



Evaluation of a Systematic Method for Risk Stratification and Management of Gastrointestinal Endoscopy Patients

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Abstract

The goal of this study was to assess outcomes with respect to significant cardiopulmonary complications following endoscopy. Post-procedural cardiopulmonary complications were chosen as a marker for preprocedural preparedness. This study compares annual data before and after a systematic approach to preprocedural risk stratification and management was instituted at the Carilion Clinic, a large integrated health care system with a medical draw area of over 1 million patients serving a wide geographic area. Procedures were performed by gastroenterologist, surgeons and trainee physicians under the supervision of staff physicians at 8 endoscopy facilities. The management algorithms used for this study were developed by a multi-disciplinary task force that included gastroenterologist, anesthesiologists, Carilion Registration and Education for Surgery (CARES) nurses, appointment schedulers and information technology specialists.

Study Hypothesis: A systematic approach to preprocedural risk stratification and management will not increase the rate of postprocedural cardiopulmonary events.

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Results: There were 14,358 cases performed between September 1, 2013 and August 31, 2014 which represents baseline annual data before the systemic approach to risk stratification and management was initiated (group 1). Of these cases, 53 had cardiopulmonary complications or a complication rate of 0.37%. There were 13,685 cases performed between September 1, 2015 and August 31, 2016, which represents annual data after the systemic approach was started (group 2). There were 41 cardiopulmonary complications, or a complication rate of 0.30%. There were no significant differences between these two groups with respect to cardiopulmonary complications with p value of 0.1571, thus confirming the study hypothesis.

Group 1 patient had 53 cardiopulmonary complications with most of these seen with Esophagogastroduodenoscopy (EGD) 40, colonoscopy accounted for 9 and Endoscopic Retrograde Cholangiopancreatography (ERCP) 4. A similar pattern for cardiopulmonary complications was seen for group 2 patients with 30 of 41 patients having EGD, colonoscopy 9 and ERCP 2.

Discussion: Our results confirm the hypothesis that a systematic approach to endoscopic preprocedural risk stratification and management will not increase postprocedural cardiopulmonary complications and in fact there was a trend toward improvement.

Additionally, this systematic method reduced costs by eliminating preprocedural testing and CARES office nursing visits for ASA I and II patients undergoing colonoscopy and EGD.

The pattern of cardiopulmonary complications suggests that EGD carries the greatest risk. The risk for ERCP is very low in our experience compared to historical data and may be related to our practice of intubated general anesthesia for all ERCP patients.

We hope the methods developed by this task force and presented in this article will be useful to other institutions interested in developing a systematic approach to preprocedural preparedness.

Introduction

It is difficult to get a good estimate for the number of endoscopic procedures performed per year

Table 1: ASA classification.

Class I	A normally healthy patient
Class II	A patient with mild systemic disease (e.g., mild asthma, controlled diabetes mellitus)
Class III	A patient with severe systemic disease (e.g., moderate-to-severe asthma, poorly controlled diabetes mellitus, pneumonia)
Class IV	A patient with severe systemic disease that is a constant threat to life (e.g., severe bronchopulmonary dysplasia, advanced cardiac disease)
Class V	A moribund patient who is not expected to survive without the operation (e.g., septic shock, severe trauma)

in the United States but it is clearly a very large number. The best data we found comes from 2009, which estimates that 6.9 million Upper Endoscopies (EGD), 11.5 million colonoscopies, and 228,000 biliary endoscopies were performed per year in the United States [1]. One suspects that the number is higher in 2017. Despite the large number of endoscopic procedures performed, there is little literature that informs best practices for preprocedural risk stratification, evaluation and management. What follows is an evaluation of a systematic approach to preprocedural preparedness. To develop this approach available literature was reviewed and expert opinion was sought. Extensive multi-disciplinary meetings were conducted that resulted in the methods articulated in this manuscript.

Prior to the systematic management approach we describe, we sought expert opinion from centers of endoscopic excellence. We were surprised to see a wide range of preprocedural evaluation and management practices ranging from open access with essentially no preprocedural risk stratification (especially in the case of open access screening colonoscopy) to a required nurse practitioner office visit by a nurse practitioner specializing in preprocedural evaluations. These preprocedural nurse practitioners were required to complete a one year mentorship under the anesthesiology department prior to seeing patients independently. While we laude the personalized care afforded by the nurse practitioner model, this is not practical for a large institution such as ours and would be cost prohibitive. Most importantly our survey failed to show a consistent (systematic) approach for risk stratification, preprocedural laboratory testing and colonoscopy preparation or medication management. Preprocedural medication management is particularly important for anticoagulant therapy, anti-platelet therapy, preprocedural antibiotics and colonoscopy preparation.

This paper focuses on ambulatory endoscopy safety and preparedness. The treatment algorithms contained in this paper represents consensus opinion developed by a multi-disciplinary task force at the Carilion Clinic. The task force included gastroenterologists, anesthesiologists and registered nurses from the Carilion Assessment, Registration and Education for Surgery (CARES) unit, appointment schedulers and information technology specialists. The group met monthly for 1 year to develop these practice guidelines.

Literature that focused on various aspects of preprocedural preparedness was reviewed prior to multidisciplinary team meetings. In many cases the available literature gives little guidance to inform best practice and therefore expert opinion was used to formulate some of these recommendations. Finally, input from clinical staff members directly involved with the preprocedural evaluation and management process was important in shaping these guidelines.

Patient safety was the primary focus of our recommendations. Reducing costs by eliminating unnecessary preprocedural testing and improving patient convenience and compliance were important secondary goals. Patient convenience and compliance were especially important considerations in developing standardized colonoscopy

preparations.

The goal of this study was to assess outcomes with respect to significant cardiopulmonary complications following endoscopic procedures performed at the Carilion Clinic. The study compares annual data before and after an enterprise wide standardized program for preprocedural preparedness was started. This standardized program addressed preprocedural risk stratification, medication management, testing and colonoscopy preparations. The recommendations presented in this article have been implemented at the Carilion Clinic for the past 2 years.

The Carilion Clinic is a Roanoke, Virginia-based integrated health care organization with seven hospitals, 685 physicians and cares for more than 1 million patients over a wide geographic area including southwest Virginia and eastern West Virginia. The Virginia Tech Carilion School of medicine is an integral part of our organization. We have active post-graduate training programs in internal medicine and surgery including subspecialty fellowship training. Relevant to this article, surgical residents and gastroenterology fellows perform procedures under the direction of staff physicians. The Carilion Clinic performs approximately 14,000 endoscopies annually including advanced biliary procedures at 8 separate endoscopy facilities.

Study hypothesis

A systematic approach to preprocedural risk stratification and management will not increase the rate of postprocedural cardiopulmonary events.

Methods

Risk stratification

Risk stratification is particularly important for gastrointestinal endoscopy as many of these procedures can be performed safely and efficiently at an Ambulatory Surgical Center (ASC). In the case of the Carilion Clinic, the Carilion Roanoke Community Hospital (CRCH) serves as our ASC. After review of the available literature we determined that the best method for preprocedural risk stratification was the American Society of Anesthesiologists (ASA) classification [2,3]. We felt that most patients classified as ASA I-III could safely have gastrointestinal procedures performed safely at an ASC location with certain specific exclusions. These exclusions are esophageal band ligation for esophageal varices and Endoscopic Retrograde Cholangiopancreatography (ERCP). These procedures carry a higher risk for immediate post-procedural complications and as such these procedures are performed at one of our hospital based endoscopy facilities irrespective of ASA classification [2,4,5].

The ASA classification system is presented below as Table 1. The classification system is a bit subjective and there appears to be significant variation among anesthesiology providers, especially for ASA class III patients. One publication advocates specific patient examples to improve correct ASA classification assignments [6]. It is important to note that all endoscopic procedures performed at the Carilion Clinic have an anesthesia provider in attendance, either

Table 2: Antibiotic prophylaxis and/or treatment to prevent local infections.

Patient condition	Procedure contemplated	Goal of prophylaxis	Per procedural antibiotic prophylaxis
Bile duct obstruction in absence of cholangitis	ERCP with complete drainage	Prevention of cholangitis	Not recommended
Bile duct obstruction in	Absence of cholangitis	ERCP within complete drainage	Recommended continue antibiotics after procedure
Solideist on in upper	EUS-FNA	Prevention of local infection	Not recommended
Solideist on in lower Distract	EUS-FNA	Prevention of local infection	Not recommended
Media stinalcysts	EUS-FNA	Prevention of cyst infection	Suggested
Pan creaticcysts	EUS-FNA	Prevention of cyst infection	Suggested
All patients	Percutaneous endoscopic feeding tube placement	Prevention of peristomal infection	Recommended
Cirrhosis with a cortege bleeding	Required for all patients regardless of endoscopic procedures	Prevention of infectious adverse events and reduction of mortality	On admission
Synthetic vascular graft and other non valvular cardio vascular devices	Any endoscopic procedure	Prevention of graft an device infection	Not recommended
Prosthetic joints	Any endoscopic procedure	Prevention of septic arthritis	Not recommended
Suggested	Suggested	Suggested	Suggested

an anesthesiologist or a nurse anesthetist under the direction of an anesthesiologist.

Initial procedural risk assessment is performed by the ordering endoscopist, who can be a surgeon or gastroenterologist. The endoscopist chooses a facility to perform the procedure understanding that procedures performed at an ASC are intended to carry a lower risk for complications. This risk assessment is complemented by the CARES department. CARES nurses review preprocedural risk in a systematic fashion including a standardized history which is incorporated into the Electronic Medical Record (EMR). This standardized history form is presented in this article as “screenshots” taken directly from the EMR (Appendix 6). If questions arise concerning appropriate facility selection, the CARES nurse can consult with an anesthesiologist specifically assigned to handle such inquiries. If the patient needs to move to a higher acuity facility the CARES nurse will notify the endoscopists and their appointment scheduler.

At the time of the CARES nursing visit additional information can be requested to help stratify patient risk. Such information may include past cardiology evaluations, cardiac testing (i.e. Electrocardiogram (ECG), Echocardiogram) as well as past pulmonary and renal evaluations.

Endoscopy patients represent a unique case for the CARES evaluation process, specifically, patients that are felt to be ASA I and II undergoing colonoscopy or EGD do not require a CARES office visit but rather have a phone visit performed by a CARES nursing staff. This modification in the protocol is particularly important for patients undergoing screening and surveillance colonoscopy. This change has greatly improved patient satisfaction and compliance as many of our patients travel long distances to have procedures performed.

Preprocedural medication management

At the time of the physician office visit a careful medication history should be obtained. Specific recommendations concerning diabetic medications, anticoagulant medications, antiplatelet drugs, antihypertensive medication and preprocedural antibiotics should be addressed. In addition, appointment schedulers address these issues at the time of the office visit.

At the time of the CARES nursing visit preprocedural medications

are again reviewed. Specific medication recommendations are addressed in our systematic management protocol. This management protocol is summarized as a color-coded chart (Appendix 7). These recommendations have been formulated by the anesthesiology department with gastroenterology input and in the case of diabetic management with endocrinology input. The importance of not withholding aspirin used as an anti-platelet drug is emphasized. Other anti-platelet drugs such as Clopidogrel (Plavix) and Prasugrel (Effient) are intentionally not covered by the management algorithm. These more potent anti-platelet drugs are directed by the patient’s endoscopists, cardiologist or primary care physician depending on the clinical situation. If management of these drugs is not clear to the patient at the time of their CARES nursing visit, the nurse will contact the appropriate physician for medication management orders. Anticoagulant medication management is directed in a similar manner.

Preprocedural testing

The endoscopy management protocol (Appendix 7) specifically addresses preprocedural testing. Of note and specific to gastrointestinal endoscopy at our institution, patients undergoing colonoscopy and EGD that are ASA I or II do not require preprocedural laboratory testing or EKG unless the patient is diabetic, taking diuretics or is on long term corticosteroid therapy. These patients require a Basic Metabolic Profile (BMP). ERCP at our institution is performed with intubated general anesthesia. Prior literature suggests an increase rate of immediate adverse events with ERCP compared to colonoscopy or EGD and as such ERCP patients undergo more extensive preprocedural testing [2].

Pre-procedural antibiotics

Recent literature gives clear guidance for preprocedural antibiotic use with gastrointestinal endoscopy [7,8]. We have incorporated these recommendations into our treatment protocols. These guidelines have been formulated as a joint effort of the American Society of Gastrointestinal Endoscopy (ASGE) and the American Heart Association (AHA). These recommendations are summarized in tabular format below Table 2. This table is taken directly from Khashab et al. [8].

To briefly summarize these recommendations, patients undergoing endoscopic procedures do not require antibiotic prophylaxis, including patients with valvular heart disease or

Table 3: ICD 9 codes used to identify cardiopulmonary complications.

425.4	cardiomyopathy, primary NEC
425.8	cardiomyopathy in diseases
425.8	tachycardia, paroxysmal atrial
427.1	tachycardia, paroxysmal ventricular
427.5	arrest, cardiac
427.89	dysrhythmias, cardiac NEC
429.3	cardiomegaly
785	symptom, tachycardia NOS
785.9	symp inv cardiovascular system NEC
785.9	complications, cardiac
415	cur pulmonale, acute
518	collapse, pulmonary
518.82	insufficiency, pulmonary NEC
518.51	acute resp fail follow truma/surgey
518.81	failure, acute respiratory
518.84	respiratory failure, acute & chronic
786.09	symp abnormality, respiratory NEC

Table 4: Cardiopulmonary complications before and after systematic approach to preprocedural management.

	Before systematic approach	After systematic approach
Total cases	14,358	13,685
Cardiopulmonary complications	53	41
Percent total cases with cardiopulmonary complications (%)	0.37	0.3

Table 5: Procedures associated with cardiopulmonary complications.

Procedure	Before systematic approach	After systematic approach
Colonoscopy / flexible sigmoidoscopy	9	9
EGD	40	30
ERCP	4	2

prosthetic joints. On the other hand, antibiotics are recommended for procedures associated with a significant risk of infection, or for patients with conditions that make them more susceptible to infection undergoing procedures associated with a high risk of bacteremia. These patients include: patients with significant neutropenia, cirrhotic patients with gastrointestinal bleeding and patients on peritoneal dialysis undergoing colonoscopy.

Colonoscopy preparation

Key to successful colonoscopy is adequate preparation. This is especially true for Adenoma Detection Rate (ADR). The literature concerning colonoscopy preparation is very helpful in directing management strategie [9-11]. Prior to instituting the standardized preparations listed in this manuscript there were at least 10 different preparations in use at the Carilion Clinic. This number has been reduced to 3 specific preparations with modifications based on the procedure time. In keeping with our established protocol (Appendix 7) [12], the patient must be NPO for 4 hours prior to the procedure but can have clear liquids prior to that time. The literature suggests that split dose preparations are more effective and better tolerated by patients in general [13,14]. On the other hand patient compliance with split dose prep can be an issue [15]. Keeping these factors in mind and especially noting that many our patients travel up to 3

hours for their procedures we chose to start spit dose preparations for colonoscopies starting after noon (12 PM). The 12 PM time was chosen primarily to promote patient compliance.

It is clear from the literature that polyethylene glycol (Miralax) based preparations are better tolerated and equally effective compared to large volume preparations for average patients undergoing colonoscopy [8,9]. Bisacodyl (Dulcolax) tablets were originally part of this preparation. Dulcolax does not seem to improve bowel preparation compared to Miralax alone but is associated with significantly more side effects compared to the Miralax alone [9,16]. For this reason, Dulcolax is not used for our colonoscopy preparations. The Miralax preparation is our standard preparation with the 4-liter polyethylene glycol electrolyte preparations (Golytely, Trilyte) reserved for patients with significant constipation or for patients that previously failed the Miralax preparation.

For documentation purposes we are in the process of changing from the Aronchick bowel preparation scale to the better validated Boston bowel preparation scale but at the time of this publication this transition has not yet occurred system wide [17,18].

Colonoscopy preparation and patient instructions are presented as Appendix 2 through 5. (For completeness, patient instructions for EGD are also listed as Appendix 1).

Evaluation of cardiopulmonary complication rates

To evaluate post procedural cardiopulmonary complications the EMR was queried for International Classification of Diseases (ICD) 9 codes applicable to post-procedural cardiopulmonary complications (Table 3). When the ICD 9 coding system changed to the ICD 10 system in the United States, these codes were mapped to the new coding system.

The rates of endoscopy related cardiopulmonary complications were compared for procedures performed between September 1, 2013 and August 31, 2014 (baseline annual data before the systematic management approach) and compared to endoscopies performed between September 1, 2015 and August 31, 2016 (annual data after the systematic management approach was in use).

Statistical analysis was performed using paired T test comparing aggregate cardiopulmonary complication rates for baseline data compared to the systematic management approach. A p value of greater than or equal to 0.05 was felt to show no significant difference between the two groups (non-inferiority) (Table 4 and 5).

Discussion

This article presents a systematic approach for preprocedural risk assessment and management of patients undergoing gastrointestinal endoscopy. The data is derived from patients undergoing gastrointestinal procedures at a large integrated health care system with a wide variety of physicians performing endoscopy at multiple sites. The endoscopists performing these procedures included gastroenterologists, surgeons and physician trainees under the supervision of staff physicians.

Our results confirm the hypothesis that a systematic approach to endoscopic preprocedural risk stratification and management did not increase postprocedural cardiopulmonary complications and in fact there was a trend toward improvement. We chose post-procedural cardiopulmonary complications as an objective marker for preprocedural preparedness.

The systematic approach presented in this article more appropriately utilized the CARES nursing staff by allowing ASA I and II patient to undergo telephone nursing visits rather than requiring a CARES office visit. This management change did not increase postprocedural cardiopulmonary complications but was more convenient for patients and improved patient satisfaction and compliance. While this probably reduced nursing costs, this may also have indirectly improved patient care by allowing CARES nursing staff more time to evaluate and manage sicker ASA III and IV patients with office visits. This is particularly germane for patients undergoing screening and surveillance colonoscopy.

Though not proven, we believe that unifying preprocedural management may have reduced additional adverse outcomes such as medication errors. Certainly, there was greater accessibility for patients undergoing CARES telephone nursing visits which may have improved patient compliance and reduced “no-show” rates. This is supported by a recent article demonstrating a 33% reduction in “no-show” rates with telephone reminder calls by a nurse one week prior to outpatient colonoscopy [19].

It was surprising to see that EGD was more often associated with cardiopulmonary complications when compared to colonoscopy. We don't have a clear explanation for this finding but wonder if airway irritation induced by EGD scope insertion could have resulted in laryngospasm. Another possible cause is pharyngeal irritation associated with scope insertion triggering vomiting with resultant aspiration. Finally, it is possible that patients presenting for EGD are more likely to have pulmonary complications from aspiration because of their underlying gastrointestinal problems (e.g. gastroesophageal reflux or a gastric emptying disorder).

It is also interesting to note the low rate of cardiopulmonary adverse events with ERCP, as ERCP cases tend to last longer and are typically performed on very ill patients. As previously noted all ERCP patients at our institution receive intubated general anesthesia for their procedures and we wonder if this level of airway management accounts for these excellent outcomes.

One area we believe could improve our systematic management model is the development of a more objective ASA classification tool. The ASA class serves as the cornerstone of our risk assessment protocol yet in many instances the ASA class seems somewhat arbitrary and subjective with significant interobserver variation even among anesthesia providers. Despite these shortcomings, the ASA classification system is widely accepted by anesthesiologists and appears to be the best validated risk assessment tool for endoscopy related cardiopulmonary complications. It is our opinion that a more objective ASA classification tool based on validated data inputs would be possible and helpful especially for care team members that are not anesthesia providers. Non-anesthesia staff members (CARES nurses) are often tasked with preprocedural risk assessment. We can envision a widely available validated phone or computer application for this purpose. This application could integrate with the EMR to bring in data that is already being entered as part of the preprocedural nursing visit.

Risk stratification is much better characterized for surgery patients as compared to endoscopy patients. Surgical risk stratification tools include surgical risk calculators but it is unclear if these risk calculators can be applied to endoscopy patients that have a much lower risk of cardiopulmonary complications [20,21].

The management strategies presented in this paper were the work product of a multidisciplinary team. The management recommendations incorporated available literature, expert opinion and input from clinical team members. We believe that institutions will find our methods helpful and we hope they will further refine and expand on our recommendations.

Conclusion

Finally, it is important to note that successful implementation of a systemic management approach requires “buy in” from a wide variety of clinical staff members in several clinical departments. We recommend a standardized educational format delivered to the entire clinical team to facilitate this process. In our case, we used a standardized power point lecture delivered by the director of ambulatory endoscopy in partnership with an anesthesiologist. We found this lecture format with a long question and answer period worked well and encouraged clinical team members to contribute useful ideas that were subsequently incorporated into our final management algorithms.

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