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TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

Current Controversies in Adult Outpatient Anesthesia

Jeffrey L. Apfelbaum, M.D. **Chicago, Illinois**

Introduction

The fast paced world of ambulatory anesthesiology continues to present anesthesiologists with an ever-changing array of challenges. This Refresher Course will provide an update on current controversial issues in adult outpatient anesthesia, including fast tracking; preoperative assessment, evaluation, and preparation; recent changes to ASA Basic Anesthesia Monitoring Standards; ramifications of recent changes to Interpretative Guidelines issued by the Center for Medicare and Medicaid Services (CMS) on our practice; and computer assisted personalized sedation. Additionally we will consider a variety of "breaking news" areas of controversy which may include topics such as patients with obesity/modified metabolic syndrome; advances in and recommendations to enhance perioperative communication; treatment decisions for patients with coronary artery stents; opportunities to incorporate one's personal outcomes data into your patient care plan; choice of anesthetic on cancer recurrence rates; and the effects of drug shortages on ambulatory surgical care.

Fast Tracking: Eliminating Intensive Post-Operative Care in Same Day Surgery Patients Using Short Acting Fast Emergence Anesthetics

Many anesthetics have the pharmacokinetic and pharmacodynamic advantages of a shorter duration of action and a more rapid rate of recovery which permit a faster emergence from anesthesia compared with their predecessors. Showing the value of these agents is required to increase their acceptance and foster further development. Less than 30 years ago, it was unthinkable that patients would be able to return home on the day of surgery. Today, advances in surgery and anesthesiology make it possible to perform the vast majority of all surgical procedures, safely and effectively on an ambulatory basis, with many patients ready to be reunited with their families within minutes of emergence from anesthesia. In today's cost sensitive healthcare environment, the processes of ambulatory surgical care must be continually re-evaluated to take advantage of advances in medicine and to optimize the efficiency of the surgical center without detriment to patient safety and satisfaction. Traditionally, ambulatory surgical patients go from the operating room to the postanesthesia care unit or recovery unit (a highly specialized intensive care unit) for their immediate postoperative recovery from anesthesia and then to a second stage recovery unit (SSRU) for preparation for home readiness. By its very nature as a specialized ICU, the PACU is an expensive, labor-intensive environment. After a set of recovery criteria [1, 2, 3] are met in the PACU, the patient is usually transferred to the SSRU. In the SSRU, the patient-to-nurse ratio is considerably higher (i.e., nursing care in the SSRU is less labor intensive) than in the PACU. Only basic monitoring and observation are performed as the patient and his or her escort are prepared for home readiness. Because of the rapid recovery of patients undergoing anesthesia with the shorter acting, faster emergence anesthetics, some have questioned if all ambulatory surgical patients need to receive intensive postoperative care in the PACU setting or whether "first stage" recovery from anesthesia can be achieved safely while still in the operating room (at least for some patients), thereby resulting in enormous potential savings.

The "SAFE" study evaluates the impact of selective patient bypass of the PACU on both the outcomes of ambulatory surgical patients and the use of resources in the surgical arena.[4] This study was designed to evaluate the rapid recovery of patients undergoing ambulatory surgery using short-acting, fast emergence anesthetic agents and to determine if policies and procedures could be developed that would allow patients to safely bypass first stage post-anesthesia care units (PACU) and whether such changes in the recovery paradigm would result in financial savings for the surgical center. Five community based facilities (hospitals or surgery centers) participated in this prospective observational study. While in the operating room at the end of the surgical procedure, anesthesiologists were asked to assess all ambulatory surgical patients for recovery using standardizing discharge criteria typically

used at the end of a PACU stay (Table 1). If the patient met the discharge criteria, they were transferred from the OR directly to the less labor intensive second stage recovery unit (SSRU). Financial data were provided from all five sites detailing all costs associated with the recovery process. Clinical data on every elective ASA 1, 2 and 3 ambulatory surgical patient were collected over a three month period. During month one, data collected established a baseline of case mix, time stamps, adverse events, bypass rates, and financial profile. During month two, an educational intervention was provided on a multi-disciplinary basis to all units in the surgical center discussing the implications of the bypass paradigm. After implementation of the paradigm (month three) weekly feedback reports were provided to the site featuring the key outcomes of the study, and these reports were distributed to the health care providers. Nearly 5,000 patients were entered into the study. The overall bypass rate increased from 15.9% in the baseline month to 58.9% in the month following the educational intervention ($p < 0.0001$). The change in process in this study went beyond reducing time spent in the PACU to eliminating the time spent in the PACU while not increasing the time spent in the operating room or SSRU. In fact, the average (SD) time spent in the SSRU was significantly shorter for patients who bypassed the PACU than for those who did not bypass the PACU. There were no significant differences in other parameters of patient outcome. Annualized savings ranged from $50,000 to $160,000 per site.

The Hows And Whys Of Preoperative Evaluation

The continued growth of outpatient surgery has created new roles for the anesthesiologist which seemingly demands skills in addition to "giving a good anesthetic." The times from induction to emergence are no longer the only important role for the perioperative physician. Particularly in the freestanding and office environments, it is often the anesthesiologist who is most involved in the direct medical care of the patient; we are the physicians who must insure that the patient is appropriately screened, evaluated, and informed prior to the day of surgery. Indeed, the anesthesiologist/patient relationship which sometimes develops often takes on a primary care quality. Although sometimes difficult to arrange, the preoperative interview and evaluation by a consultant anesthesiologist (particularly in high risk patients) can be extraordinarily beneficial. In addition to lessening anxiety about the surgery and anesthesia, in most cases, the anesthesiologist will be able to identify potential medical problems in advance, determine their etiology, and if indicated, initiate appropriate corrective measures. In most facilities, the goal is to resolve preoperative problems well in advance of the day of surgery, thereby minimizing the numbers of both cancellations and complications.

At the present time, there are several commonly used approaches to screening patients for ambulatory surgery. These include: (1) facility visit prior to the day of surgery, (2) office visit prior to the day of surgery, (3) telephone interviews/no visit, (4) review of health survey/no visit, (5) preoperative screening and visit on the morning of surgery, (6) computer assisted information gathering, and (7) the use of telemedicine technology. Each system has its own advantages and disadvantages.

Should Patient Age or ASA Physical Status Influence Case Selection?

Although the vast majority of individuals scheduled for outpatient surgery are relatively healthy (ASA Physical Status 1 and 2), practitioners are constantly being pressured by third party payors to consider "simple outpatient surgery" for patients with significant baseline co-morbidities. A survey of members of the Society for Ambulatory Anesthesia (SAMBA) revealed that half the respondents felt that their practice “pushes the envelope of patient safety by performing outpatient surgery on patients with serious pre-existing conditions,” and that 40% of respondents felt that their practice “pushes the envelope of patient safety by performing complex or lengthy surgical procedures on outpatients.” In the past, many individuals had arbitrarily stated that freestanding ambulatory surgical facilities were severely limited in the type of patients they could anesthetize, particularly with regard to age and physical status. Clinical experience, however, suggests otherwise. In a retrospective study of over 1,500 cases of patients anesthetized for ambulatory surgery, Meridy[5] was unable to demonstrate an age-related effect on the

duration of recovery or the incidence of postoperative complications. Additionally, a retrospective review of cases performed at the Methodist Ambulatory Surgicare Center in Peoria, Illinois between 1981 and 1985 demonstrated an unanticipated admission rate of 1.1% for patients over the age of 60 compared to an overall unanticipated admission rate of 0.8%. With regard to the issue of physical status, in a prospective study involving over 13,000 patients at a freestanding ambulatory surgical center, Natof [6] concluded that ASA 3 patients whose systemic diseases were well controlled preoperatively were at no higher risk for postoperative complications than ASA 1 or 2 patients. Furthermore, in 1987, the Federated Ambulatory Surgery Association (FASA) published the results of a survey involving over 87,000 patients and concluded that there appeared to be little or no cause and effect relationship between pre-existing disease and the incidence of perioperative complications[7] Chung examined predictors of adverse events in ambulatory surgery in the elderly, as well as factors contributing to prolonged stay after ambulatory surgery in elderly patients. This data demonstrated that outpatient surgery is safe in this patient population, with elderly patients sustaining more minor cardiovascular events than their younger counterparts, and less postoperative nausea and vomiting, pain, and drowsiness.[8, 9]. It is clear that geriatric and higher risk (physical status 3 and 4) patients may be considered acceptable candidates for outpatient surgery **if** their systemic diseases are well controlled and the patient's medical condition is optimized preoperatively.

The Inappropriate Patient - Who's OK And Who's Not

There are few data to reliably categorize the inappropriate adult surgical outpatient. As anesthesiologists have become more experienced with the anesthetic management of the problem surgical outpatient, the list of "inappropriate" patients has dwindled. We must individualize our decision with regard to each patient; with few exceptions, the appropriateness of a case for outpatient surgery is determined by a combination of factors including patient considerations, surgical procedure, anesthetic technique, and anesthesiologist's comfort level.

At the University of Chicago Medical Center, we have distinguished several groups of patients who may not be appropriate candidates for ambulatory surgery. As one might expect, this list is frequently modified to adapt to the ever-changing conditions of our social and medicolegal environment.

• Unstable ASA Physical Status 3 and 4: At the present time we are reluctant to proceed with elective ambulatory surgery in a medically unstable patient. Instead, we use our anesthesia perioperative medicine clinic (APMC) to screen these patients, and together with the primary care surgeon or interventionalist, establish a plan to proceed with the surgery or intervention after medical stabilization. Contrary to the original "ground rules" of ambulatory surgery, studies involving hundreds of thousands of patients seem to suggest that neither increasing age nor the presence of stable pre-existing disease affect the incidence of postoperative complications in the surgical outpatient.

• Malignant Hyperpyrexia: In our facility, overnight hospitalization and observation is usually indicated for patients with a history of malignant hyperpyrexia or with identified susceptibility to malignant hyperpyrexia. However, patients who are well educated, have a good understanding of their disease process, and have ready access to medical care may be treated as outpatients by some centers.

• **Complex** Morbid Obesity/**Complex** Sleep Apnea: Although patients who have a history of sleep apnea or who are morbidly obese without systemic disease are acceptable candidates for ambulatory surgery, we prefer overnight hospitalization and postoperative observation for morbidly obese surgical patients with significant pre-existing cardiac, pulmonary, hepatic or renal compromise or those patients with a history of complex sleep apnea. Practice guidelines for the perioperative management of patients with obstructive sleep apnea have recently been developed by the American Society of Anesthesiologists and offer recommendations for preoperative evaluation, preoperative preparation, intraoperative management, postoperative management, and "site" of surgery (inpatient vs. outpatient).[10]

• Acute Substance Abuse: Because of the increased likelihood of acute untoward cardiovascular responses when one administers an anesthetic to a patient who has recently abused illicit drugs, we preoperatively counsel these patients and inform them that any sign of recent drug abuse on the day of surgery will result in immediate

cancellation of their anesthetic. We tell them that no elective surgical procedure "is worth dying for" and encourage their preoperative participation in a rehabilitation program.

Anesthesiology directed perioperative medicine clinics are used to optimize the medical condition of a patient in preparation for surgery. These clinics have been shown to enhance patient safety[11], improve patient satisfaction [12,13], minimize preoperative consultation[14], and reduce day of surgery case cancellations and case postponements.[15]

Changes to the ASA Standards for Basic Anesthesia Monitoring

For the first time in nearly a decade, there has been a significant change to the ASA Standards for Basic Anesthesia Monitoring.[16] The standard for monitoring of ventilation has undergone significant revision: *VENTILATION: 3.2.4: During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.* Many physicians have asked if these standards apply to cases where sedation is administered in "out of operating room" locations. The Centers for Medicare and Medicaid (CMS) Revised Hospital Anesthesia Services Interpretative Guidelines seemingly provide guidance on this issue. The first section in these Interpretative Guidelines is entitled "Types of Anesthesia Services" and the first "bullet" in this section begins as follows: *Anesthesia services, which include both anesthesia and analgesia, are provided along a continuum, ranging from the application of local anesthetics for minor procedures to general anesthesia for patients who require loss of consciousness as well as control of vital body functions in order to tolerate invasive operative procedures. This continuum also includes minimal sedation, moderate sedation/analgesia ("conscious sedation"), monitored anesthesia care (MAC), and regional anesthesia.*

CMS Issues Revised Hospital Anesthesia Services Interpretive Guidelines

CMS has recently issued significant revisions to the Anesthesia Services Interpretive Guidelines.[16] These included significant revisions to the CMS compliance requirements for both pre and post anesthesia evaluations, as well as a requirement that heretofore, **ALL** anesthesia and sedation services (including mild, moderate, and deep sedation) , regardless of providers **MUST** be organized into a single anesthesia service under the direction of a qualified doctor of medicine or doctor of osteopathy. Specific portions of these Interpretive Guidelines will be addressed during the presentation.

Computer- Assisted Personalized Sedation (CAPS)

Ethicon Endo-Surgery, Inc. has recently developed a computer-assisted personalized sedation system (trade name SEDASYS®) According to the manufacturer, "the SEDASYS® System is the first computer-assisted personalized sedation (CAPS) system designed for physician/nurse teams to provide minimal-to-moderate sedation levels with propofol. By integrating drug delivery and patient monitoring, the SEDASYS® System enables physician/nurse teams to deliver personalized sedation. It automatically detects and responds to signs of over-sedation (oxygen desaturation and low respiratory rate/apnea) by stopping or reducing delivery of propofol, increasing oxygen delivery and automatically instructing patients to take a deep breath. The device is currently an investigational device limited by U.S. law to investigational use only."[17]
On May 28, 2009, the Anesthesia and Respiratory Therapy Devices Advisory Committee of the US Food and Drug Administration (FDA) concluded its deliberations and recommended to the FDA that the SEDASYS® device be approvable for the administration of propofol by physician/nurse teams for the initiation and maintenance of minimal to moderate sedation during screening and diagnostic procedures in patients undergoing colonoscopy and

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esophagoduodenoscopy procedures with the following conditions:
1) The device may only be used in adult patients (ASA I, II, and III) 70 years old or younger;
2) The device may only be used in the presence of a 3 person clinical team where one person shall have the sole responsibility of monitoring the patient, the device and managing the patient's airway. This dedicated person must have advanced training and at least the skills of a nurse;
3) Physicians utilizing the device must complete training in advanced airway management, pharmacology of propofol and opioids, patient selection, monitor training (such as SpO_2 monitoring), device set-up and maintenance with the training provided by a clinician with credentials to provide deep sedation to general anesthesia. In addition, there needs to be a program established for ongoing maintenance of training;
4) The manufacturer must complete all post-marketing studies as proposed at the time of the Advisory Panel hearing.
5) The product launch is "controlled."

On several occasions, representatives of the company have suggested that the device is compliant with ASA guidelines on sedation/analgesia by non-anesthesiologists; as a result of this claim both medical professionals and lay people have occasionally erroneously concluded that the device is consistent with ASA standards, guidelines, statements and/or policies.[18] Indeed, some individuals have mistakenly concluded that ASA has "endorsed" the product. However, this conclusion is erroneous. In the AANA-ASA Joint Statement Regarding Propofol Administration (April 14, 2004) the ASA position regarding the use of propofol is clearly stated as follows:[19]
"Whenever propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. This restriction is concordant with specific *language in the propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death."*

In April, 2010, Johnson & Johnson, the parent company of Ethicon-Endo Surgery, Inc., announced that the FDA sent the company a "not approvable" letter for the SEDASYS® Computer Assisted Personalized Sedation System. The company has recently appealed this decision. During the session, we will review many of the specifics of this device and present an update on its current approval status.

Summary

Today there is a continued trend to expand the indications for ambulatory surgery. Because outpatient anesthesia is a break from our traditional training, we are constantly being confronted with the need for change in our clinical practice patterns. We have recognized that the needs of the surgical outpatient may be very different from the inpatient and are now trying to adapt our practice patterns to meet the psychologic and pharmacologic requirements of the compacted perioperative management the outpatient receives. This Refresher Course has focused on some of the controversial problems which we as practicing clinicians must deal with every day in our practice of ambulatory anesthesia for adult patients.

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TABLE 1. DISCHARGE CRITERIA

- Awake, alert, oriented, responsive (or return to baseline)
- Minimal pain
- No active bleeding
- Vital signs stable (not likely to require pharmacologic intervention)
- Minimal nausea
- No vomiting
- If nondepolarizing neuromuscular blocking agent used, patient can perform sustained five second head lift
- Oxygen saturation of 94% on room air (three minutes or longer) OR return of oxygen saturation to baseline or higher in order to be eligible to bypass Phase I recovery (PACU), the patient must meet ALL of the above criteria, and in the judgment of the anesthesiologist, be capable of transfer to the step-down unit, with appropriate care and facility for patient management at that location

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