

RISK MANAGER



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Office-Based Surgery Safety



Deaths raise anesthesia concerns by John B. Neeld, M.D.

During the last decade of the 20th century, the American Society of Anesthesiologists made improvements in patient safety related to anesthesia its first priority and began development of practice standards and guidelines. These efforts, accompanied by increased numbers of highly-trained practitioners, improved monitoring devices. Better pharmacological agents led to a 25-fold reduction in the number of deaths attributed to anesthesia—from one in 10,000 anesthetics to one in 250,000 today. For outpatient surgery patients, the mortality figures may be as low as one in 400,000.¹

Sadly, patients undergoing procedures in offices appear to be at much greater risk than those whose procedures are completed in a hospital environment. An editorial in the *St. Petersburg Times* cited a death rate for office-based surgery in Florida of one in 8,500² and a survey published in *Plastic and Reconstructive Surgery* indicates that the death rate for liposuction procedures is one in 5,000.³ Among many factors related to the surprisingly high mortality rate are:

1. Failure to become accredited by the JCAHO, the American Association for Accreditation of Ambulatory Health Care or the American Association for Accreditation of Ambulatory Surgical Facilities, accreditation indicates that the facility at least meets minimum national standards for policies.
2. Use of antiquated anesthesia equipment that may not meet the ASA (American Society of



Unfavorable outcomes raise liposuction surgery concerns by E. Dan DeLoach, M.D., FACS

Certainly, most are aware of the publication by the Institute of Medicine reporting 100,000 deaths each year in American hospitals as the results of “medical mistakes.” Although this data has been questioned, there are already more and more questions about the safety of surgery and hospitals. Today more than ever, plastic surgery is being performed in greater numbers in an outpatient setting. Often the setting is an office-based or freestanding surgicenter. While this can be a very safe environment, it can also be one that houses inadequacies and dangers of which the surgeon may be unaware. Before you perform surgery in a facility outside your hospital, be sure you understand what resources are available and more importantly, not available at the facility.

If the American Association for Accreditation of Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgical Facilities or the State currently approves the facility, then it has already been inspected for adequacy. This would also include having adequate resuscitation and recovery equipment as well as medications.

Know who is providing your patients’ anesthesia. Is your anesthetist a board-certified Anesthesiologist, a CRNA or a PA? Be sure that you know they are qualified before you allow them to administer anesthesia to your patient. If you are providing the sedation, be sure that you have a RN dedicated only to monitoring the patient while you perform the surgery. Ascertain that vital signs and oxygen saturation are accurately monitored at all times.

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- Anesthesiologists) basic standard for intraoperative monitoring.
3. Failure to ensure routine preventive maintenance for all equipment.
 4. A pharmacy that may be inadequate to treat unexpected complications including cardiac arrhythmia and bronchospasm.
 5. Absence of pre-arranged transfer protocols in the event that an emergency requires hospital admission.
 6. Inadequately trained personnel, especially in the areas of monitoring the sedated patient, airway management and resuscitation techniques.
 7. Polypharmacy (the simultaneous or sequential use of multiple pharmacologic agents) is a common problem in prolonged procedures performed under “conscious sedation.” The additive or synergistic effects of multiple sedative/opioid drugs may result in life-threatening respiratory depression. Additionally, polypharmacy may also lead to the inappropriate use of “reversal agents” which typically have a shorter pharmacological half-life than that of the depressant drug. When reversal agents are employed, the patient may return to a sedated state in an unmonitored environment.
 8. Inadequate skills in patient assessment for anesthesia.
 9. Failure to adhere to national standards, including the ASA’s “Guidelines for Office-Based Anesthesia,” the ASA Statement on Qualifications of Anesthesia Providers in the Office-Based Setting and the ASA “Standard for Basic Anesthetic Monitoring”.⁴

Carefully select the patients who undergo surgery in a facility outside a hospital. Many facilities allow only ASA class 1 and 2 patients. Selected ASA class 3 patients can be handled safely for more limited procedures. Larger procedures, longer operative times and less-healthy patients are probably better served in a hospital environment.

In plastic surgery, we have been concerned with the number of unfavorable outcomes and deaths from liposuction surgery. This has been evaluated and several factors have surfaced. **The main causes of death have been identified as intraabdominal injury from cannula penetration, pulmonary complications from fluid shifts and emboli. Many have recommended that if the aspirate volume exceeds 5000cc, the patient should be monitored post operatively, ideally overnight.**

Lastly and most importantly, good equipment and effective drugs are safe only in the hands of well-trained professional personnel. The surgeon operating in an office environment must recognize that he/she assumes multiple responsibilities that are assumed by the institution and/or the anesthesiology department in a hospital or ambulatory surgery center. Broadly, these responsibilities are to ensure that facilities, policies, procedures and personnel are adequate and appropriate for the type of surgery performed. In particular, absent an anesthesiologist, the supervising physician should be especially trained in sedation, anesthesia and rescue techniques appropriate to the type of sedation or anesthesia being provided.

Whenever patients have elective surgery and anesthesia, they should be afforded a level of safety equal to that in the hospital environment. Patients deserve no less, and we physicians must provide no less.

References:

1. American Society of Anesthesiologists Web site, www.asahq.org
2. “Tougher In-office Surgery Rules,” *St. Petersburg Times*. October 8, 1999.
3. Grager, F.M. and deJong, R.H. “Fatal outcome from liposuction: census survey of cosmetic surgeons.” *Plastic Reconstruction Surgery*. 2000; 105: 436-446.
4. www.asahq.org ●

Careful attention to infusion volume and the time over which the infusion occurs is also important. Most plastic surgeons are using the wet technique where 1cc of infusion is placed for each 1cc aspirated. Care in timing the areas infused in relation to the time aspiration is anticipated is necessary to allow adequate vasoconstriction. **Attention to total volume infused and total lidocaine dose infused is important in avoiding cardiorespiratory complications.** It is important for the surgeon to know the volume infused and the volume aspirated at all times during the procedure. The larger the volume of liposuction done, the greater these concerns become.

Assuring patient safety is a primary concern in any facility. As more attention is focused on outpatient facilities, we too should also focus on the safety of these facilities. ●

CLOSED CLAIM ABSTRACT

by Victoria Kennedy, R.N., Senior Risk Management Consultant

INCIDENT

A 49-year-old white female presented for a laser resurfacing procedure around both eyes and mouth. She went into respiratory arrest and expired.

CLINICAL SEQUENCE

A 49-year-old white female presented to the insured physician's office for a laser resurfacing procedure around her eyes and mouth. The patient had a history of various other cosmetic procedures that included a breast augmentation and a facelift.

The patient was given a preoperative dose of Valium, and then she was given intravenous Valium, Compazine and Fentanyl. The physician then began to inject Xylocaine with Epinephrine locally around her eyes. Within 10 minutes of the injection, the patient's respirations rapidly decreased and then she went into respiratory arrest, followed by cardiac arrest. The patient's vital signs were not being monitored, and there was no resuscitative equipment on the premises. The office called 911 and attempts were made to resuscitate the patient once the Emergency Medical Technicians arrived, but the attempts were unsuccessful, and she was taken to the hospital Emergency Department where she was pronounced dead.

Claim Sequence

A lawsuit was filed against the physician, alleging that he performed the procedure with the administration of IV narcotic sedation when he had inadequate training and experience in properly administering IV sedation anesthesia. Additionally, allegations of improper monitoring of a patient under anesthesia, without the appropriate resuscitative equipment and medications available to properly and timely resuscitate a patient were made.

Disposition

Due to the liability exposure associated with this case, it was settled for a large sum of money.

Risk Management Discussion Points

- Reasons for Office-Based Surgery
- Monitoring and Equipment Recommendations
- Healthcare Professionals Involved in Monitoring and Treatment
- Surgeon's Responsibility and Liability/Anesthesiologist/Certified Nurse Anesthetists/Anesthesia PAs
- Response to Emergencies
- Postoperative Care/Transfers/Discharge

REASONS FOR OFFICE-BASED SURGERY

One of the biggest and most recent changes in the healthcare environment with the advent of managed care has been the move of many surgical procedures out of the hospital and ambulatory surgical centers and into doctors' offices. With this change,

there are more physicians with little experience in handling powerful sedating drugs and little or no emergency equipment available to save patients who experience complications. There are only a few states that have addressed guidelines and requirements for the protection of the patient during in-office procedures.

MONITORING AND EQUIPMENT RECOMMENDATIONS

While surgical procedures are increasingly being moved out of the hospital and ambulatory surgical centers and into doctor's offices, there are no federal requirements for the protection of the patient during in-office procedures. Only a few states have addressed this and implemented some requirements for office-based surgery. The American Society of Anesthesiologists (ASA) and The American College of Surgeons (ACS) have addressed this issue. The ASA has published *Guidelines for Office-Based Anesthesia* and the ACS has published *Guidelines for Optimal Office-Based Surgery*. According to some of the ASA Guidelines:

- All facilities should have, at a minimum, a reliable source of oxygen, suction and resuscitation equipment and emergency drugs. When using IV sedation, it is recommended that pulse oximetry is used.
- All equipment should be maintained, tested and inspected according to the manufacturer's specifications.
- Back-up power sufficient to ensure patient protection in the event of an emergency should be available.

HEALTHCARE PROFESSIONALS INVOLVED IN MONITORING AND TREATMENT

It is extremely important for the facility to have written policies and procedures. These should include policies related to the credentialing of the personnel along with the procedures to be followed for monitoring patients during surgical intervention. According to the ASA:

- All healthcare practitioners and nurses should hold a valid license or certificate to perform their assigned duties (a copy of the current license should be in their personnel file).
- All operating-room personnel who provide clinical care in the office should perform services commensurate with their levels of education, training and experience.

SURGEON'S RESPONSIBILITY AND LIABILITY/ANESTHESIOLOGIST/CERTIFIED NURSE ANESTHETISTS/ANESTHESIA PAs

According to the ASA *Guidelines for Office-Based Settings*, anesthesiologists should participate in all office-based surgery as an important anesthesia-safety standard. The ASA also recommends that

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if the regulatory requirements do not specifically state that an anesthesiologist must be involved in the care of the patient, then the supervising physician should be specifically trained in sedation, anesthesia and rescue techniques appropriate to the type of sedation or anesthesia being provided and to the office-based surgery performed.

Familiarity with the effects and contraindications of the pharmacological agents being used is very important.

The supervising physician must recognize that no matter whether there is an RN, an Anesthesia PA or a CRNA administering and monitoring a patient's sedation, they are **all performing a delegated medical function under the direct supervisory responsibility of the physician.** The ACS' *Optimal Guidelines for Office-Based Surgery* states that general or spinal anesthesia must be supervised by a board-certified anesthesiologist, a physician eligible to take the anesthesiology board examination or a registered CRNA, under physician supervision.

It is recommended that physicians who use the services of CRNAs should require the CRNA to have an ongoing quality assurance relationship with an anesthesiologist to provide regular review of their anesthesia practices.

RESPONSE TO EMERGENCIES

All facilities that are performing office-based surgery should have written policies and procedures for all emergencies including cardiopulmonary emergencies and other internal or external disasters such as fire.

All surgical personnel must be trained in basic life support (CPR) and must be re-certified as required.

There should be a cardiopulmonary resuscitative cart available for emergencies, and it should include, at a minimum, an "AmbuBag, a laryngoscope and a medication kit. The medication kit should include appropriate medications for treatment of anaphylaxis, cardiac arrhythmias and CPR."¹

POSTOPERATIVE CARE/TRANSFERS/DISCHARGE

Both the ASA and ACS recommend that every facility have written protocol for on-site recovery, arrangements for safe and timely transfer of patients to a pre-arranged acute care hospital when extended or emergency services are needed to protect the health of the patient and for patient discharge home.

When a patient is discharged home after a procedure, it is the responsibility of the physician to make sure the patient is recovered sufficiently to function independently. The patient should have stable vital signs and be fully oriented and able to move all extremities. When any type of sedation has been used, the patient should have a responsible adult take him/her home. Discharge instructions should be given verbally and in writing.

CONCLUSION

While only a few states have imposed regulations and guidelines for office-based surgery, the American Society of Anesthesiologists, the American College of Surgeons and other organizations that are involved with outpatient surgery are excellent resources. With so many bad outcomes being reported by the press lately coupled with MAG Mutual's experiences, we feel office-based surgery safety is something that needs to be brought to the attention of all physicians performing surgery in the office environment.

References:

American Society of Anesthesiologist Web site, www.asahq.org

"January 2000 Guidelines for Office-Based Anesthesia"

"Statement on Qualifications of Anesthesia Providers in the Office-Based Setting"

"SAMBA Ready for Uncertain Future"

1. American College of Surgeons

"Guidelines for Optimal Office-Based Surgery"
Second Edition Developed by the Board of Governors' Committee on Ambulatory Surgical Care ●

MAG Mutual does not presume to establish any standard of care or establish rules for the practice of medicine. The particular patient-care strategies or range of patient-care strategies mentioned in this newsletter should be tempered by the physician's judgement.

This publication is produced to inform you of issues relating to medical professional liability insurance and other matters of importance to hospitals and physicians. Material given in this newsletter does not constitute legal advice or opinion. If you have any questions in any of the areas discussed in this publication, you should seek a qualified legal opinion.

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