
Efficacy, Safety, and Cost of Office-Based Surgery: A Multidisciplinary Perspective

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An increasing number of media reports on patient safety risks arising from office-based surgery procedures, as well as growing concerns about patient safety issues in general, have brought office-based surgery as well as its practitioners into focus and placed this very cost-effective medical practice in the eye of the

media and regulators. Concerted efforts are now being made to understand the causes and true incidence of patient safety risk associated with office-based surgery and to find ways to minimize this risk.

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A MULTIDISCIPLINARY conference was held in the spring of 2002 to review and critique the available scientific evidence of benefits, risks, and costs of office-based surgery. Another goal of this conference was to identify areas of need for future scientific study in these areas. This report summarizes the resulting discussions of efficacy, safety, and outcomes associated with office-based surgery and future efforts needed to minimize patient risk in these procedures.

Background

In an era of increasing emphasis on cost-effective delivery of medical care, a growing number of surgical procedures, which were earlier performed in hospitals, are now being performed in outpatient or ambulatory surgery facilities. Other surgical procedures have traditionally been performed in the office setting. Many physician specialties, such as dermatology, are part of the growing number of practitioners of office-based surgery. However, a growing number of widely publicized fatalities and malpractice claims from office-based surgeries have called attention to patient safety issues related to office-based surgery. Opponents of office-based surgery argue that both the superiority of the equipment and surgery-related personnel are compromised by office-based surgery, thus potentially

adversely affecting patient safety. A particularly disturbing 1999 report by the Senate Committee on Investigations, Taxation, and Government Operations found several anecdotal reports to indicate that in the state of New York, physicians were performing surgeries without proper training and were outside of their specialty.¹ In addition, many of these office-based surgeries were being performed using improper instruments and without proper rescue/resuscitation equipment.

Compounding the situation was a report in the *New England Journal of Medicine* by Rao et al.² that identified five patient deaths after tumescent liposuction between 1993 and 1998 in New York City. These reports have increased the focus of regulatory authorities on office-based surgery, which has resulted in a movement toward regulation of office-based surgery through accreditation and certification, as well as development of practice guidelines. Although this has been welcomed by most practitioners, a conflict has arisen between many specialties regarding their roles in this safety issue, with each specialty feeling under attack or unable to weigh in on this issue from a public health issue as well as a specialty advocacy issue. Contributing to the confusion is the lack of evidence available from large-scale studies on issues related to safety and efficacy of office-based surgery.

Extant studies before these reports were few, and the data they provided were mixed. A survey of all board-certified members of the American Society of Plastic and Reconstructive Surgeons (1,200 members, 75% response) reported a liposuction fatality rate of 1 in 5,000 cases.³ As a response to growing interest in

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medical policy and practice concerning the safety of office-based surgery, researchers across various disciplines are empirically exploring issues related to efficacy, safety, and outcomes of office-based surgery. This growing research interest is justified considering that reports project that nearly half of all surgical procedures this year will be performed in outpatient settings (Pateavouras, professional communication, January 2002).

Objectives

To assimilate the growing evidence on important outcomes associated with office-based surgery across a variety of specialties and to discuss in-depth issues related to the development of policy in this area, the Department of Dermatology at Wake Forest University School of Medicine organized a National Institute of Health-sponsored multidisciplinary conference entitled "Safety, Efficacy, and Costs of Office Based Surgery," which was held in the spring of 2002. The main objectives of this conference were as follows:

1. To review and synthesize existing data as well as emerging data from newer studies on the safety, efficacy, and costs of office-based surgery
2. To explore methods to study further these issues related to office-based surgery.

To generate an interdisciplinary, collaborative effort to address these scientific issues, the conference also included discussion of the experience of practitioners across specialties involved in the conduct of and the research in office-based surgery. The ultimate goal of this research and discussion is to provide a scientific basis on which rational office-based surgery policies may be formulated and implemented. This report summarizes the discussions and recommendations on these issues made at this conference.

Safety and Efficacy of Office-Based Surgery

Although there has been considerable media controversy regarding reports of decreased patient safety associated with office-based surgery, data presented by researchers and practitioners across various specialties demonstrate a very low incidence of adverse events resulting from office-based surgery. A study by Coldiron⁴ using prospective, verifiable data collected over a 19-month period since 1999 by the Florida Agency for Health Administration found that the risk to patients from office-based procedures was negligible, with the exception of liposuction under general anesthesia. Six out of eight reported deaths resulted from surgical procedures and/or anesthesia, including

three deaths caused by pulmonary emboli after liposuction under general anesthesia. There were 38 nonfatal complications of office-based surgery, and 9 of these were from liposuction procedures performed under general anesthesia. Almost all physicians involved were board certified (98%), practicing within specialty (100%), not providing their own general anesthesia or deep IV (100%), and had hospital privileges (100%).

There was considerable interspecialty discussion of these findings. A key concern expressed was the need for common terminology and definitions. Dermatologists interpret "tumescent liposuction" to exclude surgeries performed under general anesthesia; others interpret "tumescent liposuction" to include liposuction performed with tumescent (local) anesthesia, whether general anesthesia was administered concurrently or not. It appears that there are greater risks when liposuction is performed in association with general anesthesia. Anesthesiologists pointed out that the major adverse events (e.g., pulmonary embolus) were not caused by the general anesthesia. The interspecialty dialogue led to the conclusion that it is neither liposuction itself nor general anesthesia that is the major risk factor for the adverse events. Rather, it is liposuction performed under general anesthesia that is associated with more adverse events. Whether the surgery is performed in a hospital or office setting did not appear to be related to the risks.

A 1999 study by Grazer and de Jong³ of 1,200 plastic surgeons found that one death occurred in nearly 5,224 liposuction procedures. A more recent study by Lawrence et al., who conducted an anonymous survey of 517 worldwide members of the American Society of Dermatologic Surgeons (71% response rate), found that among dermatologic surgeons who perform nearly 100,000 liposuction procedures each year, only 46 serious nonfatal medical events were reported over a 7-year period (a total of over 63,000 cases were reported; Lawrence, professional communication, January 2002). The most common complication was skin necrosis, and no deaths were reported. This finding is similar to the finding by Coleman et al.,⁵ who examined medical malpractice claims from the Physicians Insurance Company of America from 1995 to 1997. The analysis found that hospital-based liposuction had more than three times the rate of malpractice settlements than office-based liposuction. Dermatologists accounted for less than 1% of the malpractice claim settlements in liposuction. The authors conclude that tumescent liposuction performed by dermatologists, which emphasizes small volume cases under local anesthesia, is a safe and valid approach, as evidenced by the relatively small number of malpractice claims. There is a

potential for large biases because of patient selection and differences in the types of surgeries performed. There was general agreement among discussants that a prospective trial design would be a better approach to establish risk factors for adverse events caused by liposuction.

Risk Management, Quality, and Regulatory Issues

Despite the efforts of the conference organizers, there were very limited data presented on the quality of office-based surgical care. This probably reflects a general lack of research in this area. In an effort to assess the quality of office-based surgical care, Fleischer et al. conducted a multicenter retrospective study of basal cell carcinoma excisions submitted to respective departments of pathology at four major university medical centers (Fleischer, professional communication, January 2002). They found that the likelihood of observing tumor in the surgical margin of a basal cell carcinoma excision was significantly higher in a hospital operating room or surgical center than in an office setting. Two major limitations of this study were discussed. First, because this was not a prospective study, the results could have been impacted by selection bias, despite the efforts of the investigators to control for tumor size, site, and patient demographics. Second, because some physician specialties are more likely than others to perform surgery in the hospital or surgical center than the office, the findings may be impacted more by differences in specialty than by differences in setting. Nevertheless, the authors concluded that there is no evidence to suggest that care is better in a hospital or surgical center compared with the office setting for this relatively minor surgical procedure that has traditionally been performed in the office setting.

Although the safety and quality of office-based surgery are under intense scrutiny, pure office-based surgery is generally considered to provide cost-effective treatment. A study by Chen et al.⁶ using data obtained from the 1992–1995 Medicare Current Beneficiary Study found the average charge for office-based removal of nonmelanoma skin cancer (NMSC) to be \$757 per episode compared with \$7,944 per episode for removal in a hospital-based setting. By reducing the share of NMSC treatment performed in an office-based setting from its current proportion of 76% to 50%, the cost to Medicare for NMSC treatment would increase an estimated \$314 million per year. The authors raise concern that strict regulations may both increase the cost of office-based surgical care and reduce patients' access to cost-effective office-based care for this common malignancy.

Although controversy has centered on the alleged risks of office-based surgery, many practitioners and their patients recognize several advantages of outpatient surgery. A dedicated surgical team in association with dependable office personnel provides exceptional continuity of care and attention to detail, resulting in decreased patient errors. Other under-emphasized benefits of office-based surgery include increased patient satisfaction, decreased incidence of infection, and superior follow-up care.

Every surgical procedure, whether performed in an office-based setting or a hospital setting, has inherent risks that can be minimized with adequate preparation. Successful risk management strategies focus on the selection of a proper surgical environment, surgical team, and appropriate patients for the outpatient setting. A dedicated area of the office should be reserved for surgical procedures and equipped with an emergency generator, appropriate instrumentation, adequate lighting, patient monitors, and proper medications, including those to treat anaphylaxis. Thorough documentation of all telephone calls, surgical procedures, emergency policies, and service and maintenance contracts should be kept. Every attempt should be made to select only patients who are suitable candidates for outpatient surgery. The process of informed consent and the establishment of a solid patient–physician relationship remain the foundation of risk management (Kent et al., professional communication, January 2002).

Of great concern is that regulatory changes will impact the performance of surgery in office-based settings. Opponents of increasing limitations caution that strict regulations may raise the cost of outpatient surgical care, indirectly resulting in increased mortality by preventing patients from receiving necessary treatment. Thirty-one states will soon require accreditation for offices performing office-based surgery. Proponents of accreditation argue that the process motivates facilities to make improvements and provides a means of external validation. They propose that physicians voluntarily seek accreditation in order to establish and document high levels of care, thus preventing the implementation of external regulations by political outsiders. However, there appears to be no scientific basis on which to establish these requirements at this time. The current evidence does not point to any improvement in quality or safety from accreditation requirements to justify the known increased costs.

Future Directions in Improving Outpatient Surgical Care

By the year 2005, it is estimated that 85% of all elective surgical procedures will be performed on an

outpatient basis (Patseavouras, professional communication, January 2002). Many legislatures, medical associations, and state medical boards have begun implementing regulations of office-based surgery. Florida's regulations exemplify state-mandated guidelines of an extensive and controversial nature. Since 1999, the state of Florida has required mandatory reporting of adverse incidents occurring during office-based surgery to an independent agency. The Florida Agency for Health Care Administration tracks all deaths, hospital transfers, procedures performed on the wrong person or at the wrong site, injuries to the brain or spinal cord, and surgical repairs of inadvertent injuries incurred during office-based surgery. In order to minimize underreporting, malpractice cases and complaints are matched with the database, and physicians not reporting incidents are investigated and face sanctions (Kent, professional communication, January 2002).

After several hearings contending proposed restrictions, Florida's first version of its current regulations went into effect in February 2000. Following the institution of a 90-day statewide moratorium on office surgery requiring general anesthesia in August 2000, an outpatient surgery safety committee was created. This committee discovered a lack of data on office surgical outcomes and concluded that insufficient evidence existed to support an increased risk of adverse events caused by office-based surgery. The committee recommended ongoing collection of critical data on office surgery, establishment of an office-surgery medical expert panel, office accreditation for standardization, mandatory risk management systems, practitioner credentialing, and mandatory transfer agreements with a hospital. Specific recommendations for level III office-based surgery (procedures requiring general anesthesia) were also provided (Kent, professional communication, January 2002).

Resulting from a compromise between the committee and the Florida Board of Medicine, Florida's current regulations require basic standards for level I surgical procedures, which include minor procedures such as excision of skin lesions, repair of lacerations, drainage of abscesses, and limited endoscopies. Rules for procedures requiring level II and level III anesthesia are increasingly more stringent regarding personnel and anesthesia requirements. All offices using intravenous sedation or general anesthesia must be accredited by the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgical Facilities, or the Accreditation Association for Ambulatory Health Care, and adverse incidents must be reported to the Medical Board of Florida. Additionally, every office

performing level II and level III surgical procedures must have a risk management program and submit detailed surgical logs. The state incorporates the American Society of Anesthesiologist's (ASA) physical status classification and, for level II and level III office surgery, requires the administration of anesthesia by an anesthesiologist, certified registered nurse anesthetist, or physician assistant. Patients with ASA status III may not undergo a level III procedure in an office setting, and all ASA status II patients over the age of 40 are required to undergo a complete medical examination before initiation of a level III procedure in the office. Physicians must comply with the ASA monitoring guidelines and have a transfer agreement with a hospital. There is also an 8-hour limit on cosmetic or plastic surgery office procedures as well as a limit on the volume of fat removal during outpatient liposuction. Additional restrictions include limitations on overnight stays in the office and the prohibition of certain procedures in the office, including procedures with an estimated blood loss of greater than 10%. The physician must assess the patient immediately before surgery and provide adequate postoperative care arrangements (Kent, professional communication, January 2002).

Although limited statistics on issues related to office-based surgery exist, research presented across various specialties provides a starting point for future investigations. For example, Fleisher et al. presented data based on a review of 170,000 Medicare patients who underwent outpatient surgery. They found that the safest place was a freestanding surgery center (0.5% complication rate), whereas hospital-based outpatient clinics were less safe (1.1% complication rate).⁷ Dr. Coldiron's update on the analysis of the Florida data (19 months of follow-up) found a total of 43 procedure-related complications involving 41 physicians since 1999, 8 of which resulted in deaths. Three deaths occurred after liposuction under general anesthesia by plastic surgeons.⁸ Another example presented at the conference by Katz et al.⁹ included data from a large study of patients aged 50 years and older who were undergoing 19,250 cataract surgeries at nine centers in the United States and Canada between 1995 and 1997. This study found that cataract surgery was a safe procedure with a low absolute risk of medical complications, and these complications did not differ by any specific type of anesthesia strategy.

Prospective data on adverse outcomes of office-based surgery, especially regarding liposuction, are greatly needed. Although the reported safe upper limit of lidocaine dosage in tumescent anesthesia is 55 mg/kg,¹⁰ many researchers question the safety of administering such large doses of lidocaine, particularly

when used as an adjunct to general anesthesia. Further studies to elucidate the pharmacokinetics of lidocaine delivered by a tumescent route and to clarify the effect of general anesthesia on hepatic clearance of lidocaine administered by the tumescent route are warranted. The Institute for Quality Improvement, a subsidiary of the Accreditation Association for Ambulatory Health Care, is currently collecting data on tumescent liposuction from over 60 centers and is expected to generate large-scale prospective data in the near future (Hanke, professional communication, January 2002).

The data presented at the conference raise several other important issues. An important observation is the need for constant update of regulation that is being put in place at the same time based on the newer data that are becoming available. Based on the evidence in Florida (no deaths or complications from conscious sedation or tumescent liposuction), one could argue for whether such strict regulation of these procedures then becomes necessary. Similarly, there are certain specialties that face greater restrictions and regulations on the performance of office-based surgery procedures, although at this point, there are no empirical data to show these differences. Also, there is the question of whether accredited offices are more likely to report complications from these surgeries than unaccredited ones. All of these questions need to be answered with the collection of data from future studies, thus making this a rich and important area for further research.

Problems with existing studies include underreporting, failure to identify confounding comorbidities in hospital settings, failure to report follow-up intervals, and selection bias inherent to retrospective studies. Additionally, several researchers encountered difficulty with the use of ICD-9 (International Classification of Diseases, 9th revision) codes, which fail to differentiate between an excision and a biopsy, and make it difficult to ascertain other outcome measures such as lesion severity, cosmesis, length of time to healing, and required follow-up care. Some researchers suggest that social and gender issues that influence patients to desire hospitalization should be taken into consideration. Future analyses of office-based surgery might also differentiate office-based surgical practices that perform only basic dermatologic procedures, such as skin biopsies and excisions, from those who use general anesthesia in the office.

Conclusions

Data presented by researchers and practitioners in various specialties such as dermatology, ophthalmol-

ogy, plastic surgery, and anesthesiology demonstrate a very low incidence of adverse events resulting from office-based surgery. Furthermore, office-based surgery offers additional benefits such as continuity of care, decreased incidence of infection, and increased patient satisfaction. Evidence presented shows that regarding the treatment of NMSCs, office-based surgery is at least as effective as that performed in hospital settings and is significantly more cost-effective. In contrast to recent reports in the media, existing studies indicate that most physicians are appropriately trained and are operating within the scope of their training. Additionally, large-scale prospective studies are greatly needed in all areas of office-based surgery to provide a basis for evidence-based guidelines.

Conference Participants

Drs. Steven R. Feldman, Rajesh Balkrishnan, Gloria Graham, John Chen, Alan Fleischer Jr., Alain Bertoni, Sally Shumaker, Neal Goldman, William Moran, Cam Enarson, and D.E. Ward (Wake Forest University School of Medicine); Dr. Ronald Wheeland (American Academy of Dermatology); Dr. Brett Coldiron (University of Cincinnati); Dr. Abraham Hartzema (University of Florida); Dr. Naomi Lawrence (Cooper University Medical Center); Dr. Rama Rao (New York University Medical Center); Dr. Marc Feldman (Cleveland Clinic Foundation); Dr. Lee Fleisher (Johns Hopkins University); Dr. Kriston Kent (Naples, FL); Dr. L. Patseavouras (Greensboro, NC); Dr. William Hanke (Accreditation Association for Ambulatory Health Care Inc.); Dr. Duane Whitaker (University of Iowa Hospital and Clinics); Dr. Jo-David Fine (University of North Carolina at Chapel Hill); and Dr. Lynn Drake (Harvard Medical School).

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