td>
<td>0.55%</td>
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<td>Gastroenterology</td>
<td>34</td>
<td>11%</td>
<td>759</td>
<td>1.4%</td>
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<tr>
<td>Neph/Int nephrology</td>
<td>4</td>
<td>1.3%</td>
<td>442</td>
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<tr>
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<td>20</td>
<td>6.4%</td>
<td>1447</td>
<td>2.6%</td>
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<tr>
<td>Rad/Int radiology</td>
<td>32</td>
<td>10.4%</td>
<td>3281</td>
<td>5.97%</td>
</tr>
<tr>
<td>ENT</td>
<td>15</td>
<td>4.2%</td>
<td>365</td>
<td>0.66%</td>
</tr>
<tr>
<td>Urology</td>
<td>11</td>
<td>3.6%</td>
<td>657</td>
<td>1.2%</td>
</tr>
<tr>
<td>Cardiology</td>
<td>28</td>
<td>9.1%</td>
<td>1443</td>
<td>2.6%</td>
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<tr>
<td>Orthopaedics</td>
<td>1</td>
<td>0.3%</td>
<td>927</td>
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<tr>
<td>Dermatology</td>
<td>4</td>
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<td>651</td>
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<td>OMFS</td>
<td>2</td>
<td>0.7%</td>
<td>144</td>
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<td>Vascular surgery</td>
<td>10</td>
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<td>129</td>
<td>0.23%</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>5</td>
<td>1.6%</td>
<td>2810</td>
<td>5.1%</td>
</tr>
<tr>
<td>Colorectal surgery</td>
<td>0</td>
<td>0</td>
<td>81</td>
<td>0.15%</td>
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</table>
Table 3: 6 years of Alabama data

Alabama data breakdown: Six years total

- Total number of physicians in state = 9210
- Total number of complications = 52
- Total number of deaths (all cause) = 5 (5.7%)
- Total number of hospital transfers/complications = 49 (94.2%)
- Total number of anesthesia complications = 2 (3.8%)
- Total number deaths (due to anesthesia) = 0
- Total number of complications due to tumescent anesthesia = 0
- % complication per physician in Alabama = 0.56%
- # of complications per year in Alabama = 8.6

Physician breakdown by specialty:

<table>
<thead>
<tr>
<th>Specialty</th>
<th># of complications</th>
<th>% of complications</th>
<th># of physicians in state</th>
<th>% of physicians in state</th>
</tr>
</thead>
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<td>Plastic surgery</td>
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<td>49</td>
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<tr>
<td>Gastroenterology</td>
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<td>27</td>
<td>51.9%</td>
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<tr>
<td>Ob-gyn</td>
<td>0</td>
<td>0</td>
<td>320</td>
<td>3.5%</td>
</tr>
<tr>
<td>Rad/Int radiology</td>
<td>0</td>
<td>0</td>
<td>531</td>
<td>5.77%</td>
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<tr>
<td>ENT</td>
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<td>0</td>
<td>84</td>
<td>0.91%</td>
</tr>
<tr>
<td>Urology</td>
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<td>0</td>
<td>88</td>
<td>0.96%</td>
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<td>Cardiology</td>
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<td>0</td>
<td>275</td>
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<tr>
<td>Orthopaedics</td>
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<td>0</td>
<td>346</td>
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<td>Oral Surgery</td>
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<td>Anesthesiology</td>
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<td>349</td>
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<tr>
<td>Colorectal surgery</td>
<td>1</td>
<td>1.9%</td>
<td>10</td>
<td>0.11%</td>
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</table>