Risk assessment in ambulatory surgery: challenges and new trends

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THE explosive growth of ambulatory surgical programs has been one of the most formidable changes in the practice of medicine in the past quarter of century. Few other events have affected so many patients in such a fundamental fashion. It has been estimated that approximately 60 to 70% of all surgical procedures performed in the United States are now being done on an outpatient basis.[1] As outpatient surgery continues to diffuse to include a wide range of procedures and be offered to more high-risk patients, it is important to examine its safety in actual settings for high-risk populations.

Although complications in ambulatory surgery are relatively uncommon, little is known about the characteristics of patients or settings that have higher rates of poor outcomes such as death, unplanned hospitalizations or emergency room visits following the procedure. This situation reflects the not uncommon phenomenon of rapid diffusion of a technology without an evidence based analysis to determine appropriate risk factors for analysis. While much has been made of the preoperative process as a vehicle for appropriate testing, the ability to truly determine the relative risk of ambulatory surgery is, at best, ambiguous despite over 20 years into its rapid growth phase.

ASA classification

The first attempt to quantify risks associated with surgery and anesthesia was undertaken by Meyer Saklad[2] in 1941 at the request of the American Society of Anesthesiologists. This effort was the first by any medical specialty to stratify risk for its patients. Saklad's system was based on mortality secondary to anesthesia due to associated preoperative medical conditions. Type of anesthesia and nature of surgery were not considerations in this system and the divisions were based on empirical experience rather than on specific sets of data and reflect the techniques and standards of practice as of 50 years ago. Four preanesthesia risk categories were established ranging from category 1 (least likely to die) to category 4 (highest expectation of mortality).

The current ASA system (Figure 1) is a modification of this work, adding an additional fifth category for moribund patients undergoing surgery in a desperate attempt to preserve life. Numerous studies have demonstrated an association of mortality with ASA class independent of anesthetic technique.[2–12] However, this information has limited application as it relates to mortality as its sole outcome and is based on anesthetic techniques as practiced more than 20 years ago. Apfelbaum[3] and Meridy,[4] for example, have noted a lack of correlation between ASA status and cancellations, unplanned admissions and other perioperative complications in outpatient surgery. It should also be noted that the original study of Saklad and subsequent derivations were not based on actual determinations of mortality and associated morbidity and mortality, either retrospectively or prospectively. Thus, while useful as a broad assessment of preoperative medical status, the current ASA classification is limited in its ability to truly establish risk or serve as a basis for formulating clinical guidelines without an associated risk index for the surgical procedure.

The Johns Hopkins risk classification system

The Johns Hopkins risk classification system[5] (Figure 2) was one of the first attempts to formulate a multifactorial risk assessment system by adding the invasiveness of the surgical procedure as a function of risk along with the more traditional preoperative medical condition. The Johns Hopkins risk classification system is based on the well established assumption that the nature of the surgery is clearly a major determinant of risk and needs to be coordinated with medical status in determining preoperative risk assessment. This system is predicated on the assumption that patients of identical medical status undergoing minor office procedures are at less risk of adverse events and in need of less preparation than those undergoing

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surgery that entail blood loss, fluid shifts, or other significant physiologic intervention and compromise. Such an assumption matches a common sense approach assumed by clinicians in virtually all types of settings and daily practice. While various systems exist for stratifying surgical and medical risk in an intensive care setting,[3,4,7–9] these have several drawbacks when applied in a general preoperative setting, especially for outpatient procedures.

This system was built upon the observations of the confidential inquiry into perioperative deaths in Great Britain as reported in 1987.[10] In that retrospective study it was determined that surgical condition was most frequently cited as the cause of death, followed by medical status and then anesthesia (Figure 3). It also proposed that mortality was most often a combination of factors rather than assignment to a single specific cause. The nature of surgical causation was not established with regard to invasiveness, site of surgery or other factors. The Johns Hopkins risk classification system proposed that the risk of surgery is a combination of several factors, including invasiveness, associated blood loss and fluid shift, entry into specific body areas (e.g., intrathoracic, intracranial), postoperative anatomic and physiologic alterations and need for postoperative intensive care monitoring. Procedures were assigned to the various categories in consultation with the surgical, anesthesia, medical and nursing staffs by which these patients are managed. Though broad in their scope and subject to potential variances in interpretation, the five categories may provide a reasonable basis for use in the practice environment, pending further verification. However, like the ASA, this system is based on assumptions and presumptions rather than actual fact.

ASA advisory on preoperative evaluation

When the ASA Preoperative Advisory Task Force began its deliberations in 1994, it agreed, during its initial phase, that the ability to determine appropriate risk, for purposes of patient testing and consultation, needed to include medical condition and the nature of the surgical procedure. The Task Force participants determined that an algorithm might be used that may fit most situations relating to the timing of the preanesthesia evaluation (Figure 4). The Task Force adopted a system that included two levels of stratification for the medical status and three for the nature of the surgical procedure. In doing so, it was using an algorithm based on the same type of flow as that adopted by the American Heart Association/American College of Cardiology guidelines and is part of the model adopted by the ASA Preanesthesia Task Force. On the basis of this algorithm, it was determined that healthy patients undergoing procedures of minor or intermediate complexity or stable patients with significant medical issues but with procedures of low risk or complexity may have their evaluation on the day of surgery with the caveat that appropriate information is available for review prior to surgery to provide reasonable assurance of a patient who is sufficiently prepared for surgery or anesthesia. This recommendation did not preclude the possible benefit of a preanesthesia evaluation prior to the day of surgery for such purposes as education, allaying anxiety, or prevention of day of surgery delays associated with last minute evaluation It simply referred to the safety of this timing of the evaluation should all parties be comfortable with it.

Conversely, patients with high medical risk having complex procedures were believed to benefit from a preanesthesia evaluation prior to the day of surgery. Exceptions to this mandate were to be made on the basis of the anesthesiologist's comfort with the nature of information provided prior to the day of surgery and the ability to appropriately prepare the patient without such a visit. However, again, this system represented a consensus of opinion rather than an actual evidence based model of appropriate risk factors and outcomes. In fact, the ASA in its report noted the paucity of appropriate data on which to base such a system and strongly advocated for more definitive studies.

Challenges from the past – and more

The ability to determine risk by measures of admission and death for ambulatory surgery are difficult due to the low frequency of events. Such a study would most certainly have to be multi-institutional and, perhaps, national in scope to capture the relevant variables to allow for a true determination of the appropriate risks associated with this endeavour. To add to the complexity of such an analysis, additional factors have come into play as confounding variables in this enterprise. Beyond the issue of medical status and type of surgery the concern of site of surgery has now come forward. As with the issue of the proliferation of procedures done in the absence of controlled studies to assess outcome, ambulatory surgery locations have expanded beyond the traditional hospital to freestanding multispecialty centres, single specialty centres and physician offices. The often cited episodic cases of deaths in physician office locations for cosmetic procedures has brought forward much attention but little objective insight into the issue of the extent to which the factors of type of surgery, medical status, anesthesia, and location of procedure interact to create a true risk assessment structure for the tens of millions of

TABLE I Number of procedures and % of total performed by location of care in 5% Medicare sample for 1994–1999

Procedure	*Outpatient hospital*	*ASC*	*Office*	*% Outpatient**
Cataract extraction	256087	163032	15917	98
TURP	4822	353	322	16.1
Inguinal hernia repair	25690	2727	312	74.5
Laparoscopic cholecystectomy	14336	200	171	39.5
D&C	6100	779	1127	80.5
Simple mastectomy	718	51	14	32
Modified radical mastectomy	1636	43	45	17
Carpal tunnel repair	13862	2860	442	92.1
Knee arthroscopy	18203	3222	353	88.5
Femoral hernia repair	821	76	19	24.9
Hysteroscopy	5178	799	651	86.2
Shoulder cuff repair	2982	319	50	48.3
Umbilical hernia repair	3271	273	59	54.1
Arteriovenous graft placement	3253	136	35	32.5
Hemorrhoidectomy	3391	360	8415	89.9
Hysterectomy, vaginal	114	6	48	2.7
All procedures	360464	175236	27980	

* Represents the total procedures performed in the outpatient hospital + ambulatory surgery centre (ASC) + office of the total number of such procedures performed in all locations of care during the same time period. TURP = transurethral resection of the prostate; D&C = dilatation and curetage.

ambulatory procedures performed annually in North America alone. During the late 1990s, office-based surgical procedures became much more common, with an estimated 5 to 8% of procedures being performed in the office in the year 2000.[11]

A recently published study by Fleisher *et al.*[12] was one of the first to address this issue. The authors utilized a 5% sample of Medicare beneficiaries from 1994–1999, matching part A and part B data to obtain both facilities and medical provider data. Patients undergoing any one of 16 surgical procedures were identified with outcome of death, hospital admission, or emergency room visit measured. The selection of surgical procedures was based upon their prevalence in the outpatient setting and their rapid diffusion from the inpatient to outpatient setting in the last ten years. Death, hospitalizations and emergency room (ER) visits on the day of surgery (calendar day), within seven days, and within 30 days of the procedure were the three outcome variables. There were 563,680 surgical procedures identified that were further stratified by site of surgery: hospital-based outpatient (360,464), free standing ambulatory centre (ASC) (175,236), and office-based (27,980) (Table I).

For the 16 procedures, there was a trend towards increasing frequency in the outpatient setting from 1994 to 1999, except for cataract surgery which was already performed in the outpatient setting 98.6% of the time in 1994 (Table I). For all 16 procedures, the proportion of surgeries in the outpatient hospital increased from 80.6% in 1994 to 88.2% in 1999. This is higher than the rate for all surgical procedures because our select criterion allowed only procedures that could be performed in the outpatient setting.

Table II shows the rates of death, ER visits, and inpatient admissions at seven and 30 days post-surgery. There were no deaths on the day of surgery in the office, four deaths in the ASC (2.3 per 100,000) and nine in the outpatient hospital (2.5 per 100,000; P = NS) Within seven days of surgery, there were ten deaths in the office (36 per 100,000), 43 deaths in the ASC (25 per 100,000) and 179 deaths in the outpatient hospital (50 per 100,000; $P < 0.05$ for ASC compared to outpatient hospital) The number of ER visits within seven days of surgery was 248 (879 per 100,000) in the office, 1,453 (829 per 100,000) in the ASC and 7,477 (2,074 per 100,000) in the outpatient hospital ($P < 0.05$ for outpatient hospital compared to either ASC or office) The number of patients admitted to an inpatient hospital within seven days was 511 (1,826 per 100,000) in the office, 1280 (730 per 100,000) in the ASC and 12,489 (3,464 per 100,000) in the outpatient hospital ($P < 0.05$ for all groups compared to each other). The rates per day at zero to seven days and eight to 30 days for the three outcome variables were also calculated (Table II). The rate of deaths per day was lower during the first seven days after surgery when compared to the subsequent 23 days, while the rate of ER visits and inpatient admissions per day were greatest during the first seven days (Table II).

TABLE II Rate of adverse events per day (per 100,000 procedures) by site of care for 16 procedures performed in Medicare beneficiaries from 1994–1999

Adverse events	*Outpatient hospital*	*ASC*	*Office*	*Overall outpatient*
Death same calendar day as procedure	2.5	2.3		2.3
Death 0-7 days	6.2	3.1	4.5	5.1
Death 8-30 days	7.3	5.6	5.2	6.6
Death 0-30 days	7.0	4.9	5.1	6.3
ER visit, 0-7 days	259.3	103.6	109.9	203.3
ER visit, 8-30 days	106.6	79.6	60.3	95.9
ER visit 0-30 days	139.0	82.9	69.9	118.1
Inpatient admission, 0-7 days	433.1	91.3	228.3	316.3
Inpatient admission, 8-30 days	115.3	74.0	74.3	100.4
Inpatient admission 0-30 days	174.5	70.2	101.0	138.4
Total procedures	360464	175236	27980	563680

ER = emergency room, ASC = ambulatory surgery centre.

TABLE III Event rates and total cases for basic demographic and location of care factors for Medicare beneficiaries undergoing 15 procedures during 1995–1999 used for logistic regression analysis

	Inpatient admission	*ER visit*	*Death*	*Total cases*	*Inpatient admission rate per 100,000 procedures 0-7 days*	*ER visit rate per 100,000 procedures 0-7 days*	*Death rate per 100,000 procedures 0-7 days*
Male	5,529	3,746	102	181,723	3,043	2,061	56
Female	6,603	4,759	104	301,857	2,187	1,577	34
Age							
65-69	2,212	1,559	31	80,782	2,738	1,930	38
70-74	2,951	2,083	45	121,642	2,426	1,712	37
75-79	3,027	2,127	54	129,077	2,345	1,648	42
80-84	2,292	1,610	39	93,921	2,440	1,714	42
85+	1,650	1,126	37	58,158	2,837	1,936	64
Office	401	209	8	23,225	1,727	900	34
Outpatient hospital	10,281	6,384	156	303,696	3,385	2,102	51
ASC	1,058	1,256	36	150,519	703	834	24

ER = emergency room, ASC = ambulatory surgery centre.

The absence of any large scale evaluation of the safety of outpatient surgery has led some authors to estimate that the rate of operative mortality associated with anesthesia and surgery in the outpatient setting (either in the operating room or postanesthesia care unit) is of the order of 0.25 to 0.5 per 100,000 outpatient surgeries.[9] These estimates were based upon insurance claims of intraoperative mortality related to anesthesia in healthy individuals undergoing elective inpatient surgery[10] and have questionable applicability to the fastest growing surgical population in the United States - the rapidly expanding geriatric population. The study of Fleisher *et al.* calculated the same-day mortality rate in a population over age 65 to be 2.5 per 100,000 or five to ten times greater than these estimates. Further, as seen in Table III, age alone does not appear to be an independent risk factor once the patient population enters into the geriatric grouping until age 85, versus the traditional and unsubstantiated age 70 used for the current classification systems.

The influence of location of care varied by procedure. For those models with sufficient sample size, the risk-adjusted odds ratio for hospitalization and death within seven days for office-based care is shown in Table IV. Hemorrhoidectomy in the office was associated with a significantly lower risk-adjusted rate of adverse events compared to ASCs, while cataract surgery, hysteroscopy, inguinal hernia repair, arterio-venous (A-V) graft placement, knee arthroscopy, transurethral resection of the prostate (TURP) and umbilical hernia repair were associated with significantly higher rates, frequently higher than outpatient hospitals.

TABLE IV Increased risk associated with office care compared to the ASC for a given procedure when each risk procedure was evaluated individually

Effect	*Odds ratio for increased risk of office care compared to ASC*	*95% Wald confidence limits*	
Hemorrhoidectomy	0.146	0.076	0.281
Cataract extraction	1.555	1.288	1.877
Hysteroscopy	2.313	1.094	4.890
Inguinal hernia repair	3.818	2.335	6.243
A-V graft placement	4.046	1.580	10.361
Knee arthroscopy	4.718	2.472	9.005
TURP	7.491	4.162	13.481
Umbilical hernia repair	10.793	3.731	31.223

*Adjusted for age, gender, race and prior admission history. A-V = arterio-venous; TURP = transurethral resection of the prostate

Conclusion

There is a great deal of interest in safety in health care, and the surgical suite is perhaps one of the greatest areas of interest due to the potential for life threatening risk. Nonetheless, the availability of appropriate risk assessment strategies is but in its infancy despite an exponential growth of ambulatory surgery. While there is reason to believe this growth has been conducted in a safe fashion, the increasing acuity of patients and procedures performed in a multiplicity of settings reinforce the need for a scientific determination of risk to aid clinicians and policy makers alike in their work.

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