MONITORED ANESTHESIA CARE VERSUS MODERATE SEDATION IN THE ENDOSCOPY SETTING: A RETROSPECTIVE CHART REVIEW

A Scholarly Project Submitted in Partial Fulfillment of

The Requirements for the Degree of

Master of Science in Nursing

in

The Onanian School of Nursing

Rhode Island College

September 17, 2023

by

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Abstract

Sedation is a state of depression in the level of consciousness that is medically induced allowing for decreased consciousness, reduction in sensation, and relaxation. Two methods of sedation administered in the acute care setting of an endoscopy unit are moderate sedation and monitored anesthesia care (MAC). When it comes to recovery from sedation and eligibility to reach discharge criteria whether one method of sedation is superior to the other or if both are comparable is a topic of more research. A retrospective chart review of a hospital's endoscopy unit was conducted to determine if one method of sedation over the other leads to a prompter recovery and discharge time. This retrospective chart review also examined age, gender, and type of endoscopic procedure and if any of those variables had a relationship to discharge time. Results from this project concluded that in nearly all categories, discharge time was slightly sooner for moderate sedation cases compared to MAC cases. Endoscopy departments should in turn consider the importance of recovery from sedation and minimizing discharge time and its effect on the health care system and providing quality patient care. Implications for advanced nursing practice include research and education on sedation induction and recovery process in the endoscopy suite to support patient quality care, safety, cost effectiveness, and department efficiency.

Key Words: monitored anesthesia care versus moderate sedation in endoscopic procedures; moderate sedation; conscious sedation; sedation in endoscopy; anesthesia in endoscopy; monitored anesthesia care; propofol in endoscopy; fentanyl and midazolam in endoscopy; recovery times in endoscopy; patient sedation outcomes; sedation recovery times for colonoscopy; sedation recovery times for esophagogastroduodenoscopy; American College of Gastroenterology practice standards; ASA classification.

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MONITORED ANESTHESIA CARE VERSUS MODERATE SEDATION IN THE ENDOSCOPY SETTING: A RETROSPECTIVE CHART REVIEW

Background/Statement of the Problem

"Sedation is a drug-induced depression in the level of consciousness" (Early et al., 2018, p. 327). According to the American Society of Anesthesiologists (ASA, 2022b) there are three purposes for sedation: amnesia, analgesia, and relaxation. Sedation is a continuum recognized by four levels: minimal sedation, moderate sedation, deep sedation, and general anesthesia (Hagan et al., 2016; Jin et al., 2020). When choosing which sedation to administer, providers must consider a patient's response to external stimulation, airway status, ventilatory status, and cardiovascular function (Hagan et al., 2016).

Sedation provided during endoscopy procedures such as esophagogastroduodenoscopy (EGD) and colonoscopy primarily include either moderate sedation, also known as conscious sedation, or monitored anesthesia care (MAC). Monitored anesthesia care is a type of deep sedation. When compared to moderate sedation in the endoscopy setting, MAC can lead to improved sedation and procedural efficiency, therefore leading to improved procedure results and recovery outcomes in a selective group of patients. One such group is the American Society of Anesthesiologists class I through III patients (ASA, 2022a).

Moderate sedation medications administered by non-anesthesia providers during endoscopic procedures prolongs discharge times when compared to anesthesia providers delivering MAC (Hagan et al., 2016; Poulos et al., 2013; Wang et al., 2013). Typically, non-anesthesia trained staff such as registered nurses (RNs) or gastroenterologists/proceduralists administer moderate sedation. Monitored anesthesia care is administered by an anesthesia provider such as a Certified Registered Nurse Anesthetist (CRNA) or Anesthesiologist (Lin,

2017; Stogiannou et al., 2018). Types of intravenous sedation generally incorporates the use of different analgesic, sedative, and/or amnestic medications. Moderate sedation uses primarily the drugs fentanyl and midazolam, a combination which creates a complementary and synergistic effect causing analgesia and relaxation (Lin, 2017). Monitored anesthesia care utilizes the drugs propofol and/or dexmedetomidine to place the patient in an amnestic state while undergoing the procedure.

In the United States, within the past two decades, MAC in the endoscopy setting is becoming more commonplace. Lin (2017) stated between 2003-2013, for routine outpatient endoscopic procedures in low-risk patients, the use of propofol sedation increased from 14-48% and 14-53% for Medicare and privately insured patients respectively. Krigel et al. (2019) noted between 2006-2015 the use of anesthesia assistance during outpatient colonoscopies had more than doubled. In 2006, the percent of anesthesia provided sedation was 16.7% and increased to 58.1% in 2015; a 41.4% increase in anesthesia utilization over a nine-year period (Krigel et al., 2019).

Monitored anesthesia care is a preferred method of sedation over moderate sedation in the endoscopy setting because it leads to increased patient safety by way of deeper sedation, advanced airway management, and improved patient outcomes post-procedure (ASA, 2022b). Because MAC is a deeper form of sedation, its use over moderate sedation leads to a reduced incidence of patient intra-procedure physical discomfort and awareness, improved patient compliance for a smoother procedural process, enhanced airway protection and maintenance during procedure, and shortened recovery times post-procedure, which contributes to increased patient and provider satisfaction with the entire endoscopy process. The use of MAC over moderate sedation also allows for better utilization of the post anesthesia care unit (PACU) of the

endoscopy facility. Increased patient turnover due to shorter recovery times results in more efficient use of resources and increased revenue for facilities (Navidi & Kiai, 2019).

Therefore, the purpose of this retrospective chart review is to determine if the administration of MAC when compared to moderate sedation results in decreased patient recovery time in an endoscopy unit.

Literature Review

A literature review was conducted from 2009-2022 of peer reviewed journal articles written in the English language. Databases searched included CINHAL Plus, Ovid, and PubMed. Search terms included monitored anesthesia care versus moderate sedation in endoscopic procedures, moderate sedation, conscious sedation, sedation in endoscopy, anesthesia in endoscopy, monitored anesthesia care, propofol in endoscopy, fentanyl and midazolam in endoscopy, recovery times in endoscopy, patient sedation outcomes, sedation recovery times for colonoscopy, sedation recovery times for esophagogastroduodenoscopy, American College of Gastroenterology practice standards, and ASA classification.

Comparison of Sedation Methods

As previously mentioned, sedation occurs on a continuum. Hagan et al. (2016) and Jin et al. (2020) have noted the four hierarchal levels of sedation: minimal sedation, moderate sedation, deep sedation, and general anesthesia. Minimal sedation or anxiolysis is a light sedation with a sedative medication such as a benzodiazepine to produce a relaxed state where the person can respond normally to verbal commands (Halliday, 2006). As defined by The Joint Commission (TJC) and the ASA, moderate sedation is a deeper state of drug induced depression in the level of consciousness and is “intended to facilitate the successful performance of the diagnostic or therapeutic procedure while providing patient comfort and cooperation” (ASA, 2022b, p. 1). Known as deep sedation, which is deeper than moderate sedation, MAC is more likely to provoke depths of sedation that could cause physiologic derangements such as compromise the patient’s hemodynamic, respiratory, and/or airway status (ASA, 2022b). The deepest method of sedation known as general anesthesia, most often requires intubation and ventilatory support, and the use of anesthetic gases and/or paralytic medication and is administered by an anesthesia

credentialed provider (Lin, 2017). With general anesthesia, the patient is not arousable even to repeated painful stimulation (Halliday, 2006).

Moderate Sedation in Endoscopy

In 2018, the American Society for Gastrointestinal Endoscopy (ASGE) proposed that moderate sedation, which is the administration of a combination of a benzodiazepine and opioid analgesic, is both safe and effective for routine EGD and colonoscopy in adult patients with low health risks and without risk for sedation related adverse events (Early et al., 2018). Moderate sedation can be used in an array of areas for sedation such as diagnostic testing, procedural areas, and surgeries. With moderate sedation, a person can respond purposefully to verbal commands and/or light tactile stimulation, maintain a patent airway, and breathe independently (Halliday, 2006).

The medications of choice for moderate sedation and analgesia are midazolam, a benzodiazepine, and fentanyl, an opioid. These medications have reversal agents in the event the patient becomes over sedated. Flumazenil is the reversal agent for benzodiazepines and naloxone reverses opioids (Benzoni & Cascella, 2022).

Nurses who care for patients receiving moderate sedation have increased responsibilities such as understanding the medications used for moderate sedation and their effects, administering reversal agents when needed, monitoring a patient's condition, sedation level, and/or responsiveness level, and assessing for any complications (Halliday, 2006). Nurses managing a patient under moderate sedation need to be confident with monitoring level of consciousness, vital signs, cardiac rhythm, oxygen saturation, and in some cases capnography. The nurse must monitor for any deviations from patient baseline.

Midazolam and Fentanyl

Midazolam, known by the brand name Versed, is a benzodiazepine with sedative, anxiolytic, hypnotic, and amnestic effects. It is water soluble and upon entering the blood stream crosses the blood brain barrier and acts as a central nervous system depressant (Lin, 2017). Midazolam is given intermittently through intravenous bolus doses. It is initially given in a dose of 2-2.5 mg with additional 1mg doses repeated every 2 to 5 minutes as needed (Benzoni & Cascella, 2022). The usual total dose of midazolam given during gastrointestinal endoscopy ranges from 2-10mg. A dose of greater than 5mg is typically not necessary in a young healthy adult, and a dose of less than 3.5mg is commonly expected in an older debilitated adult (Benzoni & Cascella, 2022; Lin, 2017). For individuals over the age of sixty and/or with chronic disease or comorbidities it is recommended initiating midazolam at a lower dose of 0.5-1mg given over at least 30 seconds and titrating upward as needed (Benzoni & Cascella, 2022). The time of onset for midazolam is 2 to 3 minutes; duration to maximum effect or peak is 5 to 10 minutes with a half-life of 1.5 to 2.5 hours (Benzoni & Cascella, 2022). Midazolam is metabolized hepatically and excreted renally (Lin, 2017).

Fentanyl is a synthetic opioid agonist which binds to the body's opioid receptors; it is lipid soluble and rapidly redistributes from the central nervous system (Benzoni & Cascella, 2022; Lin, 2017). Fentanyl has strong analgesic properties and is eighty times stronger than morphine (Lin, 2017). The usual dose for an endoscopy patient is 50-200mcg. An initial dose of fentanyl is 1-1.5mcg/kg then titrate to 1mcg/kg every 3 minutes (Benzoni & Cascella, 2022). For example, a 50kg person (110 pounds), would receive an initial bolus dose of 50mcg then 50mcg every 3 minutes as needed thereafter up to a maximum dose of 200mcg. Onset of action for fentanyl is 1 to 2 minutes; peak effect occurs in 3 to 5 minutes; half-life is 30 to 60 minutes

(Benzoni & Cascella, 2022). Fentanyl it is metabolized by the liver and excreted by the kidneys (Lin, 2017).

Deep Sedation (MAC) in Endoscopy

Propofol has become a popular medication used in sedation, as it has proven to be less sedating for patients than moderate sedation, and patients spend less time sleeping post-procedure (Halliday, 2006). With deep sedation, a person cannot be easily aroused and would require repeated painful stimulation. Unlike moderate sedation, patients in a state of deep sedation are likely to have impaired spontaneous ventilation and also airway obstruction (Lim et al., 2019).

Due to potential adverse cardiopulmonary effects and its narrow therapeutic index, propofol must be administered by a practitioner trained in providing general anesthesia (Sahinovic et al., 2018). The anesthesia practitioner is required in order to be able to convert to general anesthesia should an emergent need occur. An important differentiation between MAC and moderate sedation is that a provider of MAC must be qualified for and ready at any given time to convert from deep sedation to general anesthesia (ASA, 2022b).

In the United States, the Food and Drug Administration (FDA) has limited the use of propofol to only those trained in the management of general anesthesia, or, where appropriate, doctors trained in intensive care (Stogiannou et al., 2018). The American Association of Anesthesiologists guidelines and Centers for Medicare and Medicaid regulations stipulate that propofol should only be administered by those trained to rescue patients from a state of deep sedation and who are independently focused on the patient's sedation level and airway, and not involved in the endoscopic procedure (Poulos et al., 2013).

Propofol and Dexmedetomidine

Propofol, also known as Diprivan, is a short-acting medication with sedative, amnestic, and hypnotic properties (Lin, 2017). Its preparation includes a mixture in soybean oil and eggs so it is contraindicated in those with soy or egg allergy (Lin, 2017). Propofol is a highly lipophilic plasma protein bound, and is able to move into the central nervous system and tissues quickly as it potentiates its effect through the inhibitory neurotransmitter GABA (Lin, 2017; Sahinovic et al., 2018; Thomson et al., 2010). Propofol dosing in a healthy adult is 1-2mg/kg and 0.5-1mg/kg for an older or decompensated individual (Benzoni & Cascella, 2022). From injection to onset, action is 15 to 30 seconds; peak effect occurs within 1 to 2 minutes; and half-life is only 4 to 8 minutes (Benzoni & Cascella, 2022; Lin, 2017). There are no medication reversal agents for propofol as the reversal agent for propofol is non-pharmacologic, and it is the use of a bag mask ventilation for hypoventilation (Benzoni & Cascella, 2022). Propofol is metabolized by the liver and excreted by the kidneys, however, pharmacokinetics does not change in patients with renal or hepatic impairment, therefore propofol is safe to give despite liver or kidney disease (Lin, 2017).

Dexmedetomidine, or Precedex, is an alpha-2 adrenergic receptor agonist with sedative and analgesic properties (Kaur & Singh, 2011). Unlike propofol, it does not cause respiratory depression and has cardiovascular stabilizing effects (Benzoni & Cascella, 2022; Kaur & Singh, 2011). Dexmedetomidine is a sedation alternative in patients with soybean or egg allergy. Dosing for dexmedetomidine is 1mcg/kg; time of onset is 3 to 5 minutes with peak effect occurrence at 15 minutes; elimination half-life is 2 hours (Benzoni & Cascella, 2022; Kaur & Singh, 2011). Dexmedetomidine is metabolized in the liver and excreted in the urine and feces, and dose adjustments are required for those with hepatic failure (Kaur & Singh, 2011).

Type of Sedation and Discharge Time

Baseline psychomotor activity is a measure of the patient's ability to return to baseline activities of daily living without any impairments. Sedation in any form has the risk of prolonging a patient's recovery and discharge time, and return to baseline function. Delayed discharge and increased time spent in PACU uses additional health care resources. Reducing the amount of time from completion of the procedure to patient discharge and return to full functional capacity is significant to patients, providers, and the health care system (Hagan et al., 2016).

The Modified Aldrete Score (MAS) is a criterion used to measure recovery from sedation based on the patient's physical and mental condition (Appendix A). This scoring system can be used in the PACU to determine when a patient returns to baseline pre-sedation status and can be safely discharged (Jin et al., 2020). With the MAS, the higher the score the more improved the recovery status. Five items are measured on the MAS: reflex ability, oxygen saturation, breathing, circulation, and consciousness (Jin et al., 2020). Patients are given up to 2 points per item and a recovery score of 10 points (the maximum score) is deemed fully recovered.

In a retrospective cohort trial, Poulos et al. (2013) found that propofol alone led to prompter recovery and less time spent in the endoscopy unit compared with midazolam and fentanyl for both EGD and colonoscopy. Patients who were in the propofol group obtained a MAS of 9 and were dischargeable earlier in half the time than patients in the midazolam/fentanyl group. In patients who underwent an EGD, a MAS of 9 was reached sooner at 9±7 minutes for those who received propofol versus 19±11 minutes for those who received midazolam/fentanyl. For patients who had a colonoscopy, time to reach a MAS of 9 was 9±8 minutes and 18±11 respectively; findings were significant with $p<0.05$ (Poulos et al., 2013).

Poulos et al. (2013) also determined that in addition to recovering from MAC/propofol sedation sooner, patients in this group reported less discomfort during the procedure, were less likely to remember the procedure, had higher satisfaction ratings, and felt the amount of sedation received was adequate.

In examining recovery efficiency and discharge time, an observational analysis by Trummel et al. (2009) determined that recovery time from removal of scope time to nursing "discharge criteria met" time, the propofol administered anesthesiologist group recovered and was ready for discharge faster. Results showed that the standard group (received moderate sedation) no longer seemed sedated after an average of 40±26.7 minutes and were ready for discharge in an average of 109±54.5 minutes; whereas the anesthesiologist group no longer seemed sedated after an average of 19±8.2 minutes and were ready for discharge after 56.4±30.7 minutes.

Jin et al. (2020) conducted a retrospective chart review of electronic medical records for 1,310 patients who had EGDs for screening purposes. Recovery time was measured by the length of time the patient spent in the recovery area until adequate for discharge. The authors concluded that patients who received higher doses of midazolam had longer discharge times; however, a comparison between discharge times based on whether moderate sedation or MAC was administered were not compared, only the individual medications affecting discharge time were noted.

In their meta-analysis, Wang et al. (2013) provided data on recovery and discharge times for various gastrointestinal procedures. Wang et al. (2013) examined several aspects of sedation including but not limited to recovery time from sedation, post anesthesia recovery score (PARS), and discharge time from the endoscopy suite. Based on the MAS, the PARS is part of a two-part

scoring system used in the PACU to measure if a patient meets discharge criteria. It requires a minimum score of 8 out of 15 to proceed with the recovery process and measures 5 patient criteria: activity, respiration, circulation, consciousness, and oxygen saturation (Canacari, 2018). Wang et al. (2013) noted that propofol sedation when compared to traditional or moderate sedation results in a higher PARS sooner and quicker recovery and discharge time.

A randomized double-blind study performed by Padmanabhan et al. (2017) on outpatient colonoscopies, noted that time in the PACU to discharge was relatively the same between moderate sedation and MAC groups. Discharge time for the moderate sedation group was 38.5 minutes with a mean standard deviation of 7.8 and discharge time for the MAC group was 38.0 minutes with a mean standard deviation of 6.0. The same study however, pointed out that there were increased difficulties in PACU associated with the moderate sedation group (15%) over the MAC group (4%). While in PACU, adverse effects such as nausea or emesis was noted in 11% of the moderate sedation cases compared to 1% of MAC cases (Padmanabhan et al., 2017). Such adverse effects noted to be greater in the moderate sedation group hardly affected discharge times, however.

Lim et al. (2019) performed a systematic review and meta-analysis comparing the effectiveness and safety of moderate sedation to deep sedation (MAC) for colonoscopies. Factors examined included patient and physician satisfaction, recall of procedure, desaturation, and recovery time (Lim et al., 2019). It was concluded that moderate sedation was comparable to deep sedation (MAC) with no difference in respect to recovery time between the two groups.

In a randomized equivalence trial, Schroeder et al. (2016), revealed no significant differences in recovery times between the midazolam/fentanyl group and propofol group undergoing colonoscopy. Recovery time for the midazolam/fentanyl group (n=136) was

33.6±15.0 minutes and 35.0±7.3 minutes for the propofol group (n=126); however, 8 (out of 136) patients all from the midazolam/fentanyl group required greater than 60 minutes in the PACU, whereas this was not the case in the propofol group. Schroeder et al. (2016) observed that although there was no significant difference in recovery times between the two groups, doses of midazolam administered in the midazolam/fentanyl group were less than the mean average of 6mg. Therefore, it should be noted that if the midazolam doses were more often at or greater than 6mg there may have been a more noticeable time difference in the recovery period between the groups (Schroeder et al., 2016).

The increasing use of MAC over moderate sedation in an acute care setting, such as endoscopy, has been found to be an effective method of sedation, as it causes less recall of the procedure for the patient and equates to higher patient and physician satisfaction scores (Poulos et al., 2013). Whether MAC versus moderate sedation is cost effective has been debatable. Lin (2017) states anesthesia services in endoscopy cost the U.S. health care system 3.2 billion dollars over a ten-year period. Anesthesia services to administer sedation during the procedure is a separate charge and ranges from $150 to $1500 per case (Early et al., 2018). There is an increased cost for the facility and the patient, but perhaps a shortened recovery time which allows the patient to be discharged from the facility sooner. This may be an effective cost savings measure. There are sources noting the high cost of anesthesia, but the quicker patient discharge rates from providing MAC balances out (Navidi & Kiai, 2019; Poulos et al., 2013). Monitored anesthesia care has been studied and findings propose a prompter recovery and discharge time from the endoscopy department, yet there are sources stating no significant difference between the use of MAC over moderate sedation effecting recovery and discharge times (Lim at al., 2019; Padmanabhan et al., 2017; Schroeder et al., 2016). Wang et al. (2013)

and Poulos et al. (2013) are reputable sources primarily studying the use of propofol exceeding midazolam/fentanyl in decreased discharge times, but are outdated. More studies and more up-to-date research are needed to determine if MAC should be universally and solely implemented in endoscopy settings.

Theoretical Framework

The theory used to guide this project was The Donabedian Model, which was initially formulated by physician Avedis Donabedian in 1966. In his work which spanned decades, Donabedian essentially pioneered what is a persistent concept in health care today, quality care. The National Academy of Medicine (NAM) defines health care quality as the "degree to which health care services increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (McInerny & Sachdeva, 2013, p. S7). In his model, Donabedian noted that quality in health care can be measured by assessing the structures, processes, and outcomes of care (Donabedian, 2003) (Appendix B). This model became the first widely used theoretical framework to measure health care quality, and has been a foundation of the accreditation process for The Joint Commission (McEwen & Wills, 2019).

The Donabedian Model appropriately guided this project in that delivery of quality health care can be something examined and applied in the endoscopy setting. The data collected and examined in this retrospective chart review can be applied to help facilitate top quality care delivery for endoscopy patients. Quality health care implies not only care delivered to and received by patients, but care provided by the healthcare system.

In Donabedian's Model, the three elements, structure, process, and outcome are interrelated and hierarchal. This triad can be used to gather information and draw conclusions regarding the health care system's quality of care (Donabedian, 2003). Structure is the foundation of good health care, it influences process, and has a secondary direct influence on outcome (Shi & Singh, 2022). Process is the actual delivery of health care and is directly linked to outcome (Donabedian, 2003). Process includes interpersonal aspects of care such as communication, respect, and compassion, and technical aspects of care such as treatment

procedures, cost, and waiting time (Shi & Singh, 2022). Outcome is an indicator of quality and allows for quality improvement measures (Donabedian, 2003). Outcomes are measured and compared against pre-determined benchmarks and examples include patient satisfaction, recovery, and improvement (Shi & Singh, 2022). Together, structures and processes influence quality outcomes.

The aspects of structure, process, and outcome relate to recovery and discharge from sedation in endoscopy. In the health care facility's endoscopy setting, structure, and process equates to the quality of the outcomes. Trummel et al. (2009) emphasized that a quality state of sedation for a patient during an endoscopic procedure equates to improved quality of care. Increased use of MAC sedation through adequate staffing and an abundance of resources (structure) leads to decreased patient waiting time for the procedure and more efficient use of the PACU, which offsets the cost of services provided (process), and leads to a speedier recovery period from sedation, quicker discharge time, and increased patient satisfaction (outcome).

Understanding and improving the structure and process of the endoscopy setting can help to improve quality care. To improve quality, the element of process, the actual delivery of healthcare, can be looked at to improve clinical practice guidelines and cost efficiency measures, these are processes that improve quality (Shi & Singh, 2022). The data collected and results of this project may help improve delivery of care in the endoscopy setting. Highlighting the benefit of anesthesia services creates improved utilization of the setting in efficiency and cost effectiveness.

Methods

Purpose

In the United States most all endoscopy procedures are performed with some type of sedation (Hagan et al., 2016; Lin, 2017). Over the last two decades, there has been a shift in the method of sedation utilized in the endoscopy setting. Despite its increased cost, the use of anesthesia provided sedation or MAC has increased considerably over recent years and continues to rise (Krigel et al., 2019). Therefore, the purpose of this retrospective chart review was to determine if the administration of MAC when compared to moderate sedation resulted in decreased patient recovery time in an endoscopy unit.

Design

This project was a comparative design in which data was collected through a retrospective chart review of patient's electronic health records (EHRs).

Site and Sample

A convenience sample, of EHRs of adults in an acute care endoscopy hospital-based outpatient setting was used for this project. The retrieval of retrospective chart data was collected from a single acute care hospital-based endoscopy unit located in a 247 bed Magnet designated teaching hospital in the Northeast. The endoscopy unit of this hospital is a nursing department under the Direction of Emergency Services, Endoscopy Services, and Vascular and Interventional Radiology (VIR) Nursing. The endoscopy suite includes 5 procedure rooms, between 8-12 recovery bays, and sees approximately 25 endoscopy cases per day for an array of gastrointestinal conditions.

Male and female records of patients between the ages of 18 through 75, who underwent an EGD, colonoscopy, or both procedures were included. The age of 75 was used as the maximum age for this project as this is appropriate to evidence-based guidelines recommended

by the American Cancer Society for colonoscopy screening (Wolf et al., 2018). The actual number of electronic health records was 25 MAC case records and 24 moderate sedation case records with a close to equal ratio of male to female patients for each group.

Measurement and Data Collection

Demographic data collected included age (18 to 75 years) and gender. Age ranges collected were listed in increments by decade. Gender was listed as male or female. Method of sedation utilized (MAC or moderate sedation), type of procedure performed (EGD, colonoscopy, or both), time to discharge post-procedure (from time "in recovery" or time "in phase II" to "phase II care complete," which designates completion of recovery period), and the length of time the patient spent in the PACU post-procedure as measured in minutes was collected. Minutes spent in PACU included the duration of time the patient spent in PACU from arrival to the return of baseline function adequate for discharge.

Procedures

Support from the Chief Nursing Officer of the facility, and a letter stating permission was obtained (Appendix C). Institutional Review Board (IRB) approval from the hospital's organization (Appendix D), and Rhode Island College (Appendix E) were obtained. Patient electronic record data was reviewed and extracted by the Clinical Lead Endoscopy Registered Nurse and entered into a data collection table created by this author (Appendix F).

The Clinical Lead Endoscopy Registered Nurse randomly selected a convenience sample of EHRs for this project through the existing PACU documentation of outpatient procedures in patients that met the inclusion criteria. Records reviewed were from January 1, 2022 to May 31, 2022 of patients who had either an EGD, colonoscopy, or both and received either moderate sedation or MAC for their procedure.

The Clinical Lead Endoscopy Registered Nurse obtained the variables with equal approximation given to each category (i.e., age, gender, and procedure type). Any patient identifiers, such as name and date of birth, were completely anonymous to this author. However, patient medical record numbers, were used for each case in the event the data was not all extracted in one sitting and so as not to select duplicate records. Time to discharge was acquired from the endoscopy EHRs "event times" flowsheet, which included pre-procedure, intra-procedure, and post-procedure times. Only post-procedure times were examined, which included "in recovery," "in phase II," and "phase II care complete" times. Upon selecting the appropriate variables from the EHRs and flowsheets, the Clinical Lead Endoscopy Registered Nurse entered them into the data collection table constructed by this author (Appendix F).

All data was stored and reviewed in the privacy of a locked office and on password protected computer that only the Clinical Lead Endoscopy Registered Nurse and this author had access to. All data will be destroyed per the IRB policy at the conclusion of the data analysis.

Analysis

The major purpose of this project was to conduct a retrospective chart review to determine if the administration of MAC when compared to moderate sedation resulted in decreased patient recovery time in an endoscopy unit. Data collection involved extracting data from patients EHRs and analyzing it to answer the project question. Several other variables were also compared to sedation intervention and time to discharge and included age range, gender, and procedure type.

The variable of patient age was collected and then categorized by decade. There were six age categories. Age ranges were listed as 18-29, 30-39, 40-49, 50-59, 60-69, and 70-75 years. Each age decade was statistically compared against total time to full recovery adequate for

discharge. The mean average of discharge time for each age category was measured in minutes. This comparison was performed for both the MAC and moderate sedation categories separately. The time to discharge in minutes was calculated between the time of "in recovery" and time of recovery care complete designated as "phase II care complete." The mean average discharge time was calculated for each age decade and compared according to MAC and moderate sedation respectively. Age was compared to determine if age and time to discharge had any relationship to the method of sedation used.

To compare the variable of gender, the number of males and the number of females were counted separately for each sample. For instance, the number of males who received MAC were counted and the number of males in the moderate sedation sample were counted. The mean average discharge time was then calculated for all males included in each sample. This was repeated for females for MAC and moderate sedation respectively. Gender was compared to determine if there was any difference between males and females in time to discharge and the method of sedation used.

The type of procedure was used as a variable to examine discharge time differences for MAC versus moderate sedation for each of the three procedure types. For both MAC and moderate sedation, procedure types were listed as EGD, colonoscopy, or both. The mean average discharge times were calculated for MAC and moderate sedation EGDs, colonoscopies, and combination procedures. The type of procedure performed was compared to the method of sedation and discharge time to see if any relationship existed.

The ultimate goal was to conclude from the data analysis which sedation method if any is most effective in promoting a prompter discharge time. To measure the data, the method of central tendency using the mean average was employed. Means were calculated as each variable

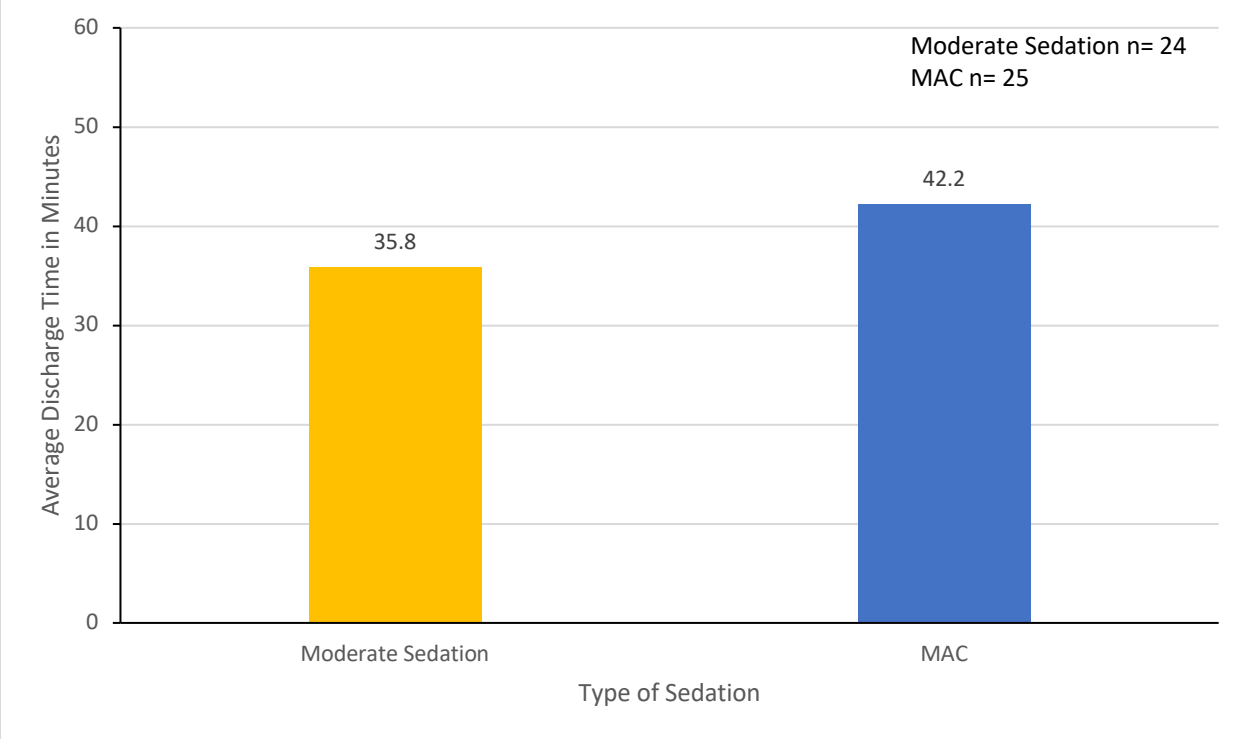
was compared one at a time to show if any relationship existed between the variables (such as age and discharge time). Bar graphs were used to depict the data. By evaluating the relationship, if any, between the variables the objective was to propose which sedation strategy is more time advantageous for endoscopy patients, and if so in which categories.

Results

The data from a convenience sample of 49 EHRs were selected to be included in this project. Of the 49 EHRs, 24 were moderate sedation and 25 were MAC sedation. Additional variables procured from the EHRs including age, gender, and type of procedure (EGD, colonoscopy, or both) were of mixed numerical quantities among the 49 records. Patients who received moderate sedation were recovered and adequate for discharge on an average of 35.8 minutes. Patients who received MAC were recovered and adequate for discharge on an average of 42.2 minutes. There is a difference of 6.4 minutes between the two groups with the moderate sedation group ready for discharge at almost six and a half minutes sooner (Figure 1).

Figure 1

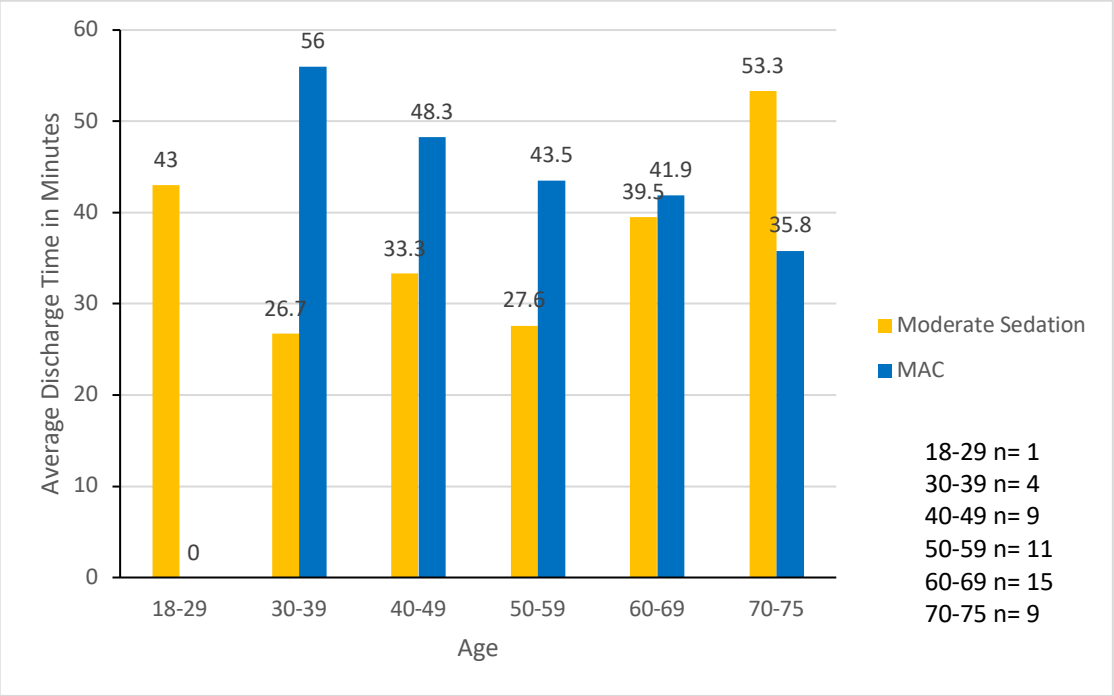
Moderate Sedation versus MAC Discharge Times



Ages of patients were examined to determine if age has an effect on the time to discharge after receiving MAC or moderate sedation. The average discharge time for moderate and MAC sedation based on age by decade was calculated for each decade from age 18-75 beginning at 18-29 years and ending at 70-75 years. The total number of records reviewed for ages 50 and older came to a total of 35 records and for under the age of 50 there were a total of 14 records reviewed. Averages for moderate sedation discharge time related to age included: a mean of 43 minutes for ages 18-29, 26.7 minutes for ages 30-39, 33.3 minutes for ages 40-49, 27.6 minutes for ages 50-59, 39.5 minutes for ages 60-69, and 53.3 minutes for ages 70-75. Averages in minutes for MAC discharge time related to age included: there was no data collected for MAC in the 18-29 age group, a mean of 56 minutes for ages 30-39, 48.3 minutes for ages 40-49, 43.5 minutes for ages 50-59, 41.9 minutes for ages 60-69, and 35.8 minutes for ages 70-75 (Figure 2).

Figure 2

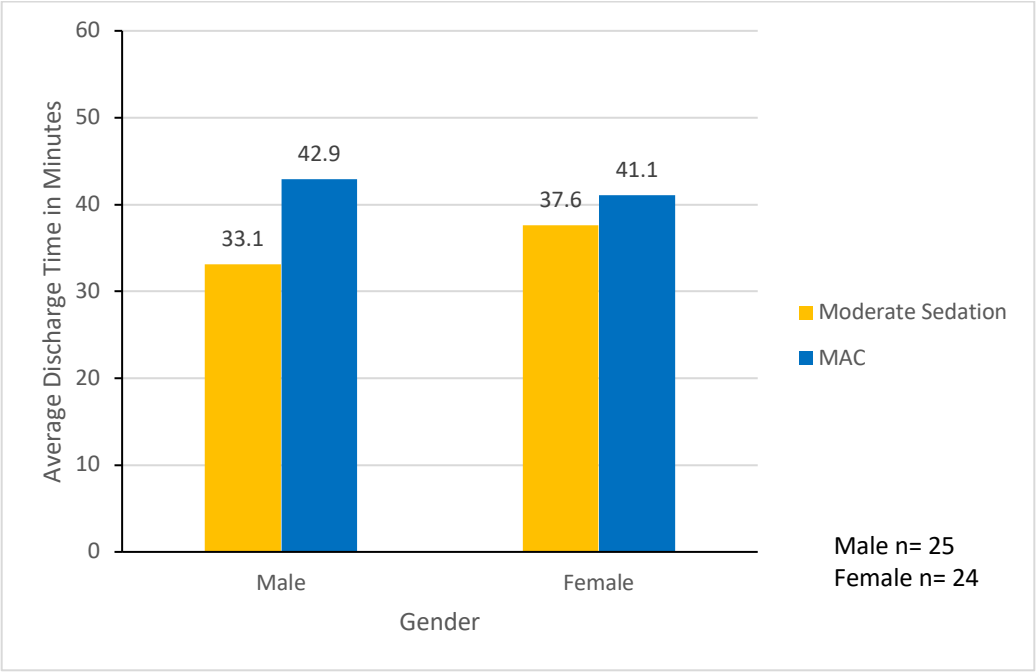
Moderate Sedation versus MAC Discharge Times by Age



Averages of discharge times based on gender were collected to determine if there was any relationship between gender and the method of sedation. Data was extracted from 25 male EHRs and 24 female EHRs. Of the male EHRs, a total of 10 received moderate sedation and a total of 15 received MAC. From the female EHRs, 10 females received MAC and 14 moderate sedation. The average discharge time for males receiving moderate sedation was 33.1 minutes. The average discharge time in minutes for males receiving MAC was 42.9 minutes. Average discharge time for females who received moderate sedation was 37.6 minutes. Average discharge time for females who received MAC was 41.1 minutes. For moderate sedation, there was a difference of 4.5 minutes of males being ready for discharge sooner than females, and for MAC, a difference of only 1.8 minutes of females being ready for discharge sooner than males (Figure 3).

Figure 3

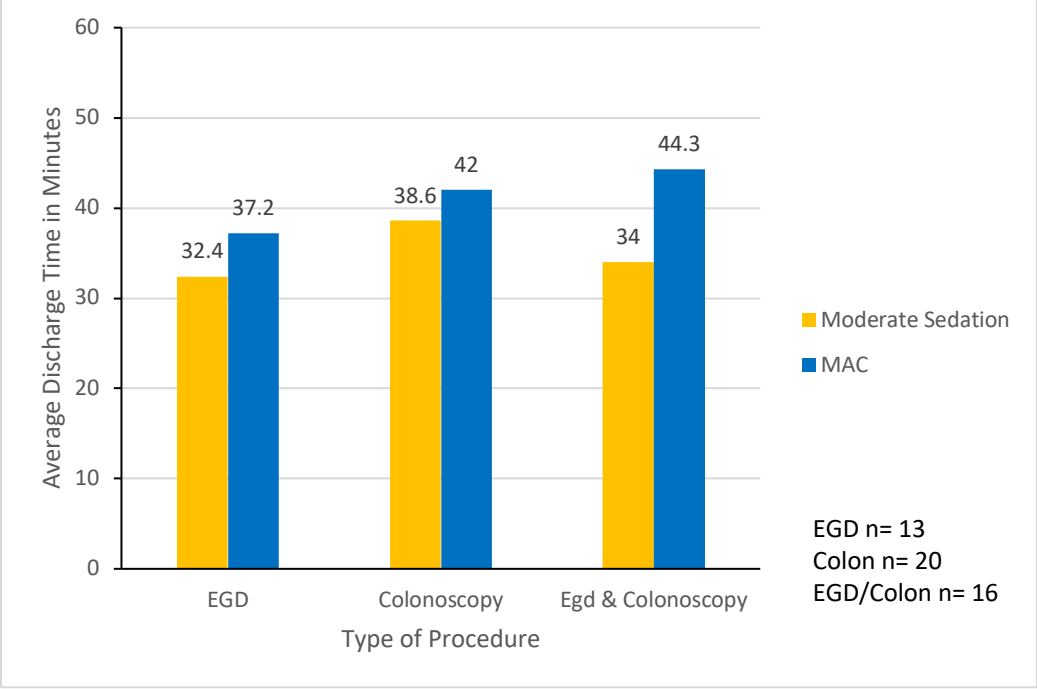
Moderate sedation versus MAC Discharge Times by Gender



The type of procedure the patient received was collected to determine if there were any associations between discharge times, the type of procedure, and the method of sedation. Of the 49 EHRs reviewed, 13 had an EGD, 20 had a colonoscopy, and 16 had both an EGD and colonoscopy in a combined procedure. There was a total of 8 EGDs that received moderate sedation and 5 which received MAC. For moderate sedation EGDs, the average discharge time was 32.4 minutes. For the EGDs receiving MAC, the average discharge time was 37.2 minutes. There was a total of 12 colonoscopies that were moderate sedation, and 8 which were MAC sedation. The average discharge time for moderate sedation colonoscopies was 38.6 minutes. The average discharge time for MAC colonoscopies was 42 minutes. There was a total of 4 moderate sedation combined procedures, and 12 MAC combined procedures. Of the moderate sedation combination procedures, average discharge time was 34 minutes. With the MAC combination procedures, average discharge time was 44.3 minutes (Figure 4).

Figure 4

Moderate Sedation versus MAC Discharge Times by Type of Procedure



Summary and Conclusions

The objectives for administering sedation in the endoscopy setting for procedures such as EGDs and colonoscopies are to lessen patient anxiety, relieve discomfort, increase the likelihood of a smooth and uninterrupted examination, and reduce a patient's memory of the event (Early et al., 2018). "Any type of sedation may prolong recovery times, use extra resources, and delay the patient's return to baseline function. Minimizing the time from procedure completion to discharge and complete psychomotor recovery is of great interest to physicians, patients, and health care economists" (Hagan et al., 2016, p. 200). The purpose of this retrospective chart review was to determine if the administration of MAC when compared to moderate sedation resulted in decreased patient recovery time in an endoscopy unit.

The types of sedation examined in this retrospective chart review were moderate sedation and deep sedation, also known as MAC. Despite increased costs, the use of MAC continues to rise and become more prevalent in endoscopy centers (Hagan et al., 2016; Krigel et al., 2019; Lin 2017). Research from a decade ago concluded that MAC was superior to moderate sedation in time to patient discharge. More recent literature, however, has suggested that there is no difference in patient recovery times between MAC and moderate sedation for routine EGDs and colonoscopies.

Moderate sedation is a state of sedation in between minimal sedation or anxiolysis and deep sedation. In endoscopic procedures performed with moderate sedation, the patient maintains ventilation and cardiovascular function independently and is able to make purposeful movements to verbal or light tactile stimulation. In the case of endoscopic procedures using MAC sedation, the patient cannot be aroused easily and arousal would require repeated or prolonged noxious stimulation. With MAC, the patient is unable to make purposeful movements

or respond to verbal or tactile prompts. Airway support may be required during deep sedation and cardiovascular function may be compromised for instance resulting in hypotension. It is critical that practitioners such as anesthesiologists or CRNAs trained in advanced airway assessment and protection skills and providing general anesthesia such as through endotracheal intubation are responsible for administering deep sedation (Early et al., 2018).

This project was a retrospective chart review in that data was collected from former EHRs from a hospital's endoscopy unit. Twenty-four records of patients that received moderate sedation and 25 records of patients that received MAC were reviewed. The Clinical Lead Endoscopy Registered Nurse of the hospital's endoscopy department extracted the required data from former electronic records from a computer located in the privacy of her office on the hospital's premises. The Clinical Lead Endoscopy Registered Nurse input the data into a data collection table constructed by this author. Data included: the method of sedation (moderate sedation or MAC), age and gender of the patient, the type of procedure performed (whether patient underwent an EGD, colonoscopy, or both), and times spent entering and leaving the recovery suite. Data was then analyzed and mean averages were calculated and depicted in bar graphs. Mean averages included time it took to discharge (in minutes) related to sedation method, age (by decade) related to sedation method, gender related to sedation method, and type of endoscopic procedure related to sedation method.

The predicted outcome of this retrospective chart review was to explore and evaluate the benefits of MAC contributing to improved patient recovery or discharge times compared to that of non-anesthesia administered moderate sedation in the endoscopy environment. It was initially predicted that MAC sedation resulted in prompter discharge time than moderate sedation. In contrast, the results of this project revealed that moderate sedation led to prompter discharge

times in all categories except for the age group of 70-75 years in which the patients who received MAC recovered and were ready for discharge much sooner.

When examining ages, patients were between the ages of 18-75 years old. In all age categories, except the age 70-75 group, patients who received moderate sedation were ready for discharge sooner than those who received MAC. The moderate sedation 30-39 age group was the first ready for discharge at an average of 26.7 minutes followed by the 50-59 age group at 27.6 minutes. The 70-75 age group took the longest to recover and were ready for discharge after receiving moderate sedation at an average of 53.3 minutes. For the MAC groups, the trend for discharge times decreased as patients aged, resulting in older patients being ready for discharge sooner than younger patients. After receiving MAC sedation, the 70-75 age group was ready for discharge at 35.8 minutes whereas the 30-39 age group was ready for discharge in 56 minutes.

As for type of sedation and discharge times related to gender there were 25 male records randomly selected and 24 female records randomly selected. For males, those who received moderate sedation were adequate for discharge sooner than those who received MAC by an average difference of 9.8 minutes. Time difference between sedation types was not as significant with females as with males. For females, those who received moderate sedation were ready for discharge sooner than those who received MAC by an average difference of 3.5 minutes. In looking at discharge times between genders, males who received moderate sedation were ready for discharge sooner than females who received moderate sedation by a total of 4.5 minutes. This was the opposite in MAC cases by gender as females who received MAC were ready for discharge 1.8 minutes sooner than males.

The type of endoscopic procedure the patient received whether EGD, colonoscopy, or a combination of the two was examined in order to determine if the type of sedation and the

procedure performed related to the length of stay in PACU. The moderate sedation procedure discharge time after an EGD was an average time of 32.4 minutes, average discharge time after a colonoscopy was 38.6 minutes, and average discharge time after both an EGD and colonoscopy was 34 minutes. This revealed that patients who received a combined procedure with moderate sedation were ready for discharge sooner than patients who received a moderate sedation colonoscopy alone. As for the MAC procedures, the average discharge time after an EGD was 37.2 minutes, average discharge time after a colonoscopy was 42 minutes, and average discharge time after both an EGD and colonoscopy was 44.3 minutes. In all types of procedures, times to discharge after having moderate sedation was quicker than after having received MAC. The most significant discharge time was between moderate sedation and MAC combined procedures with a difference of 10.3 minutes with moderate sedation combination procedures being discharged sooner. Moderate sedation EGDs were discharged at 4.8 minutes sooner than MAC EGDs. Moderate sedation colonoscopies were discharged at 3.4 minutes sooner than MAC colonoscopies.

Results from this project conclude that in contrast to what was predicted, recovery from moderate sedation in the endoscopy setting has a slightly shorter, but not incredibly significant discharge time than recovery from MAC sedation. Monitored anesthesia care discharge times from entrance into the recovery phase to recovery phase care complete exceeded moderate sedation discharge times in all categories except in the 70-75 age group. Whether the use of moderate sedation over MAC in healthy individuals with limited comorbidities undergoing routine uncomplicated endoscopic procedures is more cost effective due to prompter discharge times requires more data or studies to be conducted on this topic to support this conclusion.

Limitations to this project include the small sample size (n=49), additional medications given before or during the procedure that were not accounted for, documentation discrepancies, discharge delays, and patient comorbidities. Perhaps with a larger sample size results would have been different. It was unknown if the patients received additional sedating medications prior to or during the procedure as this data was not collected. For instance, MAC patients could have received midazolam and/or fentanyl in addition to propofol which would have led to more prolonged recovery time.

For MAC and moderate sedation, the time recovery care complete documented by the PACU nurse could have been based on the time the last sedation medication was administered or the time the patient physically entered PACU. Generally, a recovery time of 30 minutes from last medication administration, 3 consecutive vital signs 15 minutes apart, and return to baseline mental and physical status indicates adequate for discharge. In this instance, the last administered dose of a moderate sedation medication could have been half way through the procedure, whereas, the last administered dose of propofol during a MAC sedation could have been minutes before exiting the procedure room. This would have led to moderate sedation patients being eligible to reach the 30-minute recovery complete time sooner than the MAC patients.

Discharge delays were not taken into account for this project. There may have been delays in the recovery period while the patient was in PACU. The nurse may have been delayed discharging the patient or charting, there may have been a wait for discharge paperwork to be completed by the physician, or waiting for the physician to sign out the patient. A number of barriers could have prolonged the patient's time spent in PACU. Further limitations include factors unaccounted for that affect drug response such as body mass index (BMI), drug or

alcohol use, comorbid conditions, and alterations in organ function all which could have prolonged or reduced discharge times.

Recommendations and Implications for Advanced Nursing Practice

Despite the benefits of MAC sedation, the results of this project revealed that overall moderate sedation at a single endoscopy setting led to prompter patient recovery and discharge times than did MAC. This project examined only discharge times in relation to method of sedation and did not look at other variables relating to sedation such as respiratory and hemodynamic stability, patient sedation quality and compliance, or physician and patient satisfaction. According to existing literature, the benefits of MAC compared to the use of moderate sedation in endoscopy care settings promotes increased relaxation and analgesia for the patient and increased patient safety in regards to airway management and protection, improved oxygenation, and better controlled hemodynamic status (Cho, 2021). To better determine which patients may benefit most from MAC compared to moderate sedation, future studies on topics related to sedation in the endoscopy setting can be researched by the advanced practice provider.

In addition, a future recommendation is for the advanced practice registered nurse (APRN) to conduct research studies of endoscopy nurses' knowledge and confidence. The APRN can plan to develop a study such as a quality improvement project to evaluate endoscopy nurses' baseline knowledge. The APRN could assess endoscopy nurses' knowledge regarding: sedation including moderate and deep sedation, the administration, function as well as pharmacokinetics and pharmacodynamics of sedation medications including fentanyl, midazolam, and propofol, advanced airway skills, and their interpretation and response toward respiratory compromise, and hemodynamic instability.

The APRN can act as a leader and educator to develop educational, training, or competency programs implemented by APRNs (such as Acute Care Nurse Practitioners, Clinical Nurse Specialists, and CRNAs) to teach novice nurses new to the endoscopy setting about

sedation, advanced assessment skills, physiologic responses, and patient outcomes. As for the expert endoscopy nurses, gathering a baseline knowledge assessment could in turn be used as a teaching model for review of endoscopy fundamentals such as medications, sedation response, assessment skills, monitor interpretation, airway criteria, patient hemodynamic and respiratory responses, and indicated interventions.

Educational programs implemented by the APRN can increase endoscopy nurses' competence and confidence with the administration of moderate sedation, enhance continual and follow-up patient assessment, identifying potential complications of moderate sedation, and intervening when necessary. Another important task in a setting where sedation is administered is teaching and maintenance of advanced cardiac life support (ACLS) skills and certification. The APRN is at a level to teach ACLS to Registered Nurses (RNs).

Advanced Practice Registered Nurses contribute to enhancing current endoscopy practice by promoting routine education and evaluation of professional nursing skills to ultimately benefit patient outcomes such as discharge times. Advanced Practice Registered Nurses in the endoscopy setting are specially trained to administer and monitor a more effective and reliable form of sedation such as with CRNAs. Acute Care Nurse Practitioners specializing in gastroenterology (GI) are APRNs who can work with physicians and patients to promote optimum patient care and successful and satisfactory outcomes. The APRN can act as a resource and leader, and collaborate with members of the endoscopy team including RNs, managers, anesthesiologists, gastroenterologists and fellows, and other ancillary staff.

By implementing evidence-based practice the APRN can work individually with the patient to determine what type of sedation is best for them. For instance, if the patient is a healthy, young adult without comorbidities, an endoscopic procedure with moderate sedation

may be the most suitable and cost effective. The APRN can interview and assess the patient prior to the procedure to determine which sedation method is best suited based on prior sedation history and response, allergies, current medications, past medical history, and ASA classification.

In the future, more research on this topic should be designed and implemented in order to enhance knowledge on the most patient beneficial (safe, effective, least risk of complication, most efficient, and with optimal outcomes) form of sedation during endoscopic procedures. Another element to be examined, aside from patient discharge times, could be patient satisfaction scores based on their endoscopy experience including their sedation and recovery periods. For example, are there any disparities in satisfaction scores noted between patients who received moderate sedation and those who received MAC? To be incorporated in such future research, a more complex patient participation should include diversity through age, gender, race, ethnic and cultural background, and socioeconomics as well as regional variations, and type of setting (i.e., hospital, community clinic, ambulatory care center) to address the needs of the endoscopy patient population across the continuum.

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Appendix A

Chart 1. The 'modified' Aldrete Scale

RESPIRATION	2	1	0
	Able to take deep breath and cough	Dyspnea/Shallow Breathing	Apnea
O2 SATURATION	2	1	0
	Maintains > 92% on room air	Needs O2 inhalation to maintain O2 saturation > 90%	Saturation < 90% even with supplemental O2
CONSCIOUSNESS	2	1	0
	Fully awake	Arousable on calling	Not responding
CIRCULATION	2	1	0
	BP ± 20mmHg pre op	BP ± 20-50mmHg pre op	BP ± 50mmHg pre op
ACTIVITY	2	1	0
	Able to move 4 extremities voluntarily or on command	Able to move 2 extremities voluntarily or on command	Able to move 0 extremities voluntarily or on command

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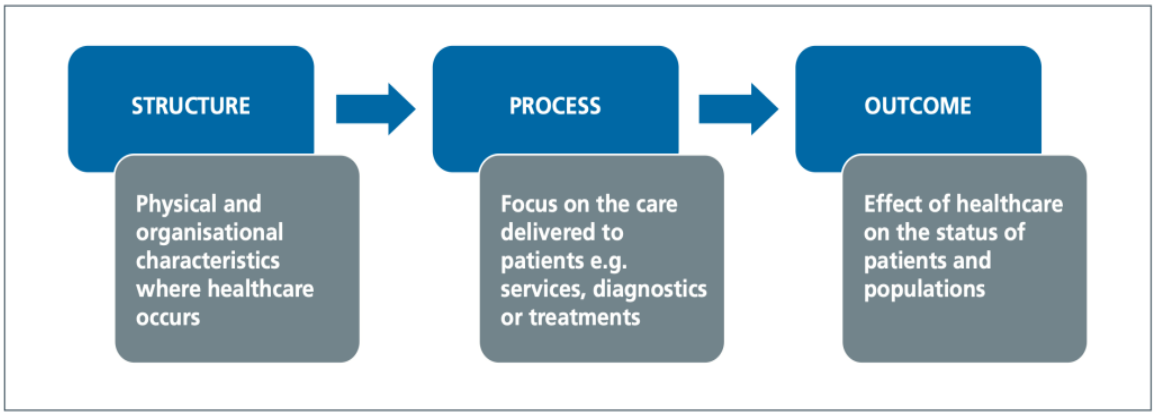
Appendix B

Figure 1: The Donabedian model for quality of care



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Appendix C

12/15/2022

To Whom It May Concern:

I am aware that Ilana Oakes, RN will be conducting a study in the Endoscopy Unit at The Miriam Hospital regarding Monitored Anesthesia Care versus Moderate Sedation in the Endoscopy Setting. Ilana has informed me this will be a retrospective chart review study.

I support this effort and will provide any assistance necessary for the successful implementation of the study. If you have any questions, please do not hesitate to contact me at (401) 793-2072

Sincerely,

Vanzetta James, DNP, MBA, RN, CCRN-K, NEA-BC,
Senior Vice President Patient Care Services and Chief Nursing Officer
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Appendix D

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Providence, RI 02903-4771
Tel 401 444-6246, Fax 401 444-7960

E. P. Bradley Hospital Rhode Island Hospital The Miriam Hospital Newport Hospital Gateway Healthcare

March 27, 2023

TO: FROM: SUBJECT:

PROJECT TITLE: CMTT/PROJ:

ACTION:
EFFECTIVE DATE: RESPONSE ACCEPTED: NEXT REPORT DUE:

EXPEDITED REVIEW CATEGORY:

Kara Misto, PhD, RN Research Protection Office New Project: APPROVED

[1988869-1, 2 and 3] Monitored Anesthesia Care versus Moderate Sedation in the Endoscopy Setting: A Retrospective Chart Review

000223

APPROVED
February 3, 2023
March 25, 2023
February 2, 2025
45 CFR 46.110(b)(1), Category 5

The Board reviewed the submission on February 3, 2023 and determined MODIFICATIONS were REQUIRED in order to secure approval. The submission received Expedited Review based on applicable federal regulations and institutional policy. The RESPONSE/FOLLOW-UP packages required by the IRB have been reviewed by EXPEDITED REVIEW and the conditions of approval have been satisfied.

If you have any questions, please contact Sara Spangenberger at (401) 444-6756 or sspangenberger@lifespan.org. Please include your project title and CMTT/PROJ or IRBNet ID in all correspondence with this committee.

The following institution(s) rely on Lifespan IRB 1 for initial and subsequent review of the research: 1. Lifespan - The Miriam Hospital

PI RESPONSIBILITIES
It is the responsibility of the Principal Investigator to ensure that the study is conducted as approved by the IRB. IRB determinations and specific findings for the conduct of this research are listed below.

IRB DETERMINATIONS/SPECIFIC FINDINGS
This project has been determined to be a MINIMAL RISK project.

Informed Consent

Human Subjects Protection Review of this research project is complete. If this research has external funding, research activity may not commence until an activation notice is received from Lifespan Grants & Contracts.

Consent: General waiver of informed consent permitted [46.116(f)(1)]

HIPAA
HIPAA: Waiver of Authorization permitted

MODIFICATIONS AND AMENDMENTS
All **protocol modifications/changes** must be approved by the IRB before any changes are implemented, except when necessary to eliminate immediate hazards to subjects.

REPORTING OF EVENTS
All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events including subject deaths must be reported in accordance with institutional policy. All FDA and sponsor reporting requirements should also be followed, if applicable.

All NON-COMPLIANCE issues (including Protocol Deviations) or COMPLAINTS regarding this project must be reported promptly to this office.

PROTOCOL EXPIRATION
A Progress Report is due by February 2, 2025 to confirm the research is still active. Based on the risks, continuing review of research is not required unless the IRB determines otherwise. The annual Progress Report is due 60 days before the Next Report Due date. The IRB may determine at any time during the life of the study that a continuing review is required. If the IRB determines that a continuing review is necessary for this study the rational for this requirement will be documented. IRB approval of this project does not expire until the project is closed by the Principal Investigator.

STUDY CLOSURE AND RECORD RETENTION
A Closure/Final Report is required at the conclusion of the human subjects research. Investigators are required to maintain research records for the longest period of time required by applicable Federal, State regulations and institutional policy (a minimum of 3-6 years).

LIFESPAN RESEARCH DATA POLICY
Any research data that includes Protected Health Information (PHI) or a Limited Data Set (LDS), as defined by HIPAA Regulations, may only be stored on:

1. Lifespan managed storage platforms that comply with Lifespan policy "HSP-86.1 Data Backup and Storage Policy";
2. Lifespan managed computer workstations that comply with policy "HSP-90 Workstation Use Policy"; and

3. Mobile devices that comply with "HSP-102 Mobile Device Management Policy".

This includes data that originates from a Lifespan affiliated Covered Entity, personally identifiable information of Lifespan employees, or data originating from Lifespan or its affiliates that is classified as confidential.

For more information contact Lifespan IT department or Director, Research Protection Office.

IRB Compliance
The Lifespan IRB 1 complies with HHS 45 CFR 46, FDA 21 CFR Parts 50 and 56 and other federal and state laws and regulations, as applicable, as well as ICH-GCP as they correspond to the FDA/DHHS regulations.

Federalwide Assurance (FWA)

Rhode Island Hospital (RIH): FWA00001230 The Miriam Hospital (TMH): FWA00003538

OHRP IRB Registration

RIH IRB 1: IRB00000396 RIH IRB 2: IRB00004624

Emma Pendleton Bradley: FWA00001129 TMH IRB: IRB00000482 Newport Hospital: FWA00003435 Gateway Healthcare: FWA00022347

The following items are approved:

- ApplicationForm-ApplicationChartReviewPartII_SedationinEndoscopy_REVISED.pdf (UPDATED: 02/15/2023)
- ConsentWaiver-Appendix_2ConsentFormAlterations.docx(UPDATED:12/15/2022)
- CV/Resume-Misto,K.CV.pdf(UPDATED:12/20/2022)
- DataCollection-I.Oakes_DataCollectionTable.docx(UPDATED:01/30/2023)
- HIPAAWaiver-HIPAAforms_REVISED2.13.23.docx(UPDATED:02/13/2023)
- Letter-Departmentheadsignatureapprovalprocess_TMH.msg(UPDATED:12/20/2022)
- Letter-CNOSupportLetter_Oakes12.15.22.pdf(UPDATED:12/20/2022)
- Lifespan-ResearchApplicationPart1-HumanSubjectStudies-Lifespan-ResearchApplication Part 1-Human Subject Studies (UPDATED: 12/21/2022)
- Protocol-I.Oakes_IRBProposalDocumentrevised_CLEAN.docx(UPDATED:03/23/2023)
- Protocol-I.Oakes_IRBProposalDocumentrevised_TRACKCHANGES.docx(UPDATED:

  03/23/2023)

- Other-ModificationsMemo.docx(UPDATED:02/13/2023)
- Other-ModificationsMemo_2.docx(UPDATED:03/16/2023)

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

Appendix E

Greetings,

The proposal for the project referenced below has been APPROVED by the Institutional Review Board (IRB).

Project title: Monitored Anesthesia Care versus Moderate Sedation in the Endoscopy Setting: A Retrospective Chart Review

Approval #: 2223-2448
Type of review: Expedited
Proposal type: Original
Principle Investigator: Dame, Linda
Fees received: 1. No fees -- RIC supervised or sponsored
Funding status:

Approval date: 4/13/2023

Click here to access the protocol: https://ricprod.topazti.net/Elements?emailLink=11%2c102%2c125385

Your responsibilities as the Principal Investigator on this project are as follows:

1. You may implement only those materials and methods approved by the IRB. Changes to the protocol topic or methods, including the elimination of previously-approved methods, require prior approval.

2. If you are using signed consent materials, a PDF of the form(s) with the approval stamp will be uploaded to your protocol. You must use this copy with participants.

3. Unanticipated problems or adverse events must be reported within three (3) days of your knowledge of the event.

4. You must keep all research data and consent documents within your possession in a secured location for at least three (3) years after the completion of the study, including publications or presentations of any reports.

Do not reply to this "RIC_Elements" email address because it will not be received by the IRB. Send all correspondence to IRB@ric.edu.

Best Regards,

Emily Cook, Ph.D.
Professor
Chair, IRB
Rhode Island College
IRB@ric.edu

Appendix F

Data Collection Table

Sedation Type (MAC or Mod Sedation)	**Age**	**Gender**	**Procedure Type (EGD, Colon, or Both)**	**Time in recovery or in phase II**	**Time phase II care complete**	**Total time spent in recovery (in minutes)**