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Clinical Trials Study

Outpatient endoscopic sedation reversal trends at a tertiary care academic ambulatory endoscopy digestive health center vs in-hospital ambulatory procedure center using a triage protocol

Endoscopic Sedation Reversal Trends At A Tertiary Care Academic Center Using A Triage Protocol

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Abstract

BACKGROUND

Routine outpatient endoscopy is performed across a variety of outpatient settings. A known risk of performing endoscopy under moderate sedation is the potential for over-sedation, requiring the use of reversal agents. More needs to be reported on rates of reversal across different outpatient settings. Our academic tertiary care center utilizes a triage tool that directs higher-risk patients to the in-hospital Ambulatory Procedure Center (APC) for their procedure. Here, we report data on outpatient sedation reversal rates for endoscopy performed at an in-hospital APC vs. at a free-standing Ambulatory Endoscopy Digestive Health Center (AEC-DHC) following risk stratification with a triage tool.

AIM

To observe the effect of risk stratification using a triage tool on patient outcomes, primarily sedation reversal events.

METHODS

We observed all outpatient endoscopy procedures performed at AEC-DHC and APC from April 2013 to September 2019. Procedures were stratified to their respective sites using a triage tool. We evaluated each procedure for which sedation reversal with flumazenil and naloxone was recorded. Demographics and characteristics recorded include patient age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, procedure type, and reason for sedation reversal.

RESULTS

97,366 endoscopic procedures were performed at AEC-DHC and 22,494 at the APC during the study period. Of these, 17 patients at AEC-DHC and 9 at the APC underwent sedation reversals (0.017 % vs. 0.04%, P=0.06). Demographics recorded for those requiring reversal at AEC-DHC vs. APC included mean age (53.5±21 vs.

60.4±17.42 years; P = 0.23), ASA class (1.66±0.48 vs. 2.22±0.83; P = 0.20), BMI (27.7±6.7 kg/m^2 vs. 23.7±4.03 kg/m^2; P = 0.12), and female gender (66% vs. 22%; P = 0.04). The mean doses of sedative agents and reversal drugs used at AEC-DHC vs. APC were midazolam (5.9±1.7 mg vs. 8.9±3.5 mg; P = 0.01), fentanyl (147.1 ±49.9 mcg vs. 188.9±74.1 mcg; P = 0.10), flumazenil (0.3±0.18 mcg vs. 0.17±0.17 mcg; P = 0.13) and naloxone (0.32±0.10 mg vs. 0.28±0.12 mg; P = 0.35). Procedures at AEC-DHC requiring sedation reversal included colonoscopies (n = 6), esophagogastroduodenoscopy (EGD) (n = 9) and EGD/colonoscopies(n = 2), whereas APC procedures included EGDs (n = 2), EGD with gastrostomy tube placement (n = 1), ERCPs(n = 2) and EUS's (n = 4). The indications for sedation reversal at AEC-DHC included hypoxia (n = 13; 76%), excessive somnolence (n = 3; 18%), and hypotension (n = 1; 6%), whereas, at APC, these included hypoxia (n = 7; 78%) and hypotension (n = 2; 22%). No sedation-related deaths or long-term post-sedation reversal adverse outcomes occurred at either site.

CONCLUSION

Our study highlights the effectiveness of a triage tool used at our tertiary care hospital for risk stratification in minimizing sedation reversal events during outpatient endoscopy procedures. Using a triage tool for risk stratification, low rates of sedation reversal can be achieved in two ambulatory settings for EGD and colonoscopy.

Key Words: Ambulatory care; Conscious sedation; Endoscopy; Colonoscopy; Risk assessment; Risk factors

Core Tip: Our study highlights the effectiveness of a triage tool used at our tertiary care hospital for risk stratification in minimizing sedation reversal events during outpatient endoscopy procedures. By directing higher-risk patients to appropriate settings, we achieved low rates of sedation reversal, enhancing patient safety and optimizing resource utilization in ambulatory care settings. This approach can have a significant

impact on improving patient outcomes and resource allocation in similar healthcare settings.

INTRODUCTION

Endoscopy, introduced in 1868, has seen growing use by clinicians for its diagnostic and therapeutic purposes.[1] In the USA, it is estimated that approximately 20 million endoscopies are performed annually. [2] Colonoscopy ranks as the most common endoscopic procedure, followed closely by esophagogastroduodenoscopy.[3] To enhance patient comfort during these often uncomfortable procedures, sedation is frequently administered, primarily aiming to provide anxiety relief, amnesia, and pain relief, which in turn results in enhanced patient satisfaction rates and increased procedural success.[4]

In the US, the preferred method of sedation is moderate sedation, achieved using a combination of benzodiazepines and opioids.[5] However, deeper sedation using propofol is gaining popularity among physicians, particularly for more complex procedures.[6] Sedation, however, comes with its associated risks, including respiratory depression and hypotension.[7] Although endoscopy is generally considered a safe procedure, with adverse events occurring in less than 1% of cases, the risk significantly increases in patients with more severe comorbidities.[8] Therefore, there is a growing emphasis on pre-procedural assessment for endoscopic procedures.[9-11] Risk stratification has been shown to reduce mortality rates, allowing higher-risk patients to receive more meticulous care.[12]

While stratification scales are used for conditions like upper gastrointestinal bleeding, the adoption of a risk stratification scale for endoscopic procedures at a nationwide level has yet to be seen.[13]

An increasing trend of performing outpatient GI endoscopies in ambulatory surgery centers has been observed due to its lower cost, provider preference, and consumer demand. [14] One national survey revealed that outpatient procedures performed in ambulatory centers increased 300% from 1996 to 2006, while procedures performed in

hospital outpatient departments were relatively stable. However, very little has been reported on the rates of sedation reversal across different studies. [15] We assessed a triage tool used at our academic center that is used to assess risk factors for endoscopic procedures and directs higher-risk patients from a free-standing Ambulatory Endoscopy Digestive Health Center (AEC-DHC) to an in-hospital Ambulatory Procedure Center (APC) and observed the effect of this risk stratification on sedation related complications.

MATERIALS AND METHODS

Patient population

We analyzed all outpatient GI procedures performed between April 2013 and September 2019. At our tertiary-care hospital, outpatient endoscopy and colonoscopy are performed in two settings: a free-standing AEC-DHC and an in-hospital APC. Patient risk assessment for endoscopic procedures is done using a triage tool, directing higher-risk patients to the APC for management. All procedures performed under conscious sedation (using Midazolam and Fentanyl) within our study period were included in the study. Procedures performed under deep sedation were excluded.

Outcome measures

The primary outcome of the assessment was a 'sedation reversal event,' defined as any endoscopic procedure requiring Flumazenil and/or Naloxone to reverse sedation during or soon after the procedure in either of the two settings.

The indication for reversal of sedation was also recorded and included one of the following: (a) hypoxia, (b) hypotension, or (c) excessive somnolence. For *descriptive purposes* of this study, 'hypoxia' was defined as oxygen saturation < 90%, 'hypotension' was identified by a systolic blood pressure reading <90 mm of Hg or a drop in blood pressure requiring intervention and 'excessive somnolence' was characterized by difficulty arousing the patient or unresponsiveness with a brief response to rigorous stimuli.

Adverse events and outcomes, including death, were also assessed.

Demographic details

Further demographic details and characteristics were recorded for the patients who received sedation reversal during the procedure, including patient age, gender, body mass index (BMI), procedure type, indication for sedation reversal, and the American Society of Anesthesiologists (ASA) classification.

Ambulatory endoscopy triage tool

A triage tool developed by UW Health plays a significant role within our hospital by streamlining the allocation of patients to appropriate endoscopic procedure sites. The triage tool serves multiple purposes, including identifying higher-risk patients to be managed at the in-hospital APC rather than at the DHC, alongside categorizing patients who require Monitored Anesthesia Care (MAC) or deeper sedation with propofol and distinguishing patients with significant comorbidities whose procedure request is to be sent to a Triage Nurse (Figure 1).

Risk stratification using this tool assesses multiple risk factors (Figure 1). Patients meeting one or more of these risk criteria are directed toward the in-hospital care pathway.

Data extraction

Clinical data from April 2013 to September 2019 was extracted from a computerized endoscopy database of the hospital. Data was categorized for both the settings (AEC-DHC and APC) separately.

Statistical analysis

Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were represented as frequency (%) and numbers (n). All analyses were conducted using STATA version 16. To evaluate differences in characteristics such

as age, BMI, procedure type, indication for sedation reversal, and ASA grade between the two patient groups receiving sedation reversal, univariate analysis employed the Chi-square test (for categorical data) and Student's t-test (for continuous data). The null hypothesis tested was the absence of association between variables in both groups, with statistical significance defined as a P-value < 0.05.

RESULTS

Reversal rates at both settings

Across both settings, 119,860 endoscopic procedures were performed under conscious sedation from April 2013 to September 2019. The procedures that required deep sedation were excluded from the study. Of these, 97,366 (81.23%) endoscopic procedures were performed at AEC-DHC and 22,494 (18.77%) at the APC.

During the study period, 17 patients at the AEC-DHC were given flumazenil and/or naloxone, representing 0.017% of all the procedures at AEC-DHC. In contrast, nine instances of sedation reversal were recorded at the APC, making up 0.04% of the total. A difference was noted between the number of overall sedation reversal events between both settings; however, this difference was not statistically significant (P = 0.06) (Table 1).

Demographic details of patients needing sedation reversal

Demographic details of patients requiring reversal at AEC-DHC *vs* APC were compared and are provided in Table 1. A gender-based analysis demonstrated that females constitute a higher percentage in the AEC-DHC group at 64.7% (n = 11), while in the APC group, females account for only 22% (n = 2) (P = 0.04). This difference was statistically significant.

No statistical difference was observed in the mean age of individuals requiring reversal (DHC vs. APC: 53.5±21 years vs. 60.4±17.42 years; P = 0.23), and the difference in the BMI of the two groups was also insignificant (27.7±6.7 kg/m^2 vs. 23.7±4.03 kg/m^2; P = 0.06). Similarly, the ASA class distribution for the AEC-DHC cohort displays

an ASA class average of 1.66±0.48, which is comparatively lower than the ASA class average of 2.22±0.83 in the APC group (P = 0.20). Despite this variance, it is essential to emphasize that the difference did not reach statistical significance.

Drugs used for patients needing sedation reversal

The mean doses of sedatives (midazolam and fentanyl) and reversal agents used (naloxone and/or flumazenil) between the two groups are discussed in Table 2. A combination of midazolam and fentanyl was used in all the patients for sedation. However, the only statistically significant difference between the two groups was in the average doses of midazolam used (5.9 ±1.7 mg *vs* 8.9±3.5 mg; P = 0.01). For reversal, flumazenil was used in 8 cases (47%) and naloxone in 13 procedures (76.5%) at DHC *vs* 6 (66.6%) and 9 procedures (100%) APC, respectively.

Procedures requiring sedation reversal

The most frequent procedure type leading to sedation reversal at the AEC-DHC was esophagogastroduodenoscopy (EGD) (n = 9), followed by colonoscopy (n = 6) and a combination of EGD/colonoscopy (n = 2). Conversely, at APC, the need for reversal was most pronounced during endoscopic ultrasound (EUS) procedures (n = 4), followed by EGD (n = 2), endoscopic retrograde cholangiopancreatography (ERCP) (n = 2), and a single case involving EGD with gastrostomy tube placement (Figure 2). These accounted for 0.03% of total ERCPs (5694 total) and 0.07% of all EUSs (5715 total) performed during the study period.

Indications for sedation reversal

No mortalities or adverse outcomes related to sedation were documented at either site. The indications for sedation reversal at AEC-DHC contributed mainly to hypoxia (n = 13, 76% of all sedation reversal events at AEC-DHC), followed by excessive somnolence (n = 3, 18%) and hypotension (n = 1, 6%). At APC, sedation reversal indications included hypoxia (n = 7, 78%) and hypotension (n = 2, 22%) (Figure 3).

DISCUSSION

Sedation is a critical component of endoscopic procedures and aims to enhance procedural efficacy, elevate patient comfort, and contribute to the satisfaction of both patients and endoscopists. Amidst the array of available sedation techniques, conscious sedation remains the most widely employed technique, primarily owing to its superior patient tolerance and satisfaction levels, along with reduced incidence of side effects.[16] However, the administration of anesthesia comes with its risks. A study evaluating 207,134 endoscopic procedures concluded that most adverse effects during the procedure were attributed to the sedative medication used.[17] Our study aimed to assess the efficacy of risk stratification in enhancing patient outcomes by evaluating two distinct patient populations classified using a triage tool.

While the risk factors associated with sedation reversal have been examined by specific studies, to our knowledge, no study has been conducted to evaluate the impact of risk stratification on patient outcomes. [9-11] The University of Wisconsin (UW) Health triage tool is used to identify well-established risk factors for endoscopy, including cardiac disease, distortion of upper airway anatomy, oxygen dependency, thrombocytopenia, morbid obesity, pregnancy, *etc.* (Figure 1). By identifying higher-risk patients, they are transferred to the in-hospital APC for thorough monitoring and meticulous procedural care. As we confront a growing shortage of anesthesia providers, particularly impacting timely access to surgical procedures like gastrointestinal endoscopies, the necessity for practical triage tools becomes increasingly apparent. [18] These tools are vital for stratifying patients based on risk and determining the most suitable setting (inpatient *vs* ambulatory) and type of sedation (such as moderate conscious sedation, deep sedation with monitored anesthesia care or general endotracheal intubation). Given resource limitations, prioritizing endoscopic procedures becomes imperative, and innovative process for risk assessment, timely triage scheduling and stratification are crucial. This approach should not only address resource utilization but also ensure patient safety and uphold the standards of quality

care. Numerous researchers have advocated the need for pre-procedural stratification to reduce the risk of complications. Thus, we needed to fill this literature gap by reporting our findings.

Assessment of the triage tool

Endoscopic procedures in severe disease states

Endoscopic procedures have been found to increase the risk of complications in patients with cardiac diseases, particularly heart failure, and shortly after a recent myocardial infarction (MI). [19] One study found that endoscopy within one month following an MI can lead to cardiopulmonary complications in up to 1.5% of patients. In contrast, another study reported higher rates of minor cardiovascular complications in patients undergoing colonoscopy following an MI.[20,21] Pulmonary hypertension is also associated with higher rates of periprocedural complications.[22,23] The clinical value of close monitoring in these patients is undeniable. Hence, the triage tool recommends transferring patients who have experienced an MI in the last six months, heart failure, stent placement, valvular stenosis, oxygen dependency, and pulmonary hypertension to an inpatient APC for closer monitoring and care.

Implanted electronic devices.

Implanted electronic devices are at an increased risk of electromagnetic interference due to the electromagnetic field from another source on the implanted device. During endoscopic procedures, this may occur due to conduction *via* diathermy or radiation from imaging devices.[24] The American Society for Gastrointestinal Endoscopy (ASGE) advises caution when performing endoscopic procedures in individuals with implanted electronic devices, particularly in free-standing centers.[25] Although studies have not found an increased risk of adverse events in patients undergoing endoscopic electrosurgery with implanted devices, these studies are small-scale, and there is a notable research gap in this area.[26,27] Therefore, it is essential to take precautions in these patients (with cardiac defibrillators/pacemakers and/or implanted organ

stimulators that are unable to turn off), including considering transfer to an inpatient setting.

Pregnancy

Pregnancy is another factor associated with increased risk of complications during endoscopic procedures due to fetal sensitivity to maternal hypoxia and hypotension, along with the narrow safety profile of the drugs administered.[28] Most sedatives used are classified as category B or C by the Food and Drug Administration.[29] ASGE recommends avoiding endoscopy in the first trimester whenever possible, meticulous procedural care, and careful administration of sedatives by anesthesia providers.[28]

Head and Neck Abnormalities/Surgery

The ASA deemed airway management difficult for patients with oral, jaw, and neck abnormalities. [30] The ASA Taskforce guidelines also suggest that these abnormalities, coupled with the potential for deep sedation, will increase the likelihood of adverse, sedation-related events.

Young Age

Age below 18 years is another criterion for referral. While administering anesthetic agents to younger patients has been associated with increased rates of mental disorders, developmental delays, and ADHD, there is no evidence to suggest increased sedation-related complications in younger children.[31] Nonetheless, The Royal College of Emergency Medicine recommends involving senior personnel in the emergency department when administering procedural sedation to children aged 1-5 years.[32]

Comparison of results at both settings

Despite the higher risk of complications reported in the conditions used to filter patients to the APC, our study's outcomes revealed no significant difference in the sedation reversal events between the two settings (P = 0.06, CI: 95%). This finding suggests that

the triage tool effectively identified and successfully managed patients who are more likely to have adverse outcomes within the in-hospital setting. While most literature reports 30-day mortality rates associated with endoscopy ranging from 0.004% to 1.89%, one study specifically studied inpatient endoscopy mortality and found it to be as high as 5-10%. [33-35] This starkly contrasts our findings, revealing zero 30-day mortality. This outcome suggests rigorous risk stratification and management protocols likely account for this discrepancy. While the existing research supports the notion that risk stratification diminishes mortality rates associated with endoscopic procedures in specific cases, such as upper gastrointestinal bleeding, a notable gap exists in the available data pertaining to the impact of pre-procedural stratification on non-urgent endoscopic procedures.[13]

Influence of demographics on sedation reversal rates

The impact of gender on sedation rates and complications is inconsistent. While certain studies indicate that females may metabolize midazolam more rapidly with higher clearance rates, most literature fails to show a significant gender-related effect on midazolam's efficacy. [36-39] In the case of fentanyl, one study proposes that males may necessitate a 25% higher dose.[40] Conversely, Adelina H. *et al* observed elevated sedation reversal in females.[10] Our results showed that a higher proportion of female patients needed sedation reversal at AEC-DHC compared to APC. However, because we observed similar reversal rates between the two settings, it is challenging to conclude how gender influenced sedation complications. One possible interpretation is that the male population at the APC had a higher prevalence of risk factors assessed by the triage tool. This could explain the greater number of males there, and females were at a higher risk of sedation complications when risk factors were absent. However, this relationship needs to be explored further.

In our study of sedation reversal cases, only one patient (at the APC) was aged over 80 years, and none were under 18 years. Even though a higher BMI has been identified as a risk factor for sedation-related complications, and the triage tool refers patients

with a high BMI (>50 or >45 if requiring propofol) to the APC, we did not observe any significant difference in BMI between the two groups.[41] Thus, owing to the limited number of sedation reversal events in our study and the narrow distribution of age and BMI, a comprehensive analysis of either variable was not possible.

Complications of sedation

The most frequent complications associated with procedural sedation are predominantly related to respiratory and cardiovascular depression.[7] These complications include hypoxemia arising from either hypoventilation or airway blockage, hypotension, cardiac arrhythmias, and apnea. Our findings indicate hypoxia to be the most critical reason for sedation reversal events. The ASA and the American Society for Gastrointestinal Endoscopy advise using pulse oximetry during all endoscopic procedures under sedation and considering supplemental oxygen during moderate sedation and for all deep sedation procedures. [42,43]

Sedatives used

In most cases in the US, endoscopic procedures are performed under moderate sedation, achieved through a combination of benzodiazepines and narcotics.[5] The most used benzodiazepines include midazolam and diazepam. Although the efficacy of the two is comparable, midazolam is preferred by endoscopists due to its faster onset, shorter duration of action, and superior amnesia properties.[44] Among opiates, fentanyl and meperidine are the most used, and due to fentanyl's more rapid onset of action and clearance and lower rates of nausea, it is usually preferred over meperidine.[45,46] The usual dose of midazolam used is 2.5 to 5 mg, and the maximal dosage for endoscopic procedures is 6 to 7.5 mg. [44,47,48] When midazolam is used in combination with an opioid, a reduction in the dosage is required. The initial doses are 0.5 to 1 mg midazolam plus 12.5 to 75 mcg fentanyl. [49-51] A dose reduction of 20% or more is recommended for patients older than 60 and those with an ASA grade of 3 or greater. [52] The average dose of midazolam and fentanyl used at AEC-DHC was 5.9±1.7 mg and

147.1±49.9, while at the APC, it was 8.9±3.5 and 188.9±74.1 respectively, with a significant increase in the dose of midazolam. The dosage of drugs used was not per the guidelines as the average dose was greater than the recommended dosage, and the dose reduction for higher ASA grade at the APC was not done.

A nationwide analysis revealed that anesthesia was employed in up to 34.4% of colonoscopies, associated with a 13% risk of anesthesia-related complications.[53] Our findings indicated that 35.3% of procedures necessitating sedation reversal at the DHC were colonoscopies. One study evaluated patients by administering sedation on an 'as needed' basis, and 80% of patients underwent the procedure without sedation, resulting in an impressive satisfaction rate of 97.4%.[54] Consequently, one potential strategy to address the elevated incidence of anesthesia-related complications in colonoscopies is tailoring sedative use to individual needs.

ERCP and sedation reversal

Literature indicates ERCP to be associated with higher rates of sedation reversal, reaching up to 4%.[55] This is due to the complexity and length of the procedure, which often requires higher sedative doses than upper and lower GI endoscopies. [56,57] Only 0.03% of ERCP procedures required sedation reversal in our hospital. This discrepancy may be secondary to risk stratification, as all the ERCP cases requiring reversal were at the inpatient APC.

Study limitations

Owing to the retrospective nature of our study, certain limitations warrant consideration. One such limitation is our reliance on physicians for accurate record-keeping of procedures and ASA grading. The integrity of our study relies on the accuracy of record keeping; thus, it must be as precise as possible. Additionally, our ability to analyze the effectiveness of the triage tool was hindered by the relatively small number of sedation reversal events we examined. Moreover, our study was restricted by the need for more data regarding the reasoning behind referrals to the APC through

the triage tool. This limitation prevented us from conducting a comprehensive analysis of the individual components of the tool itself. The tool is also used to categorize patients for deep sedation. However, our study design did not include those patients, and thus, we could not study the procedural safety and effect of stratification in those patients. Lastly our study was not designed to assess the cost effectiveness of implementing triage tool. Previous studies however have shown that sedation reversal does add cost to the procedure.

CONCLUSION

In conclusion, our study supports using a rigorous risk stratification tool as it may help identify high-risk patients and minimize procedure-related complications. The triage tool used in our study appeared effective for minimizing sedation-related complications and reversal events despite the large number of procedures being done at outpatient endoscopy centers. It is also important to note that with appropriate risk stratification and triage, even complex procedures like EUS/ERCP can be done under conscious sedation. This approach can have a significant impact on improving patient outcomes and resource allocation in limited healthcare settings. Our results should be interpreted with caution considering the retrospective design of our study; future large-scale randomized prospective controlled trials are needed to draw concrete conclusions.

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