

## Identifying and reporting risk factors for adverse events in endoscopy. Part I: cardiopulmonary events

Joseph Romagnuolo, MD, FRCPC, MSc, Peter B. Cotton, MD, FRCP, Glenn Eisen, MD, MPH,  
John Vargo, MD, MPH, Bret T. Petersen, MD

Charleston, South Carolina; Portland, Oregon; Cleveland, Ohio; Rochester, Minnesota, USA

The risks of endoscopy procedures are likely affected by the competence of the endoscopist and the team (nursing, anesthesia, and technicians), the details of the specific procedure being performed, and the patient's anatomy, demographics, and health status. In 2008, the American Society for Gastrointestinal Endoscopy (ASGE) convened a workshop to recommend a lexicon to define and describe the adverse events (AEs) (previously commonly referred to as complications) that can result from endoscopy procedures.<sup>1</sup> One additional goal of this workshop was to standardize the reporting of factors that may predict AEs in clinical practice and in research. This list of such factors might enable the creation of risk strata (allowing comparison of AE rates by risk groups). In addition, AE rates among different groups of endoscopists and different groups of patients might be more appropriately compared

*Abbreviations: AE, adverse event; APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; MET, metabolic equivalent; MI, myocardial infarction; NSQIP, National Surgical Quality Improvement Program; POSSUM, Physiologic and Operative Severity Score for the Enumeration of Mortality and Morbidity.*

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Current affiliations: Medical University of South Carolina (J.R., P.B.C.), Charleston, South Carolina, Oregon Health and Science University (G.E.), Portland, Oregon, Cleveland Clinic (J.V.), Cleveland, Ohio, Mayo Clinic (B.T.P.), Rochester, Minnesota.

Reprint requests: Joseph Romagnuolo, MD, MUSC GI and Hepatology, 25 Courtenay Drive, ART 7100, MSC 290, Charleston, SC 29425.

by strata. Last, prospective risk assessment might enhance the quality of informed consent and facilitate decisions regarding procedural appropriateness.

The aim of this 2-part article is to summarize the body of work that has been published on this topic and to suggest the types of risk factors that need to be considered for inclusion in endoscopy reporting/database systems. Possible, but unproven, risk factors were also considered to guide further research into candidate factors and their relationship with AEs. Establishing and recording the competency of the team are beyond the scope of this article.

AEs are often organized by the type of event (eg, cardiopulmonary, bleeding, perforation). However, their frequency and type clearly vary by procedure (the risks for colonoscopy are different than those for ERCP), and some events (pancreatitis, infection) rarely or never apply to some procedures. Equally, the factors that predict those AEs also vary among procedures (eg, demographics may predict post-ERCP pancreatitis, but may have little influence on EGD complications).

Many noncardiopulmonary AEs are closely linked to the type of intervention (eg, bleeding or perforation related to polypectomy), such that each procedure (eg, colonoscopy, upper endoscopy) would have to be discussed separately under each AE heading. For a more efficient presentation of the data, we discuss them organized by procedure type rather than by AE type. In contrast, most predictors of cardiopulmonary AEs are patient-centered factors and do not vary significantly from procedure to procedure (although admittedly procedural complexity and duration may influence event rates). In addition, comorbidities do not generally predict the noncardiopulmonary events. Therefore, the cardiopulmonary AEs and their predictors, which are relatively constant across procedure types and which require a discussion of the various comorbidity indices, are discussed separately from the other AEs and their potential predictors, in part I of this 2-part article. Part II discusses predictors of noncardiopulmonary events and contains a summary and final recommendations for documentation of predictors or risk factors for both types of events.

## METHODS

A comprehensive PubMed search to June 1, 2010, yielded more than 2000 articles by using the following criteria: EGD/endoscopy, complications (n = 256); colonoscopy, complications (n = 692); EUS, complications (n = 175); ERCP, complications (n = 573); esophageal dilation, complications (n = 293); comorbidity index, endoscopy (n = 276); sedation risks, endoscopy (n = 246). A search of the Cochrane library uncovered one additional systematic review.<sup>2</sup> Abstracts from these papers were read to select articles pertaining to predictors or risk factors of AEs in endoscopy. The majority of the articles listed in the PubMed search were unfortunately not relevant to the prediction of AEs in endoscopy; 106 articles were selected as potentially relevant and critically reviewed. In addition, we reviewed references to several comorbidity indices and citations from reviews on risk assessment in endoscopy and noncardiac surgery. The data and conclusions were presented at the ASGE Adverse Events Workshop (September 5-6, 2008, Chicago, Ill). Further in-person and online discussion occurred, and the article draft was then reviewed by members of the Workshop and approved by the ASGE Quality Committee.

## RISK FACTORS FOR CARDIOPULMONARY EVENTS

Although the threshold at which an event becomes a significant AE has recently been proposed and published,<sup>1</sup> in the existing literature, the definition of a cardiopulmonary AE varies considerably and may not always be explicitly described. Gangi et al,<sup>3</sup> for example, defined a cardiovascular AE as arrhythmia, hypotension, chest pain (or angina equivalent), or myocardial infarction (MI); the event had to require intervention and had to occur soon (same or next day) after endoscopy, but intervention itself was not specifically defined.

Most of the data for scoring and predicting events are published in the context of surgery rather than endoscopy.<sup>4</sup> Surgery often involves general anesthesia (with paralytics and endotracheal intubation), which rarely applies to endoscopy. Although the deeper level of sedation may add risks, routine intubation may also decrease some risks, such as aspiration. Abdominal or thoracic surgical incisions and postoperative pain inhibiting mobility for hours or days after the procedure increase the risk of atelectasis and other cardiopulmonary problems, but this is rarely relevant to endoscopy. There are, however, several key studies looking at risk factors for cardiopulmonary events after endoscopy. Based on colonoscopy as a model, the published odds ratios for various risk factors are summarized in Table 1.<sup>5-16</sup> Age,<sup>5</sup> American Society of Anesthesiologists (ASA) physiologic classification grade,<sup>5,6</sup> type of anesthesia,<sup>2,6,7,15,16</sup> inpatient status,<sup>5</sup> nonuniversity

hospital,<sup>5</sup> and trainee involvement<sup>5,8</sup> are among the risk factors identified, with the ASA score being the most powerful predictor.<sup>5,6,14</sup> Acute Physiology and Chronic Health Evaluation (APACHE II) scores, cardiopulmonary disease, and recent MI specifically may also predict complications.<sup>9-13,17</sup> Increased body mass index and obstructive sleep apnea can predict perioperative morbidity after surgery<sup>18</sup> and may increase risk and make airway maintenance more in deep sedation (or general anesthesia without endotracheal intubation),<sup>14</sup> but for moderate sedation, unrecognized sleep apnea<sup>19</sup> did not appear to predict transient hypoxia or AEs in 1 study<sup>17</sup>; another study found that body mass index in ASA grade I-II patients predicted the number of hypoxic episodes.<sup>20</sup>

Several comorbidity indices other than the ASA physiologic classification have been studied in surgery and endoscopy. These include the Charlson comorbidity index,<sup>21</sup> the National Surgical Quality Improvement Program (NSQIP), and the Physiologic and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM).<sup>22-24</sup> Although they have been used to predict outcomes after endoscopy (eg, survival after a gastrostomy tube is placed), none has been used to predict periprocedural events. Therefore, they may be of some use in studies of the late outcomes of endoscopy procedures, but they remain unproven for prediction of procedural AEs.

## Advantages and limitations of available comorbidity indices

The ASA (or ASA physical status) score is the most widely used index of comorbidities for endoscopy because it is simple and seems to predict cardiopulmonary events.<sup>5,6,14</sup> The scale varies from I (healthy) and II (mild systemic disease) to V (moribund) and VI (brain dead). However, older studies showed low consistency (<60%) in hypothetical patients,<sup>25</sup> and more recent ones show poor interobserver reliability ( $\kappa = 0.21-0.40$ ).<sup>26</sup> The latter has also never been assessed for endoscopists or endoscopy staff. Differentiating the first 3 grades is especially subjective, so this variable is often dichotomized as III or above in predictor studies. It is also not a good predictor of noncardiopulmonary AEs<sup>27</sup> or overall AEs,<sup>28</sup> and for some procedures, like ERCP (in which younger, fitter patients may be more likely to get pancreatitis), the correlation may be an inverse one.

The APACHE II score is a complex instrument, with dimensions that include a physiology score (12 inputs), an age score, and organ failure points. However, it has a number of elements (eg, PaO<sub>2</sub> and arterial pH) that are not available for most endoscopies. Its applicability to endoscopy is questionable, yet it did seem to predict AEs after MI.<sup>4,10,13</sup>

The Charlson comorbidity index<sup>21</sup> is simply a list of 19 comorbidities (eg, diabetes, liver disease [mild vs moderate/severe], renal disease), each with an assigned weight, from 1 (eg, previous MI, congestive heart failure

**TABLE 1. Summary of literature on predicting cardiopulmonary events after colonoscopy (as a model case for endoscopic procedures)\***

Risk factor	Risk magnitude (OR)	References	Comments
Age	1.02/y	5	Events are very rare (1.1%-1.2%) <sup>5,6,28</sup>
ASA	1.8, 3.2, 7.5 (ASA grade III, IV, V)	5,6	
APACHE II	12 (for score >15), in EGD	10,13	Potentially confounded by recent MI group with a high APACHE II score
Type of anesthesia	0.3 (MAC vs GAP in ASA grade I-II); no difference if ASA grade ≥III; 0.5 (propofol vs moderate sedation)	2,6,7,15	A Cochrane review concluded that there was no difference between propofol and nonpropofol sedation regarding adverse events, but not stratified by GAP vs MAC <sup>2</sup>
Inpatient	1.5	5	
Setting (VA, nonuniversity)	1.2, 1.4	5	
Supplemental oxygen	1.2	5	
Trainee involvement	1.3	5	Risk factors in trainees also studied <sup>8</sup>
Pulmonary disease		9,17	Undiagnosed sleep apnea does not seem to predict transient hypoxia during moderate sedation <sup>17</sup>
Cardiac disease	5.2 for recent MI (within 30 d)	9-13	Potential confounding by higher APACHE II score in MI patients <sup>10,13</sup> ; others found EGD risk only increased within a few days of MI <sup>11</sup>
Obesity	~1.5 for hypoxemia	20	Body mass index may predict hypoxemia, but not necessarily AEs

AEs, Adverse events; APACHE II, Acute Physiology Score and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; GAP, gastroenterologist-administered propofol; MAC, monitored anesthesia care (generally with propofol); MI, myocardial infarction; VA, Veterans Affairs hospital.

\*A few key studies in EGD were also included in this table; risk factors (as well as baseline risk) for cardiopulmonary events may differ for different endoscopic procedures.

(CHF), diabetes without end-organ damage) to 6 (metastatic cancer). It has value in predicting life expectancy over months or years, but has not been validated for use in predicting the risk of individual interventions and would be expected to be poor at predicting events that would be expected to occur in the short term (eg, 30 days).

The POSSUM<sup>22-24</sup> score has both physiologic and operative elements predicting surgical morbidity and mortality. The physiologic set includes 12 factors that are quite simple (such as age, dyspnea [resting/exertional], blood pressure, hemoglobin/potassium, coma scale). The 6 operative elements include operative severity (major/minor surgery), multiple procedures, blood loss, peritoneal soiling, malignancy, and emergency versus elective scheduling. The elements have several grades, making it cumbersome to calculate a score manually, so a calculator is available online. However, most of the elements do not pertain to endoscopy.

NSQIP is a registry of multiple preoperative risk factors, laboratory data, operative procedure details, ASA score, Mallampati score, wound class, and postoperative events. Some of the data entry for the first sections is quite labor intensive, including smoking and alcohol histories and the elements of a comprehensive meta-

bolic panel, complete blood count, and coagulation studies. The rest of the questionnaire is lengthy (>30 questions), but straightforward, requiring yes/no answers for factors like recent (within 30 days) CHF or angina, coagulopathy, and steroid use. There are 20 factors thought to be most important including (in rough order of decreasing predictive importance) functional status (dependence [partial/total], dyspnea [resting/exertional], altered sensorium, morbid obesity, previous cardiac intervention, current smoking, stroke, hypertension, diabetes, chronic obstructive pulmonary disease (COPD), age, and hypoalbuminemia. It is not clear whether weightings are to be used in calculating a score.

Perhaps these lists of factors could be modified and shortened for endoscopy. The main problem with surgical comorbidity indices (from the endoscopy perspective) is that they predict a host of sequelae that are not relevant to most endoscopy procedures, such as wound healing, leaking anastomoses, and blood loss. Cardiopulmonary events are generally the primary concern for endoscopy in patients with significant comorbidities. Cardiac AEs have been the specific focus of several research groups, and this literature is summarized in the following.

## Specific preoperative cardiac risk assessment indices

The Goldman cardiac risk index,<sup>29</sup> based on 1001 patients undergoing noncardiac surgery, comprises 9 independent predictors of outcome. Active CHF and MI (within 6 months) were the most powerful, followed by arrhythmias, age (older than 70 years), surgery type, and poor overall/functional status (hypoxia, hypercarbia, hypokalemia, low bicarbonate, creatinine >2.5 normal, liver disease, or bedridden), translating into 3 mortality risk groups ranging from 0.2% to 56%. A modified (several elements removed: oxygen saturation [ $<90\%$ ] substituted for blood gas) Goldman index,<sup>29</sup> by using a financial database for 9 New Jersey hospitals, seemed to predict cardiac AEs, along with male sex and propofol use.<sup>3</sup> Unfortunately, the study methodology had significant limitations: random patients undergoing endoscopy (0.5%,  $n = 139$ ) were labeled as controls and were compared with the 26 case patients who had an AE among a random subset (25%,  $n = 602$ ) of those thought to be at risk (cardiac medications, cardiac enzymes ordered, or intensive care needed), curiously excluding from the analysis the rest of the at-risk group who did not have an AE. The bias introduced by these methods, however, likely led the score and propofol use to be artificially predictive of AEs because the defining factors for the at-risk group, from which the only AE cases were chosen, was already correlated with these candidate predictors.

Detsky's modified cardiac risk index<sup>30</sup> is also fairly simple; it also includes recent (inactive) CHF, previous MI, and the Canadian Cardiovascular Society Classification of Angina (I, with strenuous exercise; IV, with any physical activity).

Other similar indices have also been published,<sup>31,32</sup> and guidelines for perioperative cardiovascular evaluation for noncardiac surgery were published in 1996<sup>33</sup> and updated in 2002.<sup>34</sup> They include many of the previously mentioned features, plus valvular disease, diabetes, stroke, and diastolic pressure greater than 100 mm Hg; they divided these factors into those of minor/intermediate importance (advanced age, functional status) and those of major importance (eg, recent MI or active CHF). Poor functional status was more precisely defined: "inability to climb one flight of stairs with a bag of groceries" (ie,  $<4$ - $6$  METs [metabolic equivalents])<sup>34,35</sup> and more strictly than the definition of independence in NSQIP (activities of daily living are generally  $<4$  METs<sup>35</sup>).

Based on these varied indices, picking out the factors that come up most often and seem most important, a shorter list of risk factors can be proposed that likely encompasses those important for predicting a cardiac event during a noncardiac procedure. They include age, previous and recent MI, previous and current/recent CHF, rhythm other than sinus, diabetes, renal failure, uncontrolled hypertension, previous stroke or other neurologic

impairment, and inability to do a 4- to 6-MET activity (walk up a flight of stairs, do yard work, golf without a cart, or walk  $>4$  mph) or dependency on help doing less-than-4-MET activities (i.e., activities of daily living) because of angina, dyspnea, or other reason. Other factors such as sleep apnea, obesity, polypharmacy, severe COPD, the use of home oxygen, procedure duration, and depth of sedation also likely modify cardiopulmonary AE risk in endoscopy and deserve further study.

## Stopping antiplatelet/anticoagulant therapy

Antiplatelet and anticoagulant agents may get stopped before certain procedures, although for many routine procedures, this does not seem necessary. When they are held, however, the risk of thrombosis increases, whether of clotting a valve, throwing an embolus, or thrombosing a coronary stent; the latter (sometimes fatal) is recognized to occur after noncardiac surgery, especially in patients with high-risk coronary anatomy, within 6 weeks of bare metal stent placement and within 1 year of drug-eluting stent placement.<sup>36</sup> These risks are summarized in other reviews.<sup>36-39</sup> Of note, in some high-risk cases (recent thrombosis, recent drug-eluting coronary stent placement, mechanical valves), even a few days of holding antiplatelet or anticoagulant drugs may increase this risk significantly. However, it seems clear that noting how long a drug has been held and how long it will be before it will be restarted is relevant to cardiopulmonary AE risk; the timing and type of the previous coronary intervention are also relevant.

## SUMMARY

Our goal was to identify or develop a relatively small data set that would be useful in predicting the risk of endoscopic procedures. This review shows that this is not an easy task because there are a wide range of factors and a variety of risks. Risk assessment may also be complex when more than 1 risk factor is present because the way in which different factors interact is variable. Risk factors for cardiopulmonary AEs seem different from those for noncardiopulmonary AEs. However, factors that predict cardiopulmonary events likely also influence the *outcome* (morbidity and mortality) of noncardiopulmonary events (eg, pancreatitis or perforation) when they occur, even if they do not increase the *frequency* of those AEs.

For cardiopulmonary events, it seems that documentation should include age, inpatient versus outpatient status (perhaps also clarify for inpatients where [endoscopy suite vs other] and when [routine hours vs off-hours, elective vs urgent/emergent] the procedure is performed), trainee involvement, the type of sedation or anesthesia, supplemental oxygen use, and major comorbidities (especially cardiopulmonary, including severe COPD and sleep apnea).

**TABLE 2. Summary of the recommended cardiopulmonary adverse event predictive factors to be reported for basic, intermediate, and advanced/investigational use\***

<b>Basic</b>
Demographics
ASA class
Outpatient/inpatient/intensive care unit setting
Type of anesthesia and who administered it
Procedure duration
Current anticoagulant/antiplatelet therapy
<b>Intermediate</b>
Basic, plus:
Major comorbidity (e.g., coma, cardiomyopathy, dialysis, cirrhosis with or without ascites, oxygen-requiring chronic pulmonary disease)
Procedure duration
Trainee involvement
<b>Advanced/Investigational</b>
Intermediate, plus:
Cardiac status (previous/recent angina, myocardial infarction, heart failure, or arrhythmia)
Coronary interventions (previous/recent angioplasty/stent, bypass surgery)
Pulmonary status (resting hypoxia, severe chronic pulmonary disease, sleep apnea)
Neurologic status (stroke with residual deficit, decreased level of consciousness, or coma)
Functional status (inability to walk up a flight of stairs [or equivalent activity], dependence on someone to help with activities of daily living)
Nutritional status (including malnutrition and obesity)

ASA, American Society of Anesthesiologists.  
 \*See the summary table in part II of this 2-part series, which includes predictors of both cardiopulmonary and noncardiopulmonary adverse events.

**TABLE 3. Proposed menu items for endoscopy reporting software for the factors listed in Table 2\***

<b>Demographics</b>
Age
<b>Clinical status</b>
BMI
<20
20-30
30-40
40-45
>45
ASA grade
<b>Independence (KPS scale)</b>
Able to carry on normal activity and to work; no special care needed (KPS score 80-100)
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed (KPS score 50-70)
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly (KPS score 0-40)
<b>Coagulation issues</b>
Current anticoagulation (therapeutic INR or PTT)
Current antiplatelet effect (last dose within 48 hours)
Current prophylactic (low dose) low-molecular weight heparin (last dose within 24 hours)
<b>Recently stopped</b>
Aspirin: specify number of days since last dose
Coumadin and related nonheparin anticoagulant agents: specify number of days since last dose
Unfractionated heparin: specify number of hours since last dose
Low-molecular weight heparin: specify number of half-days since last dose
Nonaspirin antiplatelet agents: specify number of days since last dose
NSAIDs: specify number of days since last dose
Plan to restart anticoagulant or antiplatelet agents <10 days: specify anticipated delay to restart
<b>Cardiac</b>
Previous coronary intervention: bypass surgery, angioplasty without stent, drug-eluting stent, bare metal stent

(continued on next page)

Drawing from the literature on preoperative cardiac risk assessment and condensing that list of factors, other items that perhaps should be considered for recording include previous/recent MI, previous/current/recent CHF, rhythm other than sinus, diabetes, renal failure, uncontrolled hypertension, previous stroke or other neurologic impairment, inability to walk up a flight of stairs (or equivalent activity), and dependency (needing someone to help with activities of daily living). The ASA grade is most frequently used as a broad measure of fitness and inherently combines severity of comorbidities with functional status, but

**TABLE 3. (continued)**

Timing of coronary intervention (for each intervention)
<6 weeks
6 weeks to 12 months
>12 months
Previous MI
Recent MI
<1 week
1 week to 1 month
Within 6 months
6-12 months
Previous heart failure
Recent heart failure (within 1 month)
Severe cardiomyopathy (ejection fraction <25%)
Atrial flutter/fibrillation
Ventricular arrhythmia
Pulmonary
Resting hypoxia (Sao <sub>2</sub> <90% on room air)
Severe chronic pulmonary disease
Previous admission
Oxygen at home
Sleep apnea
Cardiopulmonary functional status
No limitations
Limited but able to climb 1 flight of stairs (or equivalent)
Unable to climb a flight of stairs (or equivalent)
Neurologic status
Previous stroke, no/minimal residual deficit
Previous stroke with residual deficit
Recent stroke (within 1 month)
Decreased level of consciousness
Coma
Renal/liver
Significant renal insufficiency (creatinine >2 mg/dL) but not on dialysis
Dialysis or awaiting dialysis
Portal hypertension or ascites
Other comorbidity (eg, diabetes)

**TABLE 3. (continued)**

Poor nutritional status
Albumin <2.5 g/dL
Weight loss >10%
Limited oral intake for >7 days
Other
Procedure
Status/setting
Outpatient
Inpatient
Endoscopy unit
Intensive care unit
Operating room
Emergency department
Urgent, during working hours
Urgent, outside of working hours
Trainee involvement
Hands on: 0%, 1%-25%, 25%-50%, 50%-75%, 75%-100%
Administrator/type of sedation/anesthesia
Endoscopist, moderate/conscious sedation
Endoscopist, involving propofol (deep sedation or general anesthesia without intubation)
Anesthesia team, moderate/conscious sedation
Anesthesia team, involving propofol (deep sedation or general anesthesia without intubation)
General anesthesia with intubation
Nonendoscopist/nonanesthesia sedation
Procedure duration (time from endoscope in to endoscope out)

ASA, American Society of Anesthesiologists; BMI, body mass index; INR, international normalized ratio; KPS, Karnofsky Performance Status; MI, myocardial infarction; NSAID, nonsteroidal anti-inflammatory drug; PTT, partial prothrombin time.  
 \*See the summary table in part II of this 2-part series, which includes predictors of both cardiopulmonary and noncardiopulmonary adverse events.

there are problems with interobserver agreement and lack of detail. Unfortunately, some widely recorded factors, such as the Mallampati score (because it reflects potential difficulty for intubation), are not discussed in this review because their value in predicting AEs after endoscopy has not been validated. Finally, duration of holding antiplatelet and anticoagulant agents before and after an endoscopy is relevant to the risk of delayed thrombosis. The

factors to be included in basic to advanced levels of reporting are summarized in Table 2, with a corresponding proposed menu of items for endoscopy reporting software in Table 3.

Predictors and risk factors for noncardiopulmonary AEs are discussed in detail in part II. A summary of recommendations for both the cardiopulmonary and noncardiopulmonary event predictors can be found in part II, along with a summary table of the related endoscopy database menu items that are proposed.

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