Adverse Event Reporting: Lessons Learned from 4 Years of Florida Office Data

Q1 Brett Coldiron, MD, FACP,* Ann Harriott Fisher,† Eric Adelman, DO,* Christopher B. Yelverton, MD, MBA,† Rajesh Balkrishnan, PhD,‡ Marc A. Feldman, MD, MHS,§ and Steven R. Feldman, MD, PhD†

*The Skin Cancer Center, Cincinnati, Ohio; †Center for Dermatology Research, Departments of Dermatology and Pathology, Wake Forest University School of Medicine, Winston-Salem, North Carolina; ‡Ohio State University College of Pharmacy and School of Public Health, Columbus, Ohio; §Cleveland Clinic Foundation, Cleveland, Ohio

BACKGROUND. Patient safety regulations and medical error reporting systems have been at the forefront of current health care legislature. In 2000, Florida mandated that all physicians report, to a central collecting agency, all adverse events occurring in an office setting.

PURPOSE. To analyze the scope and incidence of adverse events and deaths resulting from office surgical procedures in Florida from 2000 to 2004.

METHODS. We reviewed all reported adverse incidents (the death of a patient, serious injury, and subsequent hospital transfer) occurring in an office setting from March 1, 2000, through March 1, 2004, from the Florida Agency for Health Care Administration. We determined physician board certification status, hospital privileges, and office accreditation via telephone follow-up and Internet searches.

RESULTS. Of 286 reported office adverse events, 77 occurred in association with an office surgical procedure (19 deaths and 58 hospital transfers). There were seven complications and five deaths associated with the use of intravenous sedation or general anesthesia. There were no adverse events associated with the use of dilute local (tumescent) anesthesia. Liposuction and/or abdominoplasty under general anesthesia or intravenous sedation were the most common surgical procedures associated with a death or complication. Fifty-three percent of offices reporting an adverse incident were accredited by the Joint Commission on Accreditation of Healthcare Organizations, American Association for Accreditation of Ambulatory Surgical Facilities, or American Association for Ambulatory Health Care. Ninety-four percent of the involved physicians were board certified, and 97% had hospital privileges. Forty-two percent of the reported deaths were delayed by several hours to weeks after uneventful discharge or after hospital transfer.

CONCLUSIONS. Requiring physician board certification, physician hospital privileges, or office accreditation is not likely to reduce office adverse events. Restrictions on dilute local (tumescent) anesthesia for liposuction would not reduce adverse events and could increase adverse events if patients are shifted to riskier approaches. State and/or national legislation establishing adverse event reporting systems should be supported and should require the reporting of delayed deaths.

THE CENTER FOR DERMATOLOGY RESEARCH IS SUPPORTED BY AN EDUCATIONAL GRANT FROM GALDERMA LABORATORIES, L.P.

Q3 SINCE THE Institute of Medicine's 1999 *To Err Is Human* report revealed that "at least 44,000 and perhaps as many as 98,000 Americans die each year in hospitals as a result of medical errors,"[1] patient safety issues have been at the forefront of a national debate. Although much discussion and legislation have focused on inpatient care, attention has also been directed to the expanding outpatient setting.[2,3] Safer sedation, increased convenience and privacy, and lesser costs have all contributed to the growing demand for outpatient surgery.[4–6] Almost 70% of surgical procedures, many of these for cosmetic purposes, now occur on an outpatient basis.[7,8] In 2003, 56% of all cosmetic procedures were conducted in a physician's office, 28% in a hospital, and 16% in an ambulatory surgical center.[9] The total number of cosmetic procedures performed in the United States increased from 6.6 million in 2002 to 8.8 million in 2003—a 33% increase in just 1 year. The most common procedures were rhinoplasty (356,554 cases) and liposuction (320,022 cases).[10] Office surgical procedures, including cosmetic surgery, continue to grow in scope and number.

With this increase in office-based surgeries and cosmetic procedures, concerns about patient safety have emerged.

Address correspondence and reprint requests to: Steven R. Feldman, MD, PhD, Department of Dermatology, Wake Forest University School of Medicine, Medical Center Boulevard, Winston-Salem, NC Q2 27157–1071.

ISSN: 1076–0512 • Dermatol Surg 2005;31:000–000.

News articles highlighting the hazards of office surgery, particularly liposuction, have contributed to the growing alarm.[11–13] If errors happen so often in regulated hospitals, what about unregulated physician offices? Critics point to various systemic shortcomings, including a lack of peer review, no plans for emergency backup, and few "quality of care" reporting systems.[3] As regulators, the media, and patients assume the worst, state medical boards and legislatures have been "driven by honest concern, interspecialty competition, and public outrage" to impose restrictions on office procedures.[12] Requiring facility accreditation, limiting certain anesthesia techniques, and mandating adverse event reporting are examples of the current restrictions aimed at improving patient safety in the office setting.[14] But are these laws and regulations based on actual evidence-based data?

In 2000, the State of Florida mandated that physicians report all adverse events occurring in an office setting to the Florida Agency for Health Care Administration (AHCA). Nineteen months of this prospective and verifiable data has previously been reported by this author. In 4this article, we update the earlier study for 4 years of Florida adverse event data and analyze the type, extent, and incidence of adverse events and deaths resulting from office procedures. We hope that this type of information, collected from a standardized adverse event reporting system, will be used to develop judicious regulations that improve patient safety.

Methods and Materials

Since February 2000, Florida has required physicians to report adverse events occurring in office facilities to a central collecting body, the Florida AHCA. These reportable adverse events include the death or transfer of a patient; brain or spinal damage; procedures involving the wrong patient, surgery, or surgical site; other damages not included in the informed consent; and the removal of foreign objects.[15] As underreporting is a possible problem, the agency cross-checks this reported data with malpractice claims and spontaneous complaints. Any physician with a noted discrepancy in adverse event reporting is investigated and possibly reprimanded.[11] These range from reprimands and fines to license revocation. Each punishment is individually determined.

For this study, we obtained 4 years of incidence reports (March 1, 2000, through March 1, 2004) from the Florida AHCA, which is public domain. We obtained physician board certification status via the Internet site <www.abms.org/newsearch.asp> and office accreditation via the Web sites of various accreditation agencies. In addition, we contacted all physician offices reporting an adverse event and determined physician hospital privileges. We then confirmed this information by contacting the hospital. All filed incident reports are available for review at <www.theskincancercenter.net>.

Results

During 4 years of data collection, there were 286 incident reports. We excluded 209 of these as "background noise," or events that did not involve a surgical procedure or did not result in death, such as an anxiety attack.[11] Of the remaining 77 reported events occurring in association with an office surgical procedure, 19 resulted in patient death and 58 in hospital transfer (Tables 1 and 2).

Deaths

Of the 19 deaths, 5 occurred following liposuction performed by a plastic surgeon under general anesthesia. Two of the five deaths occurred in association with an abdominoplasty procedure as well. Three were attributed to a pulmonary or fat embolism and two to unknown causes. All five deaths following liposuction occurred several hours to 9 days after uneventful discharge. We consider this a "delayed" adverse event.

Twelve of the 19 deaths happened in association with a cosmetic procedure. In addition to the five deaths following liposuction, three occurred following abdominoplasty and one each following breast implant surgery, breast reduction, rhinoplasty and chin implant, and a face-lift. Of the 12 deaths associated with a cosmetic procedure, 6 of the procedures were performed in an accredited facility, 9 were performed under general anesthesia, and 3 were performed under intravenous sedation.

Of the seven deaths associated with a noncosmetic surgical procedure, two took place in conjunction with a pregnancy termination and two with a dialysis catheter placement. One death occurred with a liver biopsy and two delayed deaths occurred with a gastrointesinal perforation (one colonoscopy and one after an upper endoscopy).

Eight of the 19 reported deaths (42.1%) were delayed by several hours to weeks after uneventful discharge or after hospital transfer.

Surgical Incidents Not Resulting in Death

Fifty-eight surgical procedures resulted in a transfer to a hospital but not death (see Table 2). Overall, 67.2% (39 of 58) of the incidents occurred in association with a cosmetic procedure. These included 10 complications from liposuction and 4 complications from liposuction plus abdominoplasty and/or breast surgery. Thirteen of the events associated with liposuction were reported by plastic surgeons and one event by a dermatologist. Most of these (12) occurred with the use of general anesthesia.

Table 1. 18 Procedure-Related Office Surgery Deaths in Florida (3/1/00–3/1/04)

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
1, 3, 4/12/00	Obesity	Abdomino-plasty, liposuction	Shortness of breath at home following day	Plastic surgeon	General by CRNA	N	To hospital, death from pulmonary embolus	AAAASF	Y	Y
2, 4, 4/14/00	Hypertrophic breast	Breast reduction	Bronchospasm during induction	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, death	N	Y	Y
3, 11, 6/6/00	Abdominal deformity	Abdomino-plasty	Shortness of breath following day, pulmonary embolus	Plastic surgeon	General by MD anesthesiologist	N	To hospital, cardiac arrest, death	N	Y	Y
4, 20, 6/26/00	Facial dystrophy	Rhinoplasty, chin implant	Bradycardia	Facial plastic surgeon	Intravenous sedation by CRNA	Y	To hospital, death	N	Y	Y
5, 32, 8/29/00	Unwanted pregnancy	Termination of pregnancy	Anaphylaxis, cardiac arrest, death	OB-GYN	Local	Y	To hospital, death	N	Y	Y
6, 34, 9/15/00	End-stage renal disease	Hemodialysis catheter placement	Unstable blood pressure after procedure	Radiologist	Local	N	To hospital, death	AAAHC	Y	Y
7, 62, 2/13/01	Lipodystrophy of abdomen/hips	Liposuction, laser resurfacing	Death autopsy pending	Plastic surgeon	General by CRNA	N	Death that night at home	AAAASF	Y	Y
8, 102, 6/8/01	Poor dialysis catheter	Dialysis catheter replacement	Shortness of breath, hypotension, death	Interventional radiologist	Local	N	To hospital, death	N	Y	Y
9, 137, 11/29/01	Rectal bleeding	Colonoscopy	Cardiopulmonary distress, low blood pressure	Gas troenterologist	Intravenous sedation by operating MD	N	Emergency surgery, death soon after	N	Y	Y
10, 152, 2/4/02	Hemoccult positive stool	Upper endoscopy, colonoscopy	Pharyngeal/ esophageal perforation	Gas troenterologist	Intravenous sedation by operating MD	N	Taken to hospital, corrective surgery, death 8 d later	N	Y	Y

Table 1. 18 Procedure-Related Office Surgery Deaths in Florida (3/1/00–3/1/04) continued

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
11, 174, 4/2/02	Jaundice	Liver biopsy	Internal bleeding	Radiologist	Local	N	To hospital, death	N	Y	Y
12, 193, 7/29/02	Cosmetic surgery	Face-lift	Cardiopulmonary arrest in office	Plastic surgeon	Intravenous sedation by operating MD	Y	To hospital, death	AAAASF	Y	Y
13, 191, 8/7/02	Cosmetic surgery/	Neck-lift, hernia repair abdominoplasty, hernia repair	Collapsed 2 d later, pulmonary embolus	Plastic surgeon	General by MD anesthesiologist	N	Pulmonary embolus, death	AAAHC	Y	Y
14, 236, 3/21/03	Unwanted pregnancy	Termination of pregnancy	Amniotic fluid embolism	OB-GYN	IV sedation by operating MD	N	Transported to hospital, deceased	N	Y	Y
15, 280, 5/12/03	Excess abdominal skin and	Abdomino-plasty muscle laxity and liposuction	Pulmonary embolism	Plastic surgery	General by MD anesthesiologist	N	Deceased at home postsurgery day 1	AAAASF	Y	Y
16, 262, 9/25/03	Hypotrophic breasts	Breast implant	Rapid bradycardia	Plastic surgery	IV sedation by operating MD	Y	Deceased on table	N	Y	N
17, 265, 11/13/03	Brow ptosis, recessive chin	Liposuction submental area/ blepharoplasty	Deceased 24 h after surgery	Plastic surgery	General by MD anesthesiologist	N	Deceased following day, unknown cause	N	Y	Y
18, 268, 11/24/03	Fat excess abdomen	Liposuction and fat transfer	Fat embolism	Plastic surgery	General by MD anesthesiologist	N	Deceased 9 d postsurgery	AAAASF	N	Y
19, 270, 1/7/04	Macromastia	Abdomino-plasty, breast reduction	Respiratory/ renal failure postoperatively	Plastic surgery	General by MD anesthesiologist	Yes	Transported hospital, deceased 3 d postsurgery	No	Y	Y

AAASF = American Association for Accreditation of Ambulatory Surgical Facilities; AAAHC = American Association for Ambulatory Health Care; CRNA = certified registered nurse anesthetist; IV = intravenous; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; MD = medical doctor; N = no; OB-GYN = obstetrician-gynecologist; Y = yes.

Table 2. Office Procedures Resulting in Hospital Transfer in Florida (3/1/00–3/1/04)

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
1 1 2/10/00	Pregnancy	Termination of pregnancy	Uterine perforation	OB-GYN	Pudendal block by CRNA	N	To hospital, recovered	N	Y	Y
2 12 2/22/00	Skin cancer	Excision of skin cancer	2nd-degree burn of face	Dermatologist	Intravenous sedation by CRNA	N	To hospital, burns healed	N	N	Y
3 5 4/21/00	Facial laxity	Face-lift	Hematoma	Facial plastic surgeon	Intravenous sedation by MD anesthesiologist	N	To hospital, recovered	AAAHC	Y	Y
4 15 6/21/00	Abdominal lipodystrophy	Liposuction	Acute congestive heart failure, cardiomyopathy	Plastic surgeon	General by CRNA	N	To hospital, discharged 3 d later	AAAASF	Y	Y
5 14 6/22/00	Internal hemorrhoids	Hemorrhoidal artery ligation	Lost needle, vasovagal rxn	Vascular surgeon	Topical	N	To hospital, no death	N	Y	Y
6 17 6/27/00	Lipodystrophy liposuction	Cosmetic	Low BP in recovery	Plastic surgeon	General by MD anesthesiologist	N	Discharged hospital next day	AAAHC	Y	Y
7 16 6/30/00	Cosmetic breast	Mastoplexy/ augmentation	Pneumothorax	Plastic surgeon	General by CRNA	N	To hospital, discharged next day	JCAHO	Y	Y
8 22 7/10/00	Cosmetic liposuction	Liposuction, breast augmentation	Bronchcospasm on extubation	Plastic surgeon	General by MD anesthesiologist	N	To hospital, recovered	AAAHC	Y	Y
9 23 7/14/00	Nasal deformity	Rhinoplasty after procedure	Bronchcospasm	Plastic surgeon	General by MD anesthesiologist	N	To hospital discharged from hospital 21/2 h	AAAASF	Y	Y
10 21 7/18/00	Liposuction/ eye-lift	Liposuction/ blepharoplasty	Myocardial infarction	Plastic surgeon	General by MD anesthesiologist	N	To hospital, recovered	AAAHC	Y	Y

Table 2. Office Procedures Resulting in Hospital Transfer in Florida (3/1/00–3/1/04) continued

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
11 29 8/15/00	Fetal demise	Termination of pregnancy	Asystole, amniotic fluid embolus	OB-GYN	Intravenous sedation by operating MD	N	To hospital, recovered	N	Y	Y
12 35 9/19/00	Pregnancy	Pregnancy termination	Uterine perforation	OB-GYN	Regional block	N	To hospital, no death	N	Y	Y
13 36 9/19/00	Facial laxity	Rhytidectomy	Hematoma, recurrent	Facial plastic surgeon	General by CRNA	N	To hospital, no death	AAAHC	Y	Y
14 37 9/19/00	Gynecomastia	Liposuction/ excision	Hematoma/ low BP	Plastic surgeon	Intravenous sedation by CRNA	N	To hospital, recovered	AAAASF	Y	Y
15 38 9/29/00	GI bleed/ ventral hernia	Virtual colonoscopy	Bowel perforation at hernia	Radiologist	Intravenous sedation by operating MD	N	To hospital, recovered	N	Y	Y
16 39 10/31/00	Cosmetic breasts	Breast augmentation	Pneumothorax postsurgery	Plastic surgeon	Intravenous sedation by CRNA	N	To hospital, discharged 4 h later	AAAASF	Y	Y
17 41 11/08/00	Cosmetic liposuction	Liposuction	Low pO_2, no symptoms	Plastic surgeon	General by MD anesthesiologist	N	To hospital, recovered	AAAASF	Y	Y
18 46 11/20/00	Breast surgery	Breast surgery	Possible early malignant hyperthermia	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, recovered	AAAASF	Y	Y
19 47 11/30/00	Circumcision	Routine circumcision	Accidental cut of glans penis	OB-GYN	None	N	To hospital, repaired same day	N	Y	Y
20 67 2/12/01	Basal cell cancer	Excision of skin cancer	Possible TIA	Plastic surgeon	Local	N	To hospital, no death	N	Y	Y

21 82 4/10/01	Lipodystrophy	Liposuction	Gastric aspiration, laryngospasm	Plastic surgeon	Intravenous sedation by MD anesthesiologist	Yes	To hospital, no death	AAAASF	Y	Y
22 92 5/01/01	Breast implant	Breast implant	Pneumothorax	Plastic surgeon	General by CRNA	N	To hospital, no death	AAAASF	Y	Y
23 85 5/12/01	Infertility	Oocyte retrieval	Chest pain, SOB, no cause found	OB-GYN	Intravenous sedation by MD anesthesiologist	N	To hospital, no death	N	Y	Y
24 89 5/16/01	Breast implant	Breast implant	Pneumothorax	Plastic surgeon	General by MD anesthesiologist	N	To hospital, no death	AAAASF	Y	Y
25 88 5/17/01	Azoospermia	Vasectomy reversal	Pulse rate increased	Urologist	Intravenous sedation by CRNA	?	To hospital, no death	JCAHO	Y	Y
26 100 6/15/01	Hematuria, Foley catheter removal	Office cystoscopy	Syncopal episode	Urologist	Local	N	To hospital, no death	N	Y	Y
27 101 6/15/01	Undesired pregnancy	Termination of pregnancy	Uterine perforation with sigmoid colon tear	OB-GYN	Intravenous sedation by operating MD	N	To hospital, no death	N	Y	Y
28 105 6/19/01	Ptosis-blepharo-chalasis	Blepharo-plasty	Hypoxia s/p extubation, obtunded	Plastic surgeon	General by CRNA	Y	To hospital, discharged next day	AAAHC	Y	Y
29 81 7/30/01	Lipodystrophy	Liposuction	Low BP in recovery	Plastic surgeon	General by MD anesthesiologist	N	Discharged next day	AAAHC	Y	Y
30 111 8/3/01	Wrinkles	Laser peel, eyelid- and neck-lift	Respiratory failure/acute pulmonary edema	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, no death	AAAASF	Y	Y
31 115 8/16/01	Excess abdominal skin	Abdomino plasty	Premature ventricular contractions on induction	Plastic surgeon	Intravenous sedation by CRNA	?	To hospital, no death	N	Y	Y

Table 2. Office Procedures Resulting in Hospital Transfer in Florida (3/1/00–3/1/04) continued

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
32 139 12/21/01	Lipodystrophy	Liposuction	Vasovagal on discharge from office	Dermatologist	General by CRNA	N	To hospital, discharged next day	AAAHC	Y	Y
33 142 1/15/02	Lax anterior abdomen	Abdomino-plasty	Urinary retention/stricture	Plastic surgeon	General by CRNA	N	To hospital, discharged same day	AAAASF	N	Y
34 162 3/19/02	Colonic polyp	Colonoscopy pain	Chest/abdominal	Gastro-enterologist	Intravenous sedation, by operating MD	N	To hospital, no death	N	Y	Y
35 167 3/21/02	Cosmetic breast augmentation	Breast augmentation	Ventricular tachycardia	Plastic surgeon	Intravenous sedation by CRNA	Y	To hospital, no death	AAAASF	Y	Y
36 201 3/22/02	Heme-positive stool	Colonoscopy	Perforated colon during colonoscopy	Gastro-enterologist	IV sedation by operating MD	N	To hospital, no sequelae	N	Y	Y
37 173 3/26/02	Infertility	Aspiration of ovary	Hemorrhage, cardiac arrest	OB-GYN	Intravenous sedation by MD anesthesiologist	N	To hospital, no death	N	Y	Y
38 183 5/14/02	Basal cell carcinoma	Excision of skin cancer	Atrial fibrillation 2 h following procedure	Dermatologist	Local (0.4 cc 2% lidocaine)	N	Drove self to hospital; no admission	N	Y	Y
39 185 6/11/02	Colonic polyp	Colonoscopy	Bleeding during polyp removal	Gastro-enterologist	Intravenous sedation, by operating MD	N	To hospital, no death	N	Y	Y
40 196 8/8/02	Abdominal laxity	Abdomino-plasty	Sinus arrhythmias; low BP	Plastic surgeon	General by DO anesthesiologist	?	To hospital, no adverse sequelae	AAAASF	Y	Y
41 211 11/27/02	Face-lift	Face-lift	Atrial fibrillation	Plastic surgeon	General by CRNA	N	To hospital for cardioversio	AAAASF	Y	Y

Q16	42 227 2/13/03	Abdominoplasty, liposuction.	Abdomino-plasty liposuction	Hypotension, deceased P02	Plastic surgeon	General by MD anesthesiologist	?	To hospital, no death	N	Y	Y
	43 231 3/3/03	Hypotrophic breasts	Breast augmentation	Pneumothorax	Plastic surgeon	General by CRNA	N	48 h in hospital, no chest tube	AAAASF	Y	Y
	44 241 4/24/03	Infertility, endometriosis	Oocyte retrieval	Hypoxemia	OB-GYN	IV sedation x retrieval	N	Transported to hospital, no death	N	Y	Y
	45 244 5/6/03	Facial rhytids	Periorbital laser resurfacing, nasolabial fold implants	Chest pain	Plastic surgery	Local	N	Transported to hospital, no death	N	Y	Y
	46 246 5/29/03	Abdominal elastosis, lipodystrophy	Abdomino-plasty and liposuction	Postoperative elevated temperature	Plastic surgery	General by operating MD	N	Complete recovery	N	Y	Y
	47 247 5/23/03	Gynecomastia, lipodystrophy	Liposuction of chest and flanks	Hypotensive, wide-complex tachycardia	Plastic surgery	General by MD anesthesiologist	N	Transported to hospital, no death	AAAAHC	Y	Y
	48 248 6/16/03	Excessive fat	Lipectomy	Postoperative infection	Plastic surgery	General by MD anesthesiologist	N	Complete recovery	AAAASF	Y	Y
	49 250 6/17/03	Lipodystrophy	Liposuction	Bowel perforation	Plastic surgery	General by MD anesthesiologist	No	Transported to hospital, no death	AAAASF	Y	Y
	50 251 7/1/03	Pneumothorax, breast augmentation	Breast augmentation	Pneumothorax 2 wk later	Plastic surgery	General by MD anesthesiologist	N	Transported to hospital, no death	N	Y	Y
	51 254 7/22/03	D Dermatocholasis, actinic damage	Laser treatment facial rhytids	Seizure	Plastic surgery	Local by operating MD	N	Complete recovery	N	Y	Y
	52 258 9/12/03	Fat excess of hips	Liposuction/left breast implant capsular plication	Acute rise of systolic x blood pressure	Plastic surgery	General by MD anesthesiologist	Y	Complete recovery	AAAASF	Y	Y
	53 273 1/30/04	Obesity	Abdominoplasty	Cellulitis	Plastic surgeon	General by MD anesthesiologist	N	Admitted to hospital	AAAASF	Y	Y

Table 2. Office Procedures Resulting in Hospital Transfer in Florida (3/1/00–3/1/04) continued

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
54 274 2/18/04	Hypomastia	Breast augmentation	Allergic to anesthesia	Plastic surgery	General by MD anesthesiologist	Y	Transported to hospital, no death	AAAASF	Y	Y
55 276 2/27/04	Hypomastia	Breast augmentation	Pneumothorax	Plastic surgery	General by MD anesthesiologist	N	Transported to hospital, no death	AAAASF	Y	Y
56 277 6/3/03	Colon polyps	Polypectomy	Bowel perforation	Gastro-enterologist	IV sedation by CRNA	N	Transported to hospital, no death	N	Y	Y
57 279 9/22/03	Bilateral breast involution	Bilateral endoscopic breast augmentation	Irregular heart rate	Plastic surgery	General by MD anesthesiologist	N	Transported to hospital, no death	AAAASF	Y	Y
58 285 9/9/03	Ptotic skin, gastric bypass, and weight loss	Reconstructive mastopexies and abdominoplasty	Pneumothorax	Plastic surgery	General by MD anesthesiologist	N	Transported to hospital, no death	JCAHO	N	N

Q17 AAASF = American Association for Accreditation of Ambulatory Surgical Facilities; AAAHC = American Association for Ambulatory Health Care; BP = blood pressure; CRNA = certified registered nurse anesthetist; GI = gastrointestinal; IV = intravenous; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; MD = medical doctor; N = no; OB/GYN = obstetrician/gynecologist; pO_2 = oxygen partial pressure; SOB = ; TIA = transient ischemic attack; Y = yes.

Other cosmetic procedures yielded 25 adverse events. Eleven incidents occurred after breast augmentation or reduction, five after abdominoplasties, two after a face-lift, one after reconstructive mastopexies and abdominoplasty surgery, and one each following rhinoplasty, rhytidectomy, blepharoplasty, laser resurfacing and nasolabial fold implant, laser treatment and facial rhytids, and laser peel and eyelid-/neck-lift.

Noncosmetic surgery produced 19 incident reports: 5 following a colonoscopy or polypectomy, 4 after a pregnancy termination, 3 after ovarian aspiration or oocyte retrievals, 3 following skin cancer excisions, and 1 each following cytoscopy, circumcision, hemorrhoid ligation, and vasectomy reversal. There was also one report of a spinal accessory nerve laceration by a physician assistant "operating in an unsupervised fashion" in an internist's office.

Anesthesia

Twelve adverse incidents were associated with anesthesia: seven complications and five deaths (Table 3). All anesthesia complications and deaths occurred in association with cosmetic procedures and none were for medically necessary procedures. Seven of these incidents occurred with anesthesia administered by anesthesiologists (MDs), three by certified registered nurse anesthetists (CRNAs), and two by the operating plastic surgeon. Two deaths and five complications were associated with the use of general anesthesia and three deaths and two complications with the use of intravenous sedation. There were no complications or deaths associated with the use of dilute local, or tumescent, anesthesia when used alone for liposuction.

Adverse Drug Reactions

Overall, there were 45 anaphylactic reactions: 35 were due to chemotherapy infusions, 8 from radioactive dye, and 2 reported in association with lidocaine use.

Office Accreditation, Physician Certification, and Hospital Privileges

Overall, 53.2% of the offices reporting an adverse event were accredited by either JCAHO, AAAASF, or AAAHC (see Tables 1 and 2). Seven of the 19 offices reporting a death were accredited (5 accredited by AAAASF, 2 by AAAHC, none by JCAHO). Additionally, 34 of the 58 offices reporting an adverse incident without death were accredited (22 by AAAASF, 9 by AAAHC, and 3 by JCAHO). Of the 12 incidents owing to anesthesia, 75% occurred in an accredited office (8 by AAAASF, 1 by AAAHC).

The vast majority (94%) of physicians reporting an adverse incident were board certified (eight physicians reported two incidents each). Similarly, 97% of the reporting physicians had hospital privileges. No physicians were operating outside the training parameters of their reported specialty.

Physician Specialty

In terms of the specialty of the operating surgeon, plastic surgeons reported 57.9% (11 of 19) of the deaths, interventional radiologists reported 15.8% (3 of 19), gastroenterologists reported 10.5% (2 of 19), obstetrician-gynecologists reported 10.5% (2 of 19), and a facial plastic surgeon reported 5.3% (1 of 19) of the deaths.

Of the 58 adverse events not associated with a death, plastic surgeons reported 62.1% (36 of 58), obstetrician-gynecologists 13.8% (8 of 58), gastroenterologists 6.9% (4 of 58), facial plastic surgeons 5.2% (3 of 58), dermatologists 5.2% (3 of 52), and urologists 3.4% (2 of 58), and both a vascular surgeon and an interventional radiologists each reported 1.7% (1 of 58 each).

There were three adverse incidents reported by dermatologists; none resulted in a death. The first incident was a second-degree facial burn that occurred after gauze ignited during a skin cancer excision. The next incident involved a vasovagal problem following liposuction under general anesthesia administered by a CRNA. This patient was admitted to the hospital and discharged the following day. The third adverse event was atrial fibrillation following a skin cancer excision. This patient drove himself to the hospital and was not admitted.

Discussion

Medical error reduction and patient safety are topics of the utmost importance for health care practitioners and legislative administrators. The 4 years of Florida data can help clarify the actual adverse events occurring in an office setting. The various lessons learned from these data should be used to reduce medical errors and improve patient safety.

First, liposuction performed under general anesthesia continues to be a problem. Five reported deaths and 14 transfer incidents occurred as a complication of liposuction (with or without another associated procedure) under general anesthesia or deep sedation. According to the Florida data, there were no problems associated with liposuction using dilute or tumescent anesthesia. Similarly, Coleman and colleagues' study of malpractice claims supports the safety of office-based liposuction performed by dermatologists using tumescent anesthesia for small-volume fat removal.[12] In addition, Housman and colleagues' survey of 261 dermatologic surgeons performing a total of 66,570 liposuction procedures found a low rate of serious adverse events (0.68 per 1,000) and no reports of associated deaths.[16]

Table 3. Complications or Deaths Associated with General or Intravenous Anesthesia (3/1/00–3/1/04)

Case No., Raw No., Date	*Patient Problem*	*Surgical Procedure*	*Complication*	*Provider{12}*	*Anesthesia*	*Anesthesia Problem?*	*Outcome*	*Facility Accredited?*	*Board Certified?*	*Hospital Privileges?*
1 4 4/14/00	Hypertrophic breast	Breast reduction	Bronchospasm during induction	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, death after code	N	Y	Y
2 20 6/26/00	Facial dystrophy	Rhinoplasty, chin implant	Bradycardia/ death	Facial plastic surgeon	Intravenous sedation by CRNA	Yes	To hospital, death after code	No	Y	Y
3 46 11/20/00	Breast surgery	Breast surgery	Early malignant hyperthermia	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, discharged next day	AAAASF	Y	Y
4 81 7/30/01	Lipodystrophy	Liposuction	Gastric aspiration, laryngospasm	Plastic surgeon	Intravenous sedation by MD anesthesiologist	Y	To hospital, no death	AAAASF	Y	Y
5 105 6/19/01	Ptosis-blepharochalasis	Blepharo-plasty	Hypoxia after extubation, obtunded	Plastic surgeon	General by CRNA	Y	To hospital discharged next day	AAAHC	Y	Y
6 111 8/31/01	Wrinkles	Laser peel, eyelid-, and neck-lift	Respiratory failure/ acute pulmonary edema	Plastic surgeon	General by MD anesthesiologist	Y	To hospital, no death	AAAASF	Y	Y
7 167 3/21/02	Breast augmentation	Breast augmentation	Ventricular tachycardia	Plastic surgeon	Intravenous sedation by CRNA	Y	To hospital, no death	AAAASF	Y	Y
8 193 7/29/02	Cosmetic surgery	Face-lift	Cardiopulmonary arrest	Plastic surgeon	Intravenous sedation by operating physician	Y	To hospital, death	AAAASF	Y	Y
9 258 9/12/03	Fat excess of hips	Liposuction/ left breast implant capsular plication	Acute rise of systolic blood pressure	Plastic surgery	General by MD anesthesiologist	Y	Complete recovery	AAAASF	Y	Y
10 262 9/25/03	Hypotrophic breasts	Breast implant	Rapid bradycardia	Plastic surgery	IV sedation by operating MD	Y	Deceased on table	N	Y	N
11 270 1/7/04	Macromastia	Abdomino-plasty breast reduction	Respiratory and renal failure postsurgery	Plastic surgery	General by MD anesthesiologist	Yes	Transported to hospital, deceased 3 d postsurgery	AAAASF	Y	Y
12 274 2/18/04	Hypomastia	Breast augmentation	Allergic to anesthesia	Plastic surgery	General by MD anesthesiologist	Y	Transported to hospital, no death	AAAASF	Y	Y

AAASF = American Association for Accreditation of Ambulatory Surgical Facilities; AAAHC = American Association for Ambulatory Health Care; CRNA = certified registered nurse anesthetist; IV = intravenous; MD = medical doctor; N = no; OB/GYN = obstetrician/gynecologist; Y = yes.

All three studies support the safety of tumescent liposuction performed by dermatologists in an office setting. Restrictions on this procedure, therefore, would not likely reduce the number of adverse events. If regulations shift patients from tumescent liposuction to other forms of anesthesia, there is the risk of increasing adverse event rates. Unfortunately, data on the number of liposuction procedures performed and the specific anesthesia used do not exist. To accurately calculate the rate of adverse events associated with liposuction, an accurate count of the number of procedures is needed. Moreover, patients were not prospectively randomized to different treatment settings, so other factors, such as multiple surgeries, patient comorbidities, and physician experience, could underlie differences in adverse event rates.

Numerous covariables must be considered when assessing adverse outcomes associated with liposuction and general anesthesia. The anesthesia used and the associated morbidity and mortality rates seem to vary directly with the procedure's severity. As Housman and colleagues state, "intravenous sedation and general anesthesia are used more often when large-volume liposuction is performed in conjunction with other cosmetic surgical procedures."[16] This information should be taken into consideration when assessing an adverse event associated with liposuction under general anesthesia. Other variables that should be considered include the amount of fat removed per procedure, concurrent or multiple procedures, the presence of fluid overload, the administration of toxic levels of lidocaine with general anesthesia, the inpatient setting, and the use of multiple forms of anesthesia. Several studies have identified these variables as risk factors associated with liposuction.[16–19]

Furthermore, assessing the role that anesthesia plays in any type of adverse event is difficult. There are many situations and potential interactions in which general anesthetics may have an association that is not directly causal to morbidity and mortality. For instance, the fact that the patient is unconscious during a procedure could mask signs or symptoms of a problem. This delay in diagnosis could lead to higher mortality. Of the five deaths associated with anesthesia, two were due to rapid bradycardia and one each to cardiopulmonary arrest, bronchospasm during induction, and postoperative respiratory and renal failure. The various complications associated with general anesthesia include early malignant hyperthermia, gastric aspiration, hypoxia after extubation, respiratory failure and acute pulmonary edema, ventricular tachycardia, and an acute rise in systolic blood pressure. Although almost half of the Florida adverse events were associated with general anesthesia, assigning a direct causal relationship is not possible.

Next, the data also indicate a high frequency of drug reactions (45 cases reported). Medications used to treat anaphylaxis should be up to date and within easy access.

The Florida adverse event information supports the fact that a wide variety of both cosmetic and medically necessary procedures are performed in office settings. It is notable that there are no anesthesia-related deaths or transfers for medically necessary procedures. Legislation aimed at restricting office surgery for medically necessary procedures will reduce access to care and increase costs and does not appear warranted. Underinsured patients not able to afford expensive hospital facility fees may be denied access to care.

Furthermore, the Florida data do not support restrictions of surgical practice based on facility accreditation status. Several states, including Pennsylvania, Rhode Island, Florida, California, and Georgia, and several professional organizations, including the American Society of Plastic Surgeons and the American Society of Aesthetic Plastic Surgeons, require office accreditation by an outside agency.[4,5] However, the data suggest that office accreditation does not improve patient safety because over half (53%) of offices reporting an adverse event were accredited through AAAASF, AAAHC, or JCAHO. As the majority of Florida offices that reported an adverse event are accredited, restrictions that limit surgical procedures in nonaccredited offices are not supported by these data.

Likewise, restrictions limiting office surgical procedures based on physician board certification and hospital privileges are unlikely to be beneficial because 94% of the physicians reporting adverse events were board certified and 97% had hospital privileges. Physicians were not operating outside the training parameters of their reported specialty, nor were physicians operating in their offices because they could not obtain hospital privileges.

Another trend seen in the Florida data involves the high percentage (44%) of reported delayed deaths or deaths occurring several hours to weeks after uneventful discharge or after hospital transfer. This type of delayed adverse event makes the site of procedure irrelevant. State regulations and accreditation agency standards are very specific in defining the nature of an adverse event and how to report an adverse event. However, we were unable to find many specific rules requiring the reporting of delayed adverse events.[20] One notable exception includes a Tennessee Senate bill (#2316) that requires the reporting of "procedure related incidents, regardless of setting and within thirty (30) days of the procedure."[21] Another exception, found in a revision of the AAAASF standards, states that "any death occurring within thirty days of a surgical procedure performed in an accredited facility must be reported."[22] Specific rules regarding the reporting of delayed deaths in all settings should be implemented and policy shaped accordingly.

Most importantly, the data illustrate that office-based surgery, with the exception of liposuction under general anesthesia, is not an emergent hazard for patients in Florida. Like that found after 19 months, most of the

adverse events were "isolated accidents, unexpected, and probably unpreventable." Other studies also support the safety of office surgery.[7,12,23] Two studies that compared the number of Florida adverse events with the estimated number of outpatient surgeries differ significantly. Vila and colleagues found a 10-fold increase in the risk of adverse events occurring in the office setting compared with an ambulatory surgical care setting.[24] However, Venkat and colleagues, using a more thorough estimate of the number of procedures performed, found the rate of adverse events in Florida offices to be as low as that found in the ambulatory surgery center setting.[15] There is a need for a prospective study to examine this rate when the number of adverse events and the number of procedures performed are tandemly collected.[15]

Overall, the Florida data demonstrate the utility of collecting and analyzing adverse event data to improve patient safety. Governments at both the state and the federal level have started to implement adverse event reporting systems. For instance, both the Senate and the House of Representatives have passed similar bills approving the formation of patient safety organizations.[25] These organizations will gather and analyze voluntary, confidential, and legally protected adverse event and medical error information to be used to improve patient safety.[25] Similarly, six states have created patient safety centers, and 22 states have established some type of adverse event reporting system.[26]

A study conducted by the National Academy for State Health Policy concluded that it was "too early to tell what level of error and adverse event reporting improves patient safety."[26] Nonetheless, proponents point to the success of similar adverse event reporting systems used by NASA, the Veterans Administration, the aviation industry, and the Food and Drug Administration.[25,27] Thus, the federal government and many state governments have implemented adverse event reporting systems to improve patient safety.

In conclusion, patient safety and the reduction of medical errors are of the utmost importance to health care providers. Government agencies are implementing adverse event reporting systems to analyze medical mistakes, implement regulations, and improve patient safety. The Florida adverse event data now total 4 years and should be used to help shape the policy of office-based surgery, a growing and important part of our health care system.

References

1. Kohn L, Corrigan J, Donaldson M, editors. To err is human: building a safer health system. National Academy Press; 2000. Available at: www.nap.edu/books/0309068371/html/ (accessed Aug 17, 2004).
2. Lapetina EM, Armstrong E. Preventing errors in the outpatient setting: a tale of three states. Health Affairs 2002;21(4):26–39.
3. Quattrone M. Is the physician office the wild, wild west of health care? J Ambulatory Care Manage 2000;23:64–73.
4. Balkrishnan R, Gill I, Vallee J, Feldman S. No smoking gun: findings from a national survey of office-based cosmetic surgery adverse event reporting. Dermatol Surg 2003;29:1039–99.
5. Rohrich R, White P. Safety of outpatient surgery: is mandatory accreditation of outpatient surgery centers enough? Plast Reconstr Surg 2001;107:189–92.
6. Sutton J. Office-based surgery regulations: improving patient safety and quality care. Bull Am Coll Surg 2001;86:9–12.
7. Fleisher L, Pasternakm R, Herbert R, Anderson G. Inpatient hospital admission and death after outpatient surgery in elderly patients. Arch Surg 2004;139:67–72.
8. Owings M, Kozak L. Ambulatory and inpatient procedures in the United States, 1996. Vital Health Stat 1998;139:1–119.
9. American Society of Plastic Surgeons. 2003 Quick facts: cosmetic and reconstructive plastic surgery. Available at: www.plasticsurgery.org/public_education/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13619 (accessed Aug 17, 2004).
10. American Society of Plastic Surgeons. National plastic surgery statistics 2000–2003. Available at: www.plasticsurgery.org/public_education/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=12552 (accessed Aug 17, 2004).
11. Coldiron B. Office surgical incidents: 19 months of Florida data. Dermatol Surg 2002;28:710–3.
12. Coleman W, Hanke C, Lillis P, et al. Does the location of the surgery or the specialty of the physician affect malpractice claims in liposuction? Dermatol Surg 1999;25:343–7.
13. Chase M. Extreme liposuction is exposing patients to unnecessary risks. Wall Street Journal 1999 Jan 18.
14. Franko F. State laws and regulation for office based surgery. AORN J 2001;73:843–6.
15. Venkat A, Coldiron B, Balkrishnan R et al. Lower adverse event and mortality in physician offices compared with ambulatory surgery centers: a reappraisal of Florida adverse event data. 2003.
16. Housman TS, Lawrence N, Mellen BG, et al. The safety of liposuction: results of a national survey. Dermatol Surg 2002;28:971–8.
17. Grazer FM, de Jong RH. Fatal outcomes from liposuction: census survey of cosmetic surgeons. Plast Reconstr Surg. 2000;105:436–46; discussion 447–8.
18. Hanke CW, Coleman WP. Morbidity and mortality related to liposuction. Questions and answers. Dermatol Clin 1999;17:899–902, viii.
19. Rao RB, Ely SF, Hoffman RS. Deaths related to liposuction. N Engl J Med 1999;340:1471–5.
20. National Academy for State Health Policy. State mandatory reporting rules and statutes: quality and patient safety. Available at: http://www.nashp.org/_docdisp_page.cfm?LID=2A789909–5310–11D6-BCF000A0CC558925 (accessed Aug 23, 2004).
21. Ford J. Tennessee Senate Bill 2316. Available at: www.legislature.state.tn.us/info/Leg_Archives/102GA/Bills/Billsummary/5132316.htm (accessed Aug 23, 2004).
22. American Association for Accreditation of Ambulatory Surgery Facilities. Standards revisions 2003. Available at: www.aaaasf.org/standards (accessed Aug 16, 2004).
23. Morello D, Colon G, Fredricks S, et al. Patient safety in accredited office surgical facilities. Plast Reconstr Surg 2001;107:43–257.
24. Vila H, Soto R, Cantor A, Mackey D. Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers. Arch Surg 2003;138:991–5.
25. Finkelstein J. Senate passes patient safety bill. Am Med News 2004;47(30):1, 4.
26. Robeznieks A. States moving ahead on patient safety front. American Medical News. July 26, 2004. Available at: www.ama-assn.org/amednews/2004/07/26/prsb0726.htm (accessed Aug 3, 2004).
27. American Medical Association. Statement for the record of the American Medical Association to the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, re: health quality and medical records. March 7, 2002. Available at: www.ama-aasn.org/ama/pub/article/print/6303–6002.html (accessed Aug 16, 2004).

Commentary

It has been estimated that 25% of all surgical procedures in 2002 were performed in the office and that by the end of this year, over half of all surgical procedures will be performed in the outpatient setting. This growth has raised concern about patient safety in state legislatures and state boards of medicine. Although I believe that office-based cosmetic surgery is safe, there is only limited proof available to back up that opinion. This extremely important study by Coldiron and colleagues helps confirm that office-based surgery is indeed safe and that many of the suggested "fixes" to improve patient safety, such as mandatory hospital privileges, board certification, and use of accredited facilities, do not, in fact, appear to accomplish that goal. Since there are no federal and few state requirements for reporting adverse events during office-based surgeries, it is extremely difficult to thoroughly evaluate the extent, if any, of this problem. That is why their study is so important.

What is needed is a comprehensive and standardized national system of mandatory reporting of adverse events for all office-based procedures. Without a full accounting of adverse events from all states, it is simply impossible to accurately determine the safety of office-based surgical procedures. This information must include the details of the procedure, setting, facility accreditation status, anesthesia, the patient's general health and age, the physician's specialty and board certification, and whether the physician has hospital privileges to perform the procedure. To prevent underreporting, this information must be confidential and not discoverable in case of litigation.

Although office-based surgeons may believe that what they are doing is safe and in their patients' best interests, in spite of this article, without full and comprehensive collection of adverse event data, that position can never be proven. Incomplete data could possibly result in the passage of meaningless legislation or inappropriate regulations that do not improve patient safety. Data collection of this type, under the conditions described above, should be supported by all physicians who are truly concerned about providing the highest quality of care under the safest conditions possible for their patients.

RONALD G. WHEELAND, MD
AZ

Author Query Form

Journal Derm. Surg. 31-9 Part 1

Article 31327

Queries:

While preparing this paper/manuscript for typesetting, the following queries have risen.

Query No.	Description	Author Response
Q1	AU: No degree for Fisher?	
Q2	AU: Do you wish to provide an e-mail address?	
Q3	AU: Several refs were cited out of order and had to be renum-	
	bered. Pls ensure that all ref citations are as you meant.	
Q4	AU: Who is this author?	
Q7	AU: City for National Academy Press?	
Q8	AU: Spelling of Pasternakm is correct?	
Q9	AU: Inclusive pages, section, for ref 13?	
Q10	AU: Pls complete ref 15.	
Q11	AU: Are pages for ref 19 correct?	
Q12	AU: In the Provider cols in the tables, sometimes you have Plas-	
	tic surgeon and sometimes Plastic surgery. As you meant?	
Q13	AU: You seem to have more than the case no. in the first col of	
	Table 2. Same as for Table 1 or...?	
Q14	AU: What does rxn mean?	

Author Query Form

Journal Derm. Surg. 31-9 Part 1

Article 31327

Queries:

While preparing this paper/manuscript for typesetting, the following queries have risen.

Query No.	Description	Author Response
Q15	AU: Pls spell out s/p.	
Q16	AU: What does P02 mean?	
Q17	AU: Pls spell out SOB.	
Q18	AU: Pls clarify first col heading for Table 3.	
Q19	AU: Pls provide city.	