

A STUDY TO EVALUATE COMPLIANCE OF PROCEDURAL SEDATION PROTOCOLS FOR DIAGNOSTICS PROCEDURES

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfilment forthe award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management/Pharmaceutical

Management/Development Management

by

Dr. Kopal Bansal

Under the Supervision and Guidance of

Dr.Seema Mehta

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled A STUDY TO EVALUATE COMPLIANCE OF PROCEDURAL SEDATION PROTOCOLS FOR DIAGNOSTICS PROCEDURES is the Bonafede record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student- Dr.Kopal Bansal

Date

CERTIFICATE

This is to certify that DR. KOPAL BANSAL in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management)) from the IIHMR University, Jaipur has successfully completed her/his internship at (name of the organization) during February 20-May 19, 2023.

Place:

Preceptor/Head of the Organization

Date:

Name of the organization

ABBREVIATIONS
ASA- AMERICAN SOCIETY OF ANESTHESIOLOGISTS
NPO- NOTHING BY MOUTH
MRD- MEDICAL RECORDS DEPARTMENT
ERCP- ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY
ICU- INTENSIVE CARE UNIT
UGIE- UPPER GASTROINTESTINAL ENDOSCOPY
OPD- OUT PATIENT DEPARTMENT
IPD- INPATIENT DEPARTMENT
MS- MICROSOFT
RR- RESPIRATION RATE
BP- BLOOD PRESSURE
SPO2- OXYGEN SATURATION

ABSTRACT

A prospective and a retrospective study was conducted at a tertiary hospital to assess the documentation practices of procedural forms in various areas where sedation is practiced other than operating rooms. Data was collected through patient files where sedation forms were present in MRD and on floors to evaluate the efficacy with which the documentation is being done. The data collected was based on demographic features, documentation of ASA grading, airway management, monitoring of vitals, reporting of adverse events if any and the complications post sedation if any. All of the documentation was assessed as per the hospital policy. The data was analysed using MS-EXCEL to represent the results in the form of graphs and tables.

It was observed retrospectively that the adherence to set protocols in the month of September 22 was about 80-85% which improved to 95% after the sensitization of the healthcare workers including the nurses and the doctors in the month of April 23. The lack of need to document the sedation procedure showcased lack of training and lack of time among the healthcare workers which can be improved through training and skill development.

It is hence noted that medical documentation is not just a liability but an asset for the healthcare organization as it ensures efficiency and enhances patient safety. It also gives an overview of the overall patient health and pre-assessment documentation gives an idea about the level of sedation to be injected to the patient under standard norms.

Procedure sedation protocols that work is legally an essential for protecting patients and raising the standard of care generally. Additionally, they can aid in lowering the likelihood of unfavourable outcomes and complications and ensuring that medical treatments are properly carried out with the least amount of discomfort for the patient.

KEYWORDS

Procedural sedation, ASA grading, monitoring of vitals, sedation forms, post-sedation complications.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Procedural sedation is a technique which is used to manage the pain and discomfort during certain medical procedures and diagnostic tests and purposes that requires the patient cooperation.

A procedural sedation form is a typical legal document that outlines the risks and benefits of sedation during an endoscopic procedure and is designed to obtain the patient's informed consent. Compliance with this form is essential to ensure that the patient fully understands the sedation process and its potential risks, and to mitigate any liability for the healthcare provider.

The procedural sedation form includes information about the type of sedation that is used, such as mild/moderate sedation or deep sedation, as well as the potential risks associated with each. It also include information about the patient's personal details like medical history, any allergies, or medications they are currently on, and any other relevant factors that can affect their ability to withstand sedation safely. One of the major components of the sedation form is the ASA grading which remarks the patient's overall health and is divided into 6 main categories. It also contains the documentation of the monitoring of the vitals during the sedation procedure, the risks associated with the sedation, the documentation of post anaesthesia complications all of which the doctors have to document.

Procedural sedation is a planned procedure which involves a history and the evaluation of the patient's airway.

- i. Signs and symptoms
- ii. Allergies
- iii. Medications
- iv. Past medical, anesthetic, and surgical history
- v. Last meal
- vi. Events leading to the patient's condition. (4 (1))

The problem statement is incomplete documentation of the sedation form and no written evidence of whether the said guidelines have been followed or not. When a clinician does not document the procedure that is being done on a patient, it possesses potential risks. Risks like adverse reaction to the sedative drug being injected to the patient or any post sedation complication when the procedure is done to name a few.

Obtaining written consent from the patient should be practiced, which is done either on the procedural sedation form or on a separate consent form, to ensure that there is a clear record of the patient's agreement to undergo sedation as an essential component for any procedure to be performed so that the patient has the knowledge about the risks associated with it.

Procedural sedation protocol study will also help us in investigating the use of different sedative agents, doses, and routes of administration to identify the most appropriate approach for specific procedures and patient populations. Additionally, this study will also help us in exploration of the use of sedation in various settings, such as emergency department, interventional radiology, and outpatient clinics and is not limited to just operating rooms.

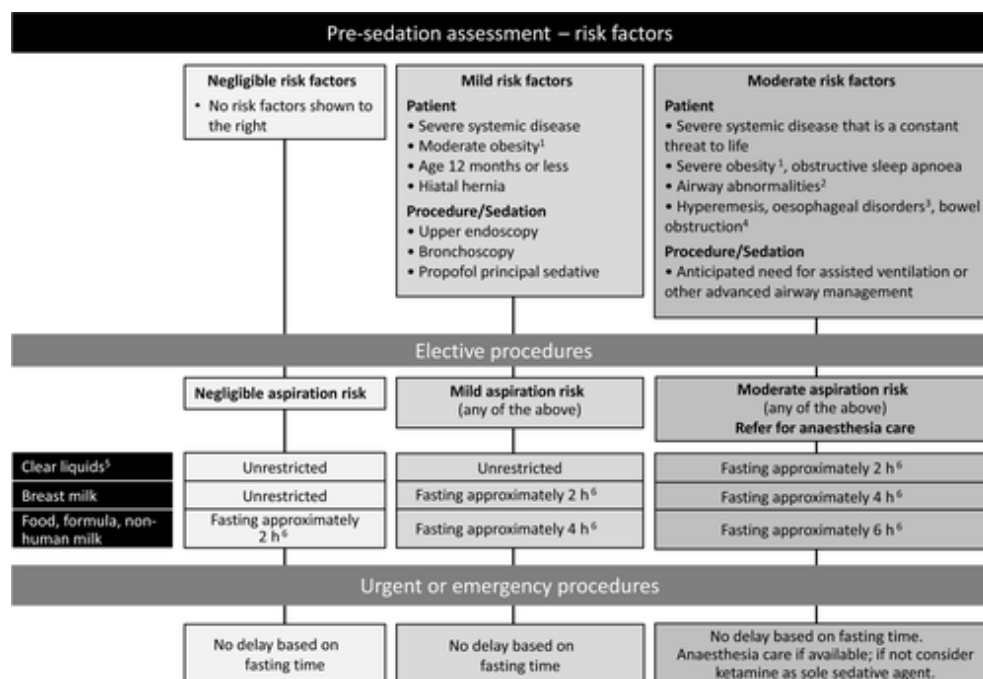


Figure 1: risk factors associated with pre-sedation assessment documentation. Adapted from (2)5

Ultimately, the goal of procedural sedation protocol research is to provide evidence-based recommendations that can guide healthcare providers in the safe and effective use of sedation, improving the quality of care for patients undergoing medical procedures.

The procedural sedation form is divided into 4 sections:

- Pre-assessment: here the ASA grading is documented, the airway management is documented, patient's details, their history of past or present illness is documented, the doctor's name administering the sedation has to be documented, the type of sedation whether mild/moderate/deep has to be administered and documented in the pre-assessment record. This gives an estimate about the patient's overall health and the ability to withstand the sedation procedure.
- Intra-procedure monitoring: here the vitals of the patients has to be monitored at the intervals of 15 minutes for 1 hour, every 30 minutes for 2 hours, and once the patient is shifted from the procedure room, then after every 4 hours for the 24 hours has to be monitored.
Vitals like temperature, pulse, BP, RR, SPO2 levels must be documented before and during the procedure to make sure no discrepancies in the patient overall patient health is notified.
- Post-procedure documentation: once the sedative agent has been administered, the anaesthetist makes sure that the vitals are in range and the patient is in a stable condition. The level of consciousness of the patient needs to be documented to establish whether the patient is responsiveness or not.
- Post- procedure discharge documentation: when the patient is shifted from the procedure room to the ward, discharge criteria have to be documented. Parameters such as post sedation complication if occurred like dizziness, vomiting, rashes, fever, headache among others and whether any complication occurred during sedation or the recovery from the drug dose. All this discharge documentation must be done by the sedation physician with their signatures and their employee id.

1.2 THE AIM OF THE STUDY AND OBJECTIVE

The major aim of the study is to improve the patient outcome by encouraging the effective and proper adherence to the sedation protocols and documentation of the findings in the form.

- 1) To check the compliance to ASA grading documentation.
- 2) To evaluate the adherence to post sedation monitoring.
- 3) To check compliance to discharge criteria of endoscopy unit.
- 4) To find out the Compliance to post anaesthesia complication reporting and its documentation.

SCOPE OF THE STUDY

The study was carried out to define the importance of proper documentation of procedural sedation forms to enhance patient safety and experience. In addition, what the healthcare professionals can do to follow the protocol and manage the sedation form documentation in the long run. For conducting the study, certain tools were used to draw results like a procedural sedation checklist, net search, interaction with the employees of the organization. The results were shown in the form of graphs and tables.

CHAPTER- 2

LITERATURE REVIEW

S.NO	AUTHOR (YEAR)	STUDY LOCATION	SAMPLE SIZE	SAMPLING TECHNIQUE	SALIENT FEATURES
1.	M.G. Roback et al, 2017	USA	46 members	PURPOSIVE SAMPLING	The aim was to continuously improve the procedural sedation practices and provide safe and effective sedation practices to the patients. The committee members from 5 different continents developed tools to monitor the outcomes of the procedural sedation and to enhance research on effective quality management. (3)
2	S. M. Green et al, 2019	USA	17 MEMBERS	STRATIFIED SAMPLING	this study talks about importance of fasting status before any diagnostic procedure that involves procedural sedation. It also talks about how sedation is different from general anaesthesia and how it

					is better than general anaesthesia. (4)
3.	G. Homfray et al, 2018	UNITED KINGDOM	740 PATIENTS	SIMPLE RANDOM SAMPLING	the median age of the population was 84 years, and they were administered propofol, morphine and midazolam. There were 2 cases of hypoxia, 10 of apnoea, 5 of hypotension but no major adverse events were reported for the patients. Overall, safe sedation practices were practiced in the hospital for high-risk patients. (4)
4.	Sam G. Campbell et al, 2015	NOVA SCOTIA, CANADA	979 samples	SIMPLE RANDOM SAMPLING	The most common sedative agent used is fentanyl and then propofol. No adverse events were recorded when administration is done of the patients.
5.	Kara Goddard et al, 2021	COLUMBIA, USA	33 samples	Simple Random sampling	Ketamine was used as a sedative agent to monitor any adverse event.

					Careful administration is important to avoid ischaemia like effects. As ketamine is a strong sedative agent and a newer drug introduced therefore adverse reactions were recorded.
6.	Kenneth Deitch DO et al, 2007	Philadelphia, USA	110 sample	RANDOM CONTROL	The study aimed to watch the effect of supplemental oxygen in reducing the chances of Hypoxia when the patient is undergoing procedural sedation. However, the change in chances of hypoxia was not significantly reduced.
7.	Steven A. Godwin, MD, et al 2005	USA	Not mentioned	Randomized control	Knowledge about procedural sedation is critical for any doctor and about the sedative agents used. The article throws light on patient criteria for sedation.
8.	Win, Ni Ni et al- 2005	Tokyo, Jaipan			Propofol and midazolam cause changes in heart rate and blood pressure rate via changes in the

					cardiac autonomic nervous system.
9.	Azriel Perel et al, 2011	Tel Aviv, Israel	21 national societies of Europe.	Not mentioned.	This article talks about the expanding practice of non-anaesthesiologists administering sedative agents for diagnosis practices. They published that only anaesthesiologists are allowed to administer anaesthesia and only a few doctors who have the privilege can administer anaesthesia to the patient.
10.	David Thomson et al, 2016	NEW SOUTH WALES, AUSTRALIA	755 samples	Convenience sampling	This study sought to determine whether the use of high flow oxygen delivery by a non-rebreather mask (NRB) during ED procedural sedation and decreased rates of hypoxia when compared with alternate oxygenation methods. The study proved to demonstrate significant reduction in cases of hypoxia among patients who were on non-rebreather mask (NRB)

					from the outset of their sedation. (6)
11.	Gita Koshy et al. 2000((3)7)	USA	274 samples	Simple random sampling	This study is about understanding and analysing the efficacy of propofol to the conventional midazolam for procedural sedation. Elderly patients with a number of co-morbidities were taken for the study and it was observed that propofol produced deeper sedation than midazolam and even the recovery was faster in patients with propofol sedation. (7)
12.	Neil Dawson, Alistair Dewar, Alasdair Gray, Alexis Leal- 2013	Scotland, United Kingdom	303 samples	Stratified sampling	This study is about the association between the ASA grade and complication rate in patients receiving procedural sedation for hip prosthesis aged 16 and above. There was no clear association between the ASA grading and the complication rate of patients receiving procedural sedation. There was a higher level

					of risk and complications seen with the higher dose of sedation to the patient. (8)
13.	Nekisa Zakeri et al, 2014	London, United Kingdom	52,553 samples	Simple random sampling	This study aims to determine the frequency of complications of sedation requiring a reversal and to identify patients at potential risk and procedural risk factors. Patients who underwent ERCP procedures and also had a higher (ASA) grade were at an increased risk of complications that requires reversal during conscious sedation. In such high-risk groups, alternative sedation strategies must be considered upon and evaluated as well.
14.	Simon Hazeldine et al, 2010	Perth, Australia	2155 samples	Simple Random sampling	This study aims to evaluate the adequacy of benzodiazepine sedation for endoscopic procedures and to identify the patient and procedure characteristics that may

					predict poor procedural characteristics. Most patients tolerate endoscopic procedures well when they are sedated with benzodiazepines and opioids. However, it is difficult to identify the minority of patients who do not tolerate these procedures well.
15.	D Joshi et al, 2014	London, United Kingdom	744 samples	Simple random sampling	This study depicts the role of propofol associated ERCP procedure and the experience associated with it. (3) It shows that propofol induced ERCP showed high success rate in the gastro-intestinal successes. It concludes that the need for propofol induced ERCP is going to increase as the rate of complex diagnostic procedures is increasing day by day. (9)

16.	Mulugeta Desalegn Kasaye et al, 2022 (4)	ETHIOPIA	419 samples	Simple random sampling	The aim of this study is to evaluate the practice of medical documentation and its associated factors among doctors and nurses at a private hospitals in the Amhara region, Ethiopia. In this study, the overall medical documentation practice at this private hospital in the Amhara Region came out to be poor. Incomplete documenting sheets, unfamiliarity with standard sheet protocols, lack of skill, inadequate staff, and lack of time were some of the major reasons for poor medical documentation practice.
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CHAPTER 3

3.METHODOLOGY

This chapter provides a comprehensive explanation of the research methodology used in this study. It describes the overall research design, the population studied, the sampling methods used, and the data collection and analysis techniques employed. This information will help the reader understand how the study was conducted and the findings that were generated.

3.1 RESEARCH QUESTION

What is the status of effective documentation and compliance with sedation protocols on patient safety and outcomes during procedural sedation?

3.2 STUDY DESIGN

This involves the overall strategy that has been implemented and the plan of action that has been used to conduct the study to reach to a probable conclusion.

3.2.1 STUDY SETTING

The study was conducted at Medanta Hospital, Gurugram which is a 1250 bedded tertiary care multispeciality hospital with approximately over 40 specialities. The study was conducted under the guidance of the Head of the quality department of the hospital spanned from March 23 to April 23.

3.2.2 RESEARCH APPROACHES

The study undertaken was a retrospective and prospective cross-sectional study in a tertiary care hospital in Delhi-NCR.

The study was conducted at Medanta Hospital, Gurgaon, India. The population of the study was all Indian patients admitted to the hospital who were between the ages of 19 and 75. The study took place over a period of 3 months, from February 20th to May 19th 2023.

The sample for the study was selected from patients who underwent sedation for diagnostic or therapeutic procedures. From the population of 200 patients, a total population of 132 patients were included where 66 in each phase 1 study and the phase 2 study respectively

were selected. The sample size was $n=132$ which was collected for both the phases. The sample size was determined according to the following formula:

$$n = N / (1 + Ne^2)$$

where n = number of samples, N = Total population, e = error tolerance)

By using 95% confidence level (margin of error= 0.05)

$$200 / (1 + (200 * 0.05 * 0.05)) = 133$$

The first phase took place from September 2022 to October 2022, and was a retrospective study to check compliance. The second phase took place in April 2023 which was a prospective study. A retrospective study is a study where the samples are selected from the past records and their outcomes are studied whereas prospective study is an outcome free study and samples are selected in the present scenarios.

The data collection approach was quantitative, and the sampling technique used was purposive sampling where this means that all patients who underwent sedative procedures had an equal chance of being selected for the study. The inclusion criteria for the study were all patients who underwent procedural sedation in GI endoscopy, bronchoscopy and Interventional Radiology. The exclusion criteria were infants, children, outpatients and ICU patients, deceased patients and radiation oncology patients. The samples were selected from the inclusion criteria with no fixed numbers from each department for the study.

The data for the study was gathered through patient files and sedation forms from the Medical Records Department (MRD) for phase 1, and live patient files and forms for phase 2. There was a dedicated checklist that was followed to check compliance of the documentation of the sedation forms. The checklist had several parameters like: whether ASA grading has been marked or not, type of sedation, fasting status, prediction of difficulty of airway management, name of the procedure, monitoring during sedation, documentation of any complications during sedation and discharge of the patients with no adverse events has been documented or not.

The checklist also includes the sedative agent that has been administered and whether the sedation has been mild/moderate/deep.

3.3 SCORE CALCULATION

The score calculation based on the responses of “YES” or “NO”. if the documentation has been done, then the response will be “YES” and if the documentation of the criteria has not been documented, then the response will be “NO”.

The percentage of both is calculated to check whether the protocol of appropriate documentation is being followed. The presence of sedating physician, the physician performing the procedure is mandatory and a nurse accompanying the patient should be present as well.

Data was collected for the following parameters:

- Name of the procedure for sedation
- Sedative agent used
- ASA grading
- Type of sedation
- Airway management
- Monitoring the vitals during sedation
- Time out of the procedure
- Any adverse events after discharge from the procedure
- Any complications during sedation

3.3.1 ASA GRADING

ASA grading is the American society of anaesthesiology score, a metric to determine if someone is healthy enough to tolerate a sedative procedure. It is a classification tool that helps in preparation for a surgery and to predicts risk that a patient possess. It classifies the condition of the patient on 6 parameters based on which the risk that the patient’s condition possess is predicted. (ASA) uses a five-point scale to assess a patient's overall health before surgery. A patient with ASA (I) is in good health, while a patient with ASA (V) has a severe, life-threatening condition. A patient with ASA (VI) is a deceased organ donor. ASA grading is like a recordkeeping for a patient’s health and the precautions that need to be taken before procedural sedation. It is the role of the anaesthesiologist to record the ASA grading.

ASA Classification	Definition	Examples
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

FIGURE 2: ASA GRADING (Adapted from (6))

3.3.2 AIRWAY MANAGEMENT

Airway assessment is one of the crucial criteria to be assessed in pre-assessment. It ensures patient safety during sedation to locate any complications of airway that the patient might possess. Loose teeth, difficulty in mouth opening, receding jaw or short fixed neck are some of the criteria that are assessed in a patient.

3.3.3 NPO STATUS

NPO status stands for nothing by mouth which is indicated for any sedative procedure or any surgery. It is ordered from midnight for minimum of 8 hours to reduce the risk of aspiration of the gastric contents during the sedation procedure. Generally, for the IPD patients, NPO should be indicated from midnight to avoid regurgitation, airway obstruction, chemical pneumonitis and bacterial pneumonia.

Stop Solid Foods	Drink Clear Liquids Until	Arrival Time
10 p.m.	4 a.m.	6 a.m.
Midnight	6 a.m.	8 a.m.
2 a.m.	8 a.m.	10 a.m.
4 a.m.	10 a.m.	12 p.m.
6 a.m.	12 p.m.	2 p.m.

TABLE-1: NPO status (adapted from UCLA HEALTH)

3.3.4 PROCEDURAL SEDATION TEAM

There are 2 physicians and a nurse that constitutes the sedation team. One anaesthesiologist who performs the sedation and monitors the vitals and the other is the physician who performs the procedure. The nurse helps in monitoring the patient and helps in injecting the medication under the guidance of the physician.

3.4 ETHICAL CONSIDERATIONS

All data collected during the study were treated as private and confidential. any information obtained from the participants, such as personal details or responses, was kept secure and anonymous. The researchers took measures to ensure that the identity of the participants remained protected throughout the study. procedures used in the study did not pose significant harm or adverse effects to the participants' well-being. The study focused on documentation compliance and auditing patient files, activities that are generally considered low-risk and do not directly expose participants to potential harm. The study was conducted without any predetermined or prejudiced influence that could sway the results in favour of a particular outcome.

CHAPTER- 4

RESULTS

This section provides the reader with a concise and clear summary of the study with the analysis of the data collected, the interpretation of the data to answer the research question.

4.1 DEMOGRAPHIC DATA

The data collected was based on demographic details of the patients. The data was collected for the age group of 19- 70 years of age where 40 were females and 92 were male patients. Most of the age group was between the range of 40-65 years of age comprising of about 80% in total.

GENDER	percentage of patients
MALE	92
FEMALE	40

table 2: PERCENTAGE OF MALE AND FEMALE

Age group	Percentage of patients
19-35	10%
36-50	25%
51-66	65%

table 3: PERCENTAGE OF AGE GROUP

4.2 PERCENTAGE OF COMPLIANCE IN PHASE I AND PHASE II

Out of the total 66 samples collected in the 1st phase of the study, 31 samples were of UGIE procedure, 10 ERCP samples, 10 Bronchoscopy samples and 15 colonoscopy samples which made 47% of UGIE samples, 15% each of ERCP and bronchoscopy samples and 23% of colonoscopy samples.

As seen in phase II study, 44% of the samples were taken of UGIE, 23% samples of ERCP procedure, 18% of colonoscopy procedure and 15% of the bronchoscopy procedure. These samples were taken in the month of April 23 which were taken prospectively.

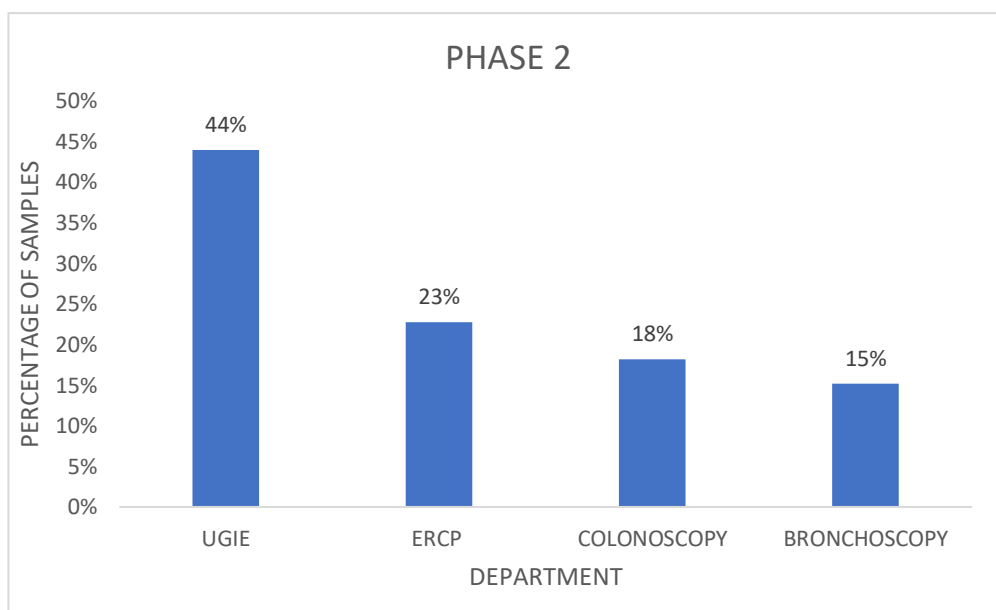
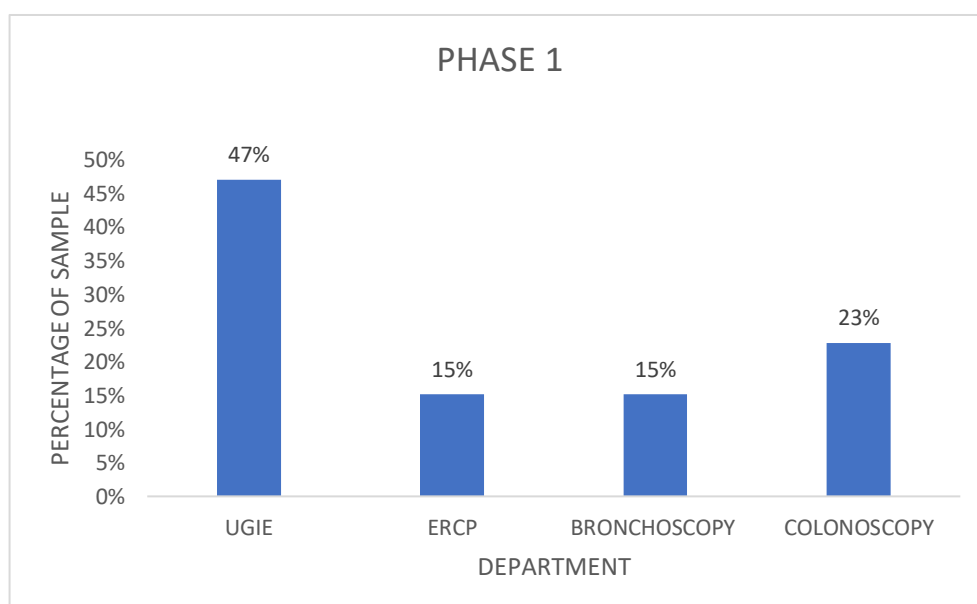


figure 3& 4 : percentage of samples collected from various departments.



PARAMETERS	SAMPLE	SAMPLE COMPLIANT	SAMPLE NON-COMPLIANT	COMPLIANCE %
ASA grading	66	57	8	86%
Prediction of difficulty in airway management	66	49	17	74%
Pre-procedural fasting status	66	62	4	94%
There should be documented evidence of the patient's informed consent	66	66	0	100%
Procedural sedation requires the presence of all the below: A doctor as seditionist A second doctor as procedurist A nurse	66	60	6	91%
Documentation of Performed time out prior to the procedure	66	63	3	95%
Monitoring during procedural sedation must be documented	66	65	66	98%
Documentation of any of the following complications arise • Yes • No • Not recorded	66	58	8	88%
Formal assessment of discharge suitability documented	66	62	4	94%

Table 4: phase 1 data compliance to various parameters

PARAMETERS	SAMPLE	SAMPLE COMPLIANT	SAMPLE NON-COMPLIANT	COMPLIANCE %
ASA grading	66	60	6	91%
Prediction of difficulty in airway management	66	59	7	89%
Pre-procedural fasting status	66	66	0	100%
There should be documented evidence of the patient's informed consent	66	66	0	100%
Procedural sedation requires the presence of all of the below: A doctor as sedationist A second doctor as proceduralist A nurse	66	63	3	95%
Documentation of Performed time out prior to the procedure	66	66	0	100%
Monitoring during procedural sedation must be documented	66	66	0	100%
Documentation of any of the following complications arise • Yes • No • Not recorded	66	65	1	98%
Formal assessment of discharge suitability documented	66	66	0	100%

Table 5: phase II data compliance post action plan

In phase II, a slightly higher number of ERCP samples were taken compared to phase I to assess whether procedural documentation had improved. Conversely, there was a decrease in UGIE procedures in phase II compared to phase I. Bronchoscopy procedures were performed in equal percentages of approximately 15% each, as access to pulmonary patients was limited and most patients were admitted to the ICU, resulting in fewer samples being taken. Similarly, colonoscopy patients were moderately represented, as most patients did not undergo colonoscopy as the sole procedure but rather in combination with other endoscopic procedures.

Both tables demonstrate the compliance of documentation in relation to prior informed consent, which remained at 100% in phase I and continued to maintain 100% compliance in phase II. The lowest compliance was observed in predicting difficulties in airway management, with a rate of 74%, but it showed an overall improvement of 15%, reaching 89% compliance.

The documentation of ASA grading was the second least recorded parameter, with approximately 86% compliance. In the second phase, it showed a slight improvement of 91%, resulting in an overall improvement of 5%. Although both parameters are highly important, there was a lack of serious attention given to documenting them.

To address this issue, an action plan was implemented, which involved sensitizing the staff, gathering their valuable feedback on the necessity of documenting procedural forms, and training them on the significance of medical documentation. Additionally, the anaesthetist was instructed to record any complications post-sedation, which showed only 88% compliance. The main reasons for non-compliance were lack of time and high patient load, leading to doctors forgetting to document post-anaesthesia complications. However, there was an overall 10% improvement in compliance during the second phase, resulting in a rate of 98%, possibly due to the scheduled NABH assessment in April 2023. Overall, there was an average improvement of 6% across all parameters, indicating a greater emphasis on documentation.

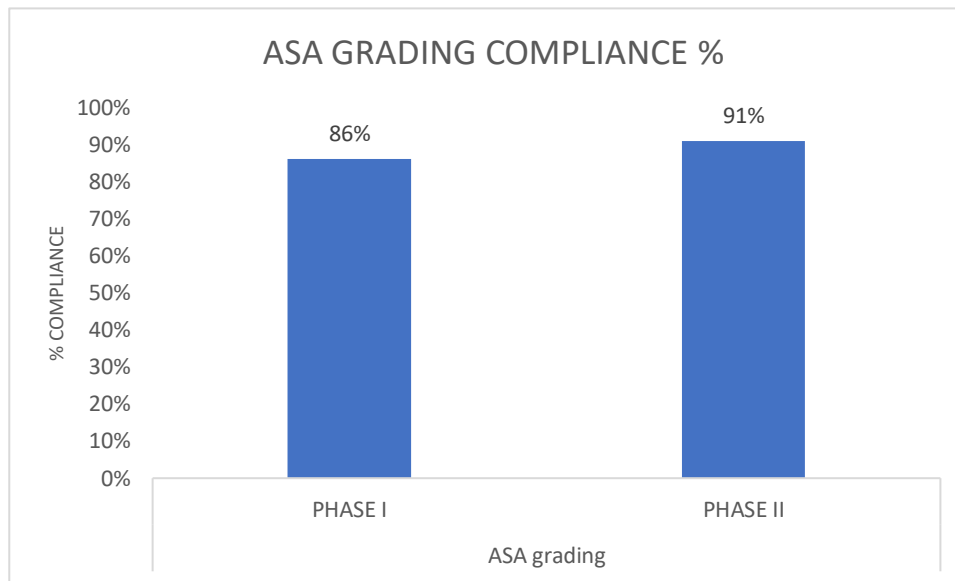


Figure 5: ASA grading compliance in phase I and phase II

ASA grading documentation here shows improvement of 5% in its documentation from phase I to phase II, hereby complying to the first objective and documentation of monitoring the vitals during the procedure shows 100% compliance in phase II hereby fulfilling the second objective of the study whereas documentation of monitoring during sedation improved by 2% reaching to 100% compliance from 98% in phase I.

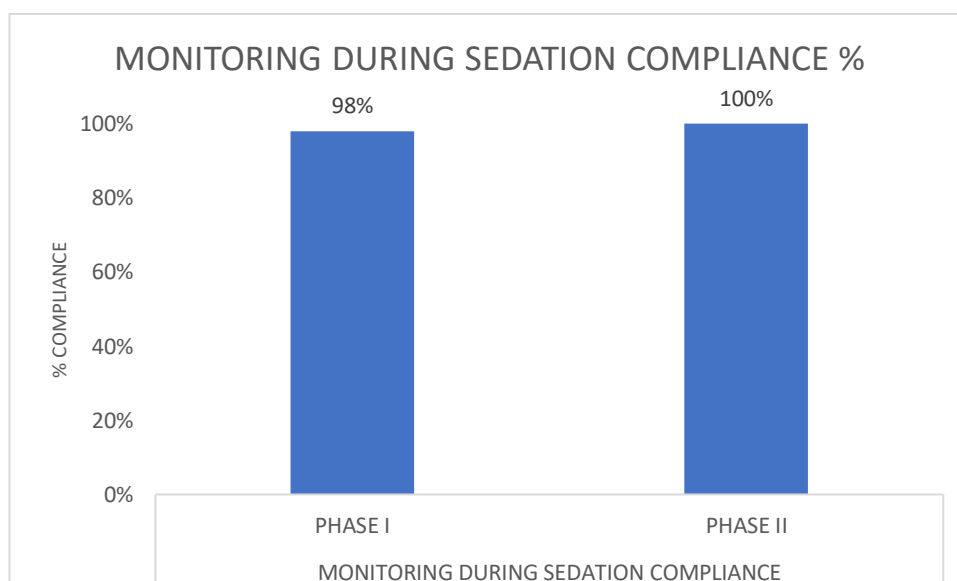


Figure 6: monitoring during sedation compliance in phase I and phase II

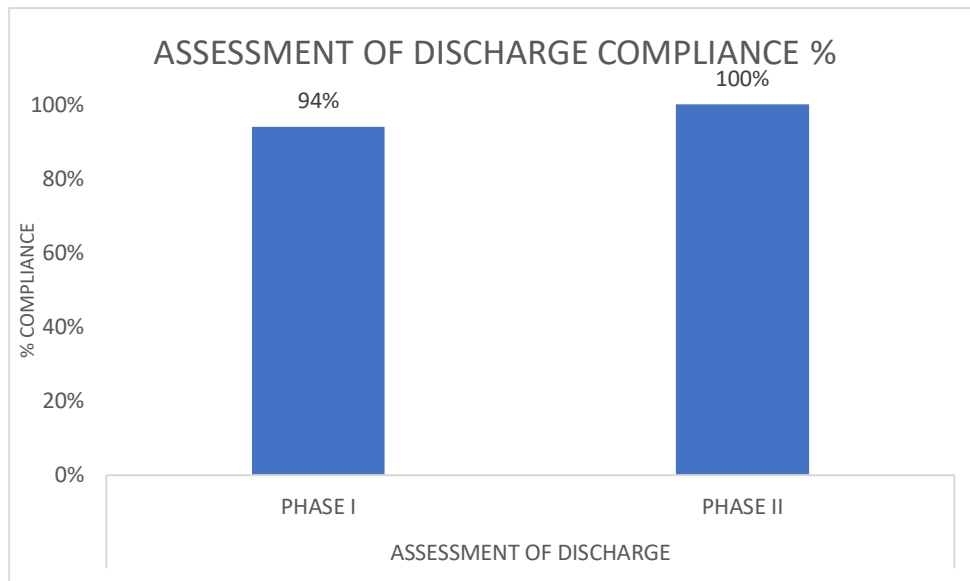


figure 7: documentation of discharge compliance in phase I and phase II

The documentation of discharge criteria fulfilment showed overall improvement from phase I to phase II of 6% from 94% to 100%. The documentation of post- sedation complication improved from 88% to 98% showing overall improvement of 10%.

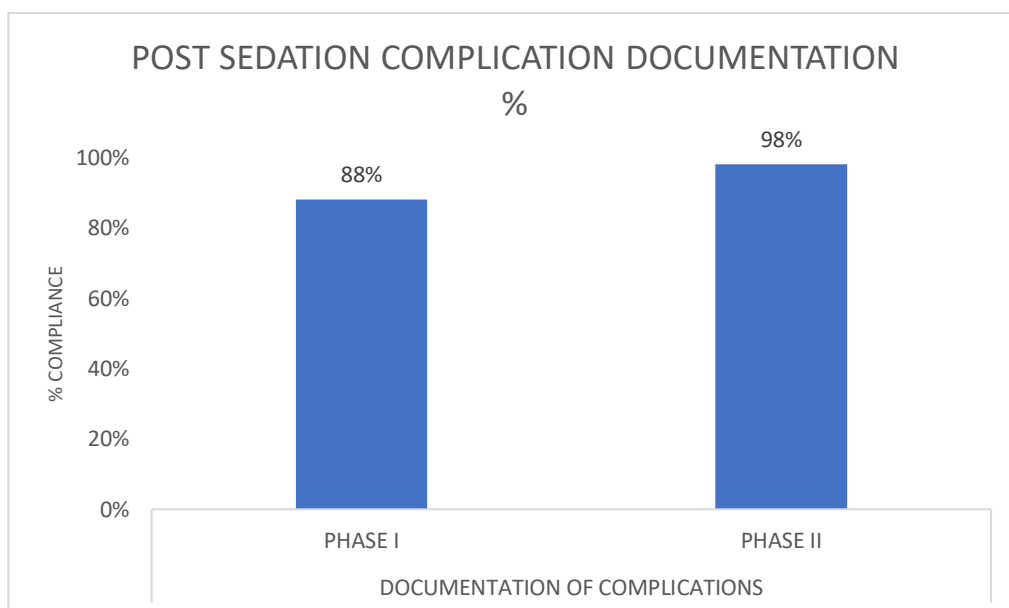


Figure 8: post- sedation complication documentation compliance in phase I and phase II

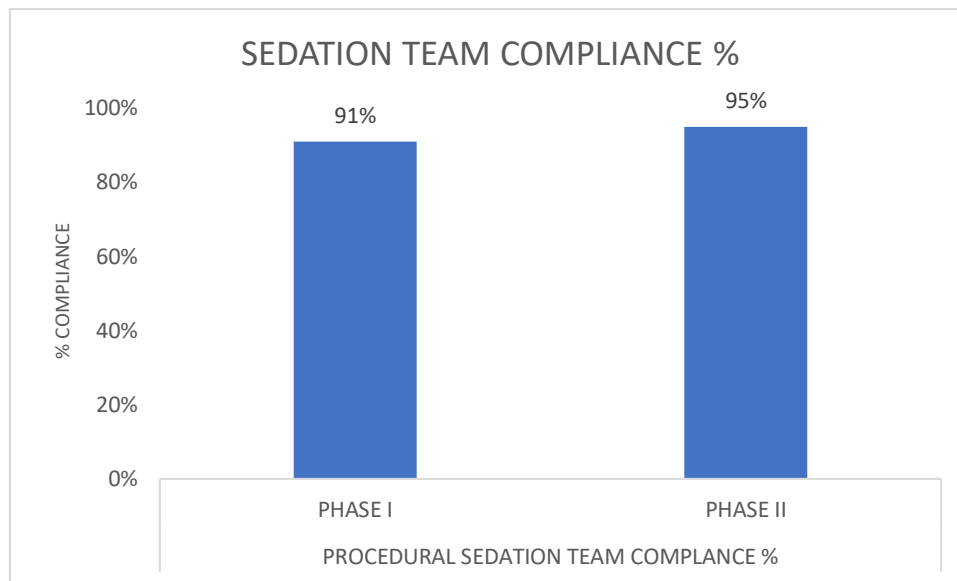


figure 9: documentation of presence of sedation team in phase I and phase II
presence of sedation team comprising of one nurse and 2 physicians along with their signatures and employee id on the form was documented well and showed improvement of 4% along with the doctors with the privileges.

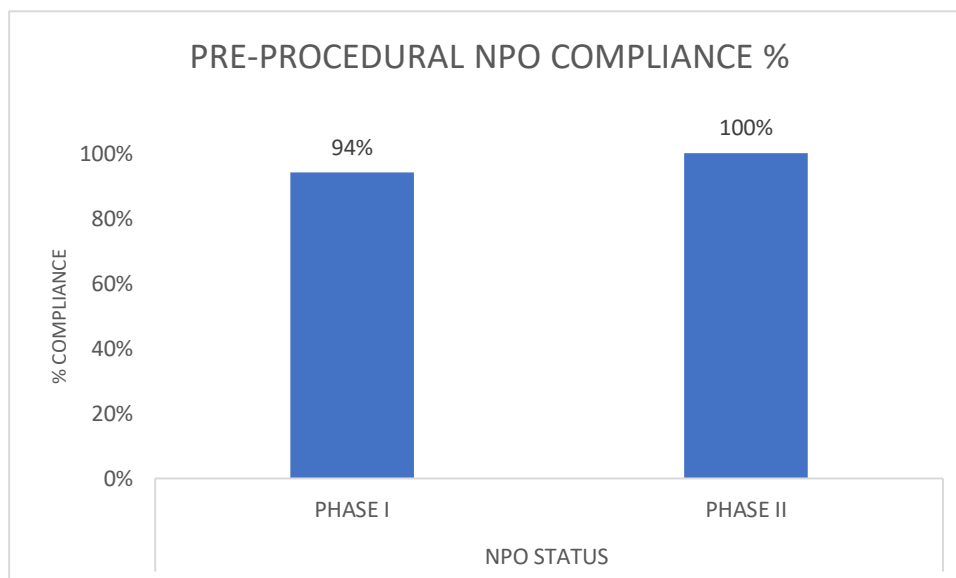


Figure 10: compliance of NPO status in phase I and phase II

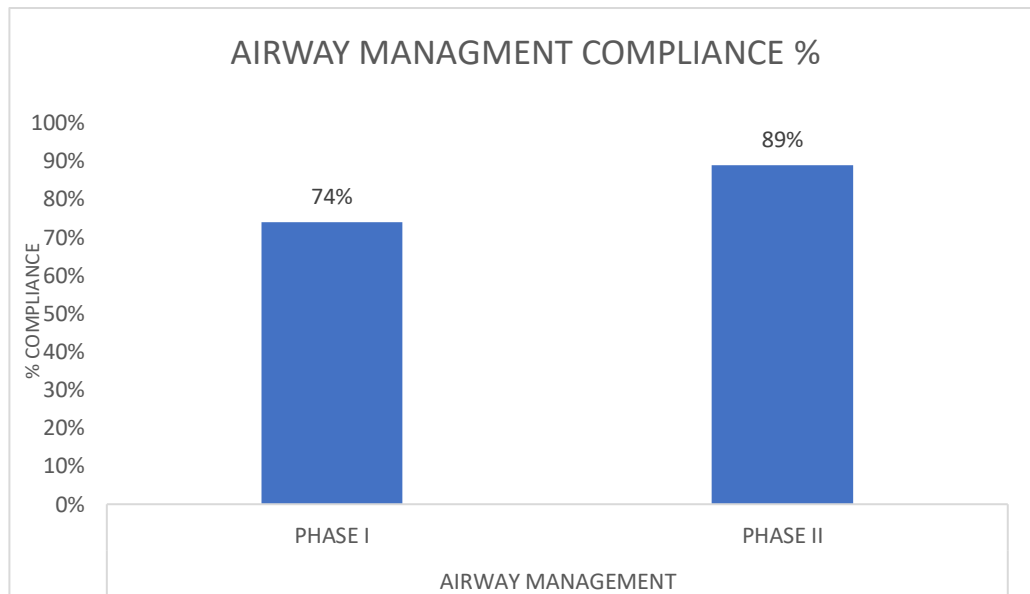


figure 11: documentation of Airway Management compliance in phase I and phase II

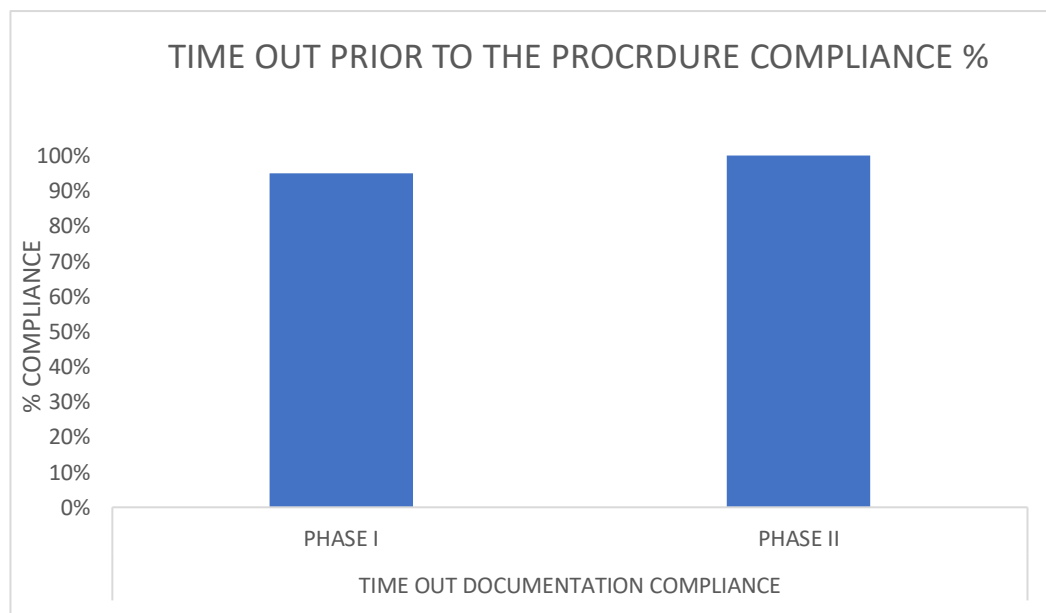


figure 12: compliance of procedure time out documentation in phase I and phase II

CHAPTER 5

DISCUSSION

Documentation of the vital signs and pre-sedation assessment is crucial for effective patient safety and treatment. As stated by an article, proper documentation and protocols are expected to lead to better outcomes for patients (5). Although our study did not cover all the procedural sedation procedures, but we still got an idea about why following the protocols is important. We can however, observe that improper documentation can lead to negligence on the part of the doctors and the nurses to detect any patient with adverse reactions and complications related to the sedation as the human body reacts to every procedure differently.

As stated by Mischa Veen et al, doctors and nurses need to be sensitized and trained about the importance of proper documentation of the procedural sedation forms, without teaching and without proper supervision, patients are directly exposed to inferior screening, insufficient or inadequate sedation (5).

Most of the sedation forms lacked the recording of the ASA grading and documentation of post- anaesthesia complications which show cases that sedation practices are taken without due diligence and in case of any adverse event, there is no concrete proof as to what was administered to the patient and at what time. Slightest of the complication such as dizziness should be recorded when it comes post sedation care.

In the phase I retrospective study, JCI audit was conducted due to which it was expected that that the compliance would be much higher than previous months, but the protocols were still not being followed due to which the need for phase 2 retrospective study evolved after the probable action plan implementation. during the phase II study, NABH audit was supposed to be conducted hence, prospective study was done and the improvement was observed in the documentation of the sedation forms both from the nurses and the doctor's side.

There was an attrition of doctors and nurses from the September 22 to April 23 and it was observed that new doctors and nurses were better trained and supervised in terms of sedation protocols and privileges. After the action plan was implemented, the doctors took initiatives in following the said protocols and monitoring the vitals diligently. The role of the anaesthesiologist and the doctor performing the procedure are pre-defined and only those physicians who hold privileges can only administer the sedative agents to the patients (6).

Another factor that affects the documentation of the sedation forms is the level of sedation given to the patient. In this study, majority of the patients were given mild sedation ranging in ASA grading I-II. The noncompliance of the protocol adherence was less as compared to patients given moderate sedation. In gastro-intestinal procedures, no patient was given severe sedation. Irrespective of the level of sedation provided to the patient, the documentation must be completed and fulfilled according to the guidelines to avoid any commotion in future.

Thomas Benzoni et al stated “that A careful assessment is mandatory for evaluating potential difficulties to ventilate. The assessment should include the presence of any anatomic features that may affect airway management, including dysmorphic or asymmetrical facial features, beard, significant malnutrition or cachexia with sunken cheeks and missing teeth, facial trauma (e.g., lacerations through the cheek or unstable bony injuries)” (6).

Although the patient’s informed consent did not possess any problem as the documentation of the same was appropriately filled according to the guidelines and all inpatients always had consent document present. The problem area could be no digitalization in the documentation of the forms and the hospital still relies on the manual data entry. The patient to nurse ratio has remarkably increased and nurses and doctors are overburdened with work where they have to fulfil all the duties without any error.

According to Mulugeta Desalegn Kasaye et al, “Those health workers with high eHealth Literacy were more likely to have good medical documentation practice than those who had low eHealth literacy. This might be due to the need for information is depending on the quality of information that has already been registered/ documented. It not only reduces the burden but only makes the documentation more effective and guided” (4).

5.1 LIMITATIONS OF THE STUDY

This study holds certain limitations. First, all the procedural sedations were not taken in consideration in the study due to confidentiality issues. The oncology department did not approve the access to the patient files as the data is sensitive.

The time span of the study was less due to which not a lot of data could be audited as NABH assessment was also due in the month of April 23. The available time was put into good use to gather as much data possible for the study.

The deceased patient files were not given an access for the study which could have hampered the results as well.

CHAPTER 6

CONCLUSION

Maintaining a checklist to audit the documentation is an important tool in keeping track of the performance in maintaining the standard guidelines and protocols in efficient documentation of procedural sedations. After the sensitization by the quality team to the healthcare workers, it was seen that there was an overall improvement in the documentation of the sedation forms in the department where the research was conducted. Improving the medical documentation practice greatly benefits from elevating the knowledge and attitude of healthcare professionals regarding the recording of both planned and delivered medical care.

The documentation of procedural sedations forms covers only a certain aspect of the medical documentation guidelines and protocols and to maintain the good documentation practices, the work environment has to be focussed to quality work which is driven towards the betterment of the patient and towards their safety.

Overall, sedation form is an important document as it fully describes the patient condition and the procedure being undertaken so that in case of any medico legal formality or any adverse event, the document can mitigate any liability both to the patient and the healthcare provider.

The audit gave us an insight about how the documentation needs to be done, what were the shortcomings which lead to the problem and lead to the solutions to fulfil the objectives of the study.

RECOMMENDATIONS

1. To enhance the sincerity towards documentation, attitude, and incitement of healthcare workers in medical documentation practice, it is important to make systematic efforts in conducting inclusive service trainings on systematic medical documentation, without any specific limitations or specifications.
2. The procedural sedation documentation should be made more digitalized in a way that it reduces the workload of the healthcare provider both the nurses and the doctors and the procedure documentation can be finished in a prescribed time.

ANNEXURE 1: CHECKLIST TO CHECK COMPLIANCE WITH PROCEDURAL SEDATION FORMS

PATIENT NAME AND UHID												
PARAMETERS												
ASA grading												
Prediction of difficulty in airway management												
Pre-procedural fasting status												
There should be documented evidence of the patient's informed consent												
Procedural sedation requires the presence of all of the below: A doctor as sedationist A second doctor as procedurist A nurse												
Level of sedation intended • Minimal • Conscious – Moderate • Deep												
Documentation of Performed time out prior to the procedure												
Which agents were used for sedation • Opioid • Benzodiazepine • Ketamine • Propofol • Narcotic • Other agent: _____												
Monitoring during procedural sedation must be documented												
Name of procedure for which sedation was required												
Documentation of any of the following complications arise • Yes • No • Not recorded												
Formal assessment of discharge suitability documented												
What was the speciality of the sedating practitioner (along with name & staff ID)												

ANNEXURE 2 (i): PROCEDURE SHEET FOR SEDATION

medanta

Patient's Label

Procedure Sheet (With / Without Sedation)

Date : _____

In case of procedure with sedation (to be filled by sedating physician) : Time : _____

Name of Sedating Physician: _____	ASA Grade (Please tick)	Definition	Description
H/O previous anesthesia / sedation: Yes ☐ No ☐ If Yes, H/O family or personal problems with anesthesia or sedation : Yes ☐ No ☐ NA ☐ H/O impairment of major organs: Yes ☐ No ☐ (If Yes _____) Laboratory results reviewed: H/O Substance Abuse: Yes ☐ No ☐ LMP in case of females (12 to 50 Years) _____ NA Relevant Examination Findings: CVS: Chest: PA: Airway Assessment: Receding Jaw Yes ☐ No ☐ Artificial denture/loose teeth Yes ☐ No ☐ Short Fixed Neck Yes ☐ No ☐ Mouth opening (more than 3 fingers) Yes ☐ No ☐ Level of sedation: Mild ☐ Moderate ☐ Deep ☐ Type of sedation: IV ☐ IM ☐ Oral ☐	☐ ASA I	A normal healthy person	Healthy, nonsmoking, no or minimal alcohol use
	☐ ASA II	A patient with mild systemic disease	Mild disease only without substantive functional limitations; e.g. current smoker, social alcohol drinker, pregnancy, obesity with BMI < 40, well controlled DM/HTN, mild lung disease
	☐ ASA III	A patient with severe systemic disease	Substantive functional limitations; one or more moderate to severe diseases e.g. poorly controlled DM/HTN, COPD
	☐ ASA IV	A patient with severe systemic disease that is a constant threat to life	e.g. Recent (<3 months) MI, CVA, TIA or CAD/ stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of EF, spesis, DIC, ESRD

Preprocedure checklist for all procedures

To be filled by doctor pre procedure : Time: _____

Name/s of doctor/s performing the procedure : _____

Pre Procedure diagnosis: _____

Is the patient on

a. Heparin Yes ☐ No ☐ b. Clopidogrel Yes ☐ No ☐ c. Aspirin Yes ☐ No ☐

Name of planned procedure : _____

All required specimen containers/slides available and labeled Yes ☐ NA ☐

High risk consent obtained if required Yes ☐ NA ☐

Blood products available if required Yes ☐ NA ☐

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To be filled by nurse (with technician, if involved) pre procedure:						Time _____
Patient identifiers checked	Yes ☐					
Consent for procedure	Yes ☐					
Consent for anaesthesia/sedation	Yes ☐	N/A ☐				
Site marking checked	Yes ☐	N/A ☐				
Equipment and implants available, correct and functional	Yes ☐					
All documents / images available, labeled and displayed	Yes ☐	N/A ☐				
NBM from _____		N/A ☐				
Preprocedure medication given if ordered	Yes ☐	N/A ☐				
Allergies	Yes ☐	No Known ☐				
Dentures removed	Yes ☐	N/A ☐				

Pre Procedure vitals						
Time	Temperature	HR /Pulse	RR	BP	SPO2	Pain Score

TIME OUT CHECKLIST :		Time: _____
The following have been verified :		
☐ Patient identifiers	Signature of Physician performing the procedure _____	
☐ Correct procedure	Signature & ID No. of Nurse _____	
☐ Side & site of Procedure	Signature & ID No. of Technician, if any _____	
	Signature of Anaesthetist/ Sedating Physician, if any _____	

Intra procedure monitoring						
Time	HR (Per Min)	RR (Per Min)	BP (mm Hg)	SpO2	ECG/Other (if specified)	Doctor/Nurse Sign. & ID No.
Procedure Start Time						
Procedure End Time						

SIGN OUT CHECKLIST :		Time : _____
Nurse verbally confirms with the team :		
Name of the procedure recorded		
Specimen label verified reading aloud patient name and ID no.		
Any equipment problem to be addressed		
Yes ☐		
Yes ☐	N/A ☐	
Yes ☐	No ☐	N/A ☐

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ANNEXURE 2 (iii): POST-PROCEDURE MONITORING THE VITALS

Post-op

Post procedure monitoring :

Time	HR (Per Min)	RR (Per Min)	BP (mm Hg)	SPO2	ECG/ Other (If specified)	Level of consciousness				Doctor/Nurse Sign. & ID No.
						Awake	Responds to verbal commands	Responds to pain	Not responding	

Medication, contrast and infusions (if any ordered stat for the procedure)

S. No.	Drug	Dose	Route	Time	Doctor's Signature	Administration Time	Doctor/Nurse Sign. & ID No.	Doctor/Nurse Sign. & ID No.

To be filled by doctor:

Post procedure diagnosis ☐ Same as pre procedure diagnosis. If No, _____

Complication during / after procedure No ☐ Yes ☐ If yes _____

Blood loss ☐ None ☐ Yes, _____ ml

Specimen sent for examination ☐ None ☐ Yes, _____

Implant used ☐ None ☐ Yes If yes, sticker placed ☐

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ANNEXURE 2(iv): POST-PROCEDURE DISCHARGE CRITERIA DOCUMENTATION

Findings/Diagram		Report attached ☐ / As below :	
Condition at transfer / discharge		Stable ☐	Fair ☐ Critical ☐
Disposition		Home ☐	Ward ☐ ICU ☐
Post procedure instructions, if any :			
<i>discharge criteria for post-op.</i>			
Signature of doctor performing the procedure: _____		Name: _____ Date: _____ Time: _____	
Discharge criteria following procedures done under sedation / anaesthesia (Please tick when met): ☐ Patient is as alert and oriented as per baseline ☐ Presence of protective reflexes (swallow and gag) ☐ Stable vital signs consistent with +20% baseline for 30 minutes after last drug dose ☐ Oxygen saturation on room air at least 94% or at baseline for 30 minutes after last drug dose ☐ Pain rating <or =3 or baseline ☐ When applicable, no visible site drainage or excessive swelling ☐ Patient is able to ambulate as well as he/ she was able to ambulate prior to procedure ☐ Patient should have minimal nausea and vomiting before discharge		Did any complication occur during sedation or recovery period: ☐ NONE If Yes, tick below: ☐ Hypotension ☐ Delayed Recovery ☐ Need for reversal agent ☐ Hypoxia (O ₂ Saturation <90%) ☐ Aspiration ☐ Vomiting ☐ Laryngospasm ☐ Bronchospasm ☐ Required Intubation ☐ Apnea ☐ Bradycardia (HR <60 bpm) ☐ Tachycardia (HR > 100bpm) ☐ Cardiac Arrhythmias ☐ Other _____	
Signature of sedating physician: _____		Date & Time: _____	
Handover in case patient shifted to ward/ICU: Signature of doctor receiving patient in ward /ICU _____			
Name : _____		Date: _____ Time: _____	

ANNEXURE 3 (i): INFORMED CONSENT FORM FOR SEDATION



Patient's Label

INFORMED CONSENT Authorization for Administration of Anesthesia / Sedation

I/my patient..... (Name of the patient) have/has to undergo
..... (Name of Surgery/Procedure) for which
Anaesthesia/Sedation services are required.

I hereby consent to the anesthesia/sedation service checked below and authorize that it can be administered by Anesthesiologist (s) or physicians who are credentialed to provide anesthesia or sedation services at Medanta - The Medicity, Gurgaon.

☐ General Anesthesia	Benefits	- Complete control of airway, breathing and circulation minimizing undue stress to the patient and allowing complete stillness during the procedure - Permits surgery in widely separated areas of the body at the same time - Can be administered without moving the patient from supine position
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes.
	Risks	- Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia - Weakness, numbness in the limbs, parasthesias
☐ Spinal or Epidural analgesia/ Anesthesia ☐ With sedation ☐ Without sedation	Benefits	- Optimum method of anesthesia for procedures in the lower half of the body - Easy post-operative mobilization - Reduced post-operative pulmonary, thromboembolic and cardiac complications
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside the spinal canal
	Risks	- Headache, Backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels - May require conversion to general anesthesia
☐ Major / Minor Nerve Block Anesthesia ☐ With sedation ☐ Without sedation	Benefits	- Patient can remain awake and breathe normally - Side effects such as nausea and vomiting are avoidable - Excellent pain relief - No need for tracheal intubation
	Technique	Drug injected near nerves providing loss of sensation to the area of operation
	Risks	- Infection, convulsions, persistent numbness, residual pain, injury to blood vessels - May require conversion to general anesthesia
☐ Monitored Anesthesia care (with sedation)	Benefits	- Safe sedation, control of patient anxiety and pain control - Protection of airway
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes producing a semi-conscious state
	Risks	- An unconscious state, depressed breathing - May require conversion to general anesthesia
☐ Anesthesia Standby (without sedation)	Benefits	Measurement of vital signs, availability of anesthesia provider for further intervention, no sedation
	Technique	Not applicable
	Risks	Anxiety and / or discomfort.
☐ Moderate/Deep/ Procedural Sedation	Benefits	- Reduce or eliminate pain and patient anxiety - Patient can breathe normally and respond to verbal commands during moderate sedation - Monitoring of Vital signs
	Technique	Drug injected into the bloodstream producing a sedative state
	Risks	- Depressed Breathing - Conversion to anesthesia

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ANNEXURE 3 (ii): BACK SIDE OF THE FORM.

2. The benefits, technique of sedation or anesthesia to be used, alternatives, risks, likelihood of success and problems related to recovery have been explained to me in my language.
3. I understand that rarely there may be unforeseen complications. In such an event the anesthesia team may change the type of anesthesia or take suitable steps taking my best interest in mind and that I give my consent for the same.
4. I have been informed that during sedation possible complications may occur and at times deeper sedation and anesthesia may be required with an anesthesiologist support during the procedure and I agree to this support.
5. During the course of the procedure, I agree to the insertion / use of monitoring lines - invasive / non-invasive, use of endoscope and any other procedure for the purposes of safe conduct of anesthesia and monitoring
6. I agree that I may be transfused blood or blood products during the course of the procedure as deemed necessary.
7. I consent to photography / video recording of procedure, which may be viewed for academic purpose only subject to the identity being adequately protected. I further give my consent to the release of professional and/or other information from the Medical Records as deemed necessary in accordance with the rules and policies of the hospital.
8. I have been advised & agree that any member of the team may perform any part of the anaesthesia / sedation according to his/ her stage of training and ability, if his experience and capability is deemed fit by the consultant anaesthesiologist.
9. I / My Relatives have been educated on the modalities of post operative /post procedure analgesia and the options of pain management such as oral/ Intravenous/intramuscular/epidural/patient controlled analgesia etc.
10. Patient/attendant to write the below line in his own handwriting if literate: "I certify that I have had opportunities to ask questions regarding the anesthesia/sedation and they have been explained to me to my satisfaction in the language I understand."

Patient's full Name _____ Signature _____ Date & Time _____

Anesthetist's or Sedating Physician's Name _____ Signature _____ Date & Time _____

ATTENDANT'S CONSENT (If applicable)

If patient is unable to give consent, state the reason _____

(Minor / unconscious/ under-sedation/ mental incapacity/disoriented, other please specify) _____

Attendant Name _____ Relationship to the patient _____

Signature _____ Date: _____ Time: _____

Statement of Interpreter (where appropriate)

I have comprehensively explained the information above along with the discussions/explanations provided by the doctors, to the patient and/or his/her attendant and in a way which I believe he/she/they can understand and the patient and/or his/her attendant have informed me that they have understood the aforesaid information completely.

Interpreter's Name _____ Signature _____ Date & Time _____

Contact No.: _____

HIGH RISK CONSENT

It has been explained to me and I have acknowledged that the risk to the patient during and after the surgery/anesthesia is high/very high due to the following problems and their implications have been explained to me in detail.

1. _____
2. _____
3. _____
4. _____

Patient's full Name _____ Signature _____ Date & Time _____

Anesthetist's Name _____ Signature _____ Date & Time _____

Reason for Attendant's Consent (where applicable)

(Minor / unconscious/ under-sedation/ mental incapacity/disoriented, other please specify) _____

Attendant Name _____ Relationship to the patient _____

Signature _____ Date _____ Time _____

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