I. Title

Prospective single-blinded randomized study of ketamine/midazolam sedation vs. fentanyl/midazolam sedation for image-guided percutaneous procedures in interventional radiology

II. Study Focus

Abstract

The long-term goal of this study is to improve patient-centered experience by decreasing pain during interventional radiology (IR) procedures. Traditionally, IR physicians use fentanyl/midazolam to provide analgesia during procedures. Our preliminary non-randomized data showed that pain scores for procedures performed in IR with ketamine/midazolam were significantly lower than with fentanyl/midazolam, both during and after the procedure. This project will assess patients undergoing image-guided percutaneous biopsy and drainage because these procedures were associated with moderately high pain scores with fentanyl/midazolam sedation. Patients undergoing procedures will be randomized according to a schedule created by a statistician to receive either fentanyl/midazolam or ketamine/midazolam sedation. A study coordinator will collect data during and following the procedures, through assessment of pain scores and a sedation questionnaire, and by documenting post-procedure medication use and adverse events. The study will test the hypothesis that intra- and post-procedure pain scores and satisfaction scores will be improved with ketamine/midazolam sedation compared with fentanyl/midazolam sedation, with no increase in complications.

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Background

Interventional radiology (IR) procedures are increasingly important alternatives to surgery and are performed in nearly 10% of the 30 million annual US inpatient hospitalizations (1). IR procedures can cause significant discomfort and are usually performed with fentanyl/midazolam sedation. Fentanyl/midazolam sedation is often contraindicated, for example in patients with prohibitively low blood pressure, or inadequate to provide sufficient anesthesia, particularly in patients with chronic pain or with a history of opiate use (2, 3). In these cases, patients either experience intense intra-procedural discomfort or IR physicians must seek anesthesiology services. There are increasing demands on anesthesia services outside of the operating room and shortages of anesthesiology providers, leading to delays in care (4, 5). There is a critical need to develop clinical protocols that ensure a better patient experience without needing anesthesiology services. This would benefit patients individually and increase the efficiency of IR services.

Sedation protocols utilizing ketamine may be an ideal alternative to fentanyl/midazolam. Whereas fentanyl/midazolam is associated with cardiorespiratory depression (6), ketamine induces deeper sedation without suppressing respiration or lowering blood pressure. Other non-anesthesiology physicians commonly use deep sedation, such as emergency room physicians who administer ketamine for procedures in the absence of anesthesiologists per emergency medicine societal guidelines (7).

Peri-procedure pain and analgesia regimens are understudied in IR, and ketamine is rarely used despite its potential benefits (8). One of the most significant barriers to the utilization of ketamine in IR sedation programs is the perception of American Society of Anesthesiologists (ASA) guidelines regarding procedural sedation. For example, the

IRB NUMBER: 24-1149

Cardiovascular and Interventional Radiological Society of Europe (CIRSE) issued a Standards of Practice on Analgesia and Sedation for Interventional Radiology in Adults that stated "anaesthetists must be involved in cases of sedation deeper than mild to moderate" based on the ASA guidance on procedural sedation (9). However, this statement did not consider more recent guidance from the ASA acknowledging the ability of non-anesthesiologist physicians to obtain deep sedation privileges in procedural clinical settings (10). In contrast to Emergency Medicine, there are very few studies of ketamine sedation in IR. One recent retrospective study reported the safety of ketamine sedation for IR procedures (11), but none have compared different sedation regimens. Our preliminary prospective non-randomized registry study demonstrated the superiority of ketamine/midazolam over fentanyl/midazolam regarding intra- and post-procedure pain scores (12). A prospective randomized comparative evaluation of the safety and benefits of fentanyl/midazolam and ketamine/midazolam is critical to support the use of ketamine in IR.

Significance

This project will provide the following significant innovations:

1. Improve patient experience and satisfaction: Prospective demonstration that ketamine/midazolam results in decreased peri-procedure pain scores and increased satisfaction scores would justify the use of ketamine in IR and potentially benefit thousands of patients undergoing painful procedures in IR units across the country.

2. Demonstrate the safety and feasibility of ketamine/midazolam sedation administered by IR providers: Showing that performing IR procedures with ketamine/midazolam is as safe or safer than performing the same procedures with fentanyl/midazolam will increase the scope of cases that IR providers can perform without the direct assistance of anesthesia providers and need for recovery in post-anesthesia care units.

3. Provide high-level data to justify the creation of societal guidelines: One barrier to IR physicians performing ketamine sedation may be an inability to obtain hospital privileges. Emergency medicine physicians have created societal guidelines to describe the use of ketamine/midazolam, enabling successful credentialing. Publishing high-quality studies that show safety and efficacy would provide a framework for IR-specific practice guidelines.

Specific Aims/Objectives

Aim 1: Prospectively compare pain and satisfaction scores in patients undergoing IR procedures with either fentanyl/midazolam or ketamine/midazolam. Patients undergoing image-guided biopsy and drainage procedures will be randomized to receive fentanyl/midazolam or ketamine/midazolam. Patients' pain will be rated using the validated 10-point Numeric Rating Scale (13) before, during, and after the procedure, and be given questionnaires based on validated anesthesia satisfaction surveys after the procedure to assess their perception of the sedation regimen (14). The difference in pain scores and responses to the satisfaction surveys will be compared using two-tailed Mann-Whitney statistical tests.

Aim 2: Prospectively compare the safety of using fentanyl/midazolam or ketamine/midazolam for sedation during IR procedures. Patient groups will be compared in terms of procedure-related adverse events (e.g., hemorrhage, pneumothorax) and sedation-related adverse events (e.g., respiratory compromise) using Fisher's exact tests.

IRB NUMBER: 24-1149

Design

The objective of the proposed study is to prospectively compare patients undergoing image-guided biopsy and drainage in IR with fentanyl/midazolam sedation versus ketamine/midazolam sedation, soliciting patients' feedback on their pain and satisfaction with sedation and collecting objective data regarding safety. Our study's approach is significant, as it would provide directly relevant data for use in IR clinical practice.

Objectives will be accomplished with the following experimental plan:

Aim 1: Prospectively compare pain and satisfaction scores in patients undergoing IR procedures with either fentanyl/midazolam or ketamine/midazolam.

Hypothesis: Compared with fentanyl/midazolam, ketamine/midazolam will provide lower intra- and post-procedural pain scores and improved patient satisfaction scores, using validated pain scale and sedation satisfaction surveys.

Rationale: The proposed prospective study will enroll patients undergoing image-guided percutaneous lung biopsy, bone biopsy, and abscess drainage in IR. Studying specific types of procedures will allow for more accurate comparisons of pain and satisfaction scores between groups.

Pain scores will be assessed in the immediate peri-procedure observation period when patients' memory for the procedure is better, in contrast to prior studies involving phone calls days or weeks later (15). The numeric rating score (NRS) is a well-validated 10-point scale to assess pain, with 0 indicating no pain and 10 severe pain (13). The NRS was formally described in the 1970s and 1980s as a simpler alternative to the Visual Analog Scale. Since then, numerous studies have demonstrated its validity and reliability (16-18).

Patient satisfaction will be assessed using a modified version of the Heidelberg peri-anesthetic questionnaire (**Appendix 1**), which is a validated tool to assess satisfaction after anesthesia (14). This tool was developed by Schiff et al., who published its validity in a study of over 1,000 patients (19), and later validated by Lemos et al. (14) among other groups (20). Questions will be modified to be more relevant to the sedation used for IR procedures (**Appendix 2**). Specifically, we will focus on the post-anesthetic recovery portion of the validated tool. Assessing satisfaction in the immediate post-procedure period will maximize patient response rate.

Design and Statistical Evaluation: In this prospective, single-center, single-blind randomized study, all patients 18 years of age and older undergoing image-guided lung and bone biopsy and percutaneous drainage who are eligible for fentanyl/midazolam or ketamine/midazolam will be recruited. Subjects will be randomized to receive fentanyl/midazolam or ketamine/midazolam. A study coordinator will be on-site to assist in patient enrollment and consent. Until a study coordinator is hired, Institute of Academic Medicine Research Scientist Adam Belcher, PhD, will be on-site for enrollment, consent, and data collection. Patients will be unaware of which regimen they ultimately receive (hence, the single-blinded design; IR physicians must be aware of the sedation regimen so that they administer appropriate doses). Image-guided procedures and procedural sedation will be performed by the study PI and IR physician colleagues. Electronic medication orders are written by IR providers in Cerner immediately before the procedure, per standard routine. Procedures will be performed with CT, CT fluoroscopy, ultrasound, or fluoroscopic guidance. Medications are stored in the Omnicells of the procedural areas, and inventory is

IRB NUMBER: 24-1149

managed by CAMC Memorial Pharmacy per standard routine. Medication administration is documented by procedural nurses per CAMC routine policy.

In the procedure room, the study coordinator will solicit and document the immediate pre-procedure NRS pain score; the maximum intra-procedure pain score will be solicited and documented immediately following the biopsy before departing the procedure room. Intra-procedure pain scores will be elicited immediately following the procedure, when the memory of the procedure would be expected to be best, as it has been shown that sedatives interfere with the formation of new memories (21, 22). Furthermore, asking patients for maximum pain scores during the procedure has been done in other studies immediately following the procedure upon return of mental status (23). If the patient does not remember the procedure, the intra-procedure pain score will be recorded as "0".

The study coordinator will document the procedure duration as the latency between the procedure time out and when the patient exits the procedure room, total amount of sedatives administered, and any immediate adverse events. REDCap will be used to store data securely.

All patients will be recovered in the peri-procedural area until recovery from sedation. For lung biopsies, patients are recovered for a minimum of 2 hours with at least two radiographs obtained to ensure that there is no expanding pneumothorax. The study PI and her IR physician colleagues will assess the patients to determine whether any peri-procedural complications occurred. In the recovery room, the study coordinator will give patients the modified peri-anesthetic questionnaire (**Appendix 2**) immediately before discharge to assess their satisfaction with sedation. The study coordinator will assist patients in completing the form.

The number of patients who report intra- and post-procedural pain will be compared using Fisher's exact tests. Average pain scores and patient satisfaction scores will be compared with Mann-Whitney U tests or Student's t-tests for non-parametric or normally distributed data. Statistical analysis will be performed using SPSS. The study PI will be responsible for the ethical design and conduct of a research study and will supervise other IR physicians and the study coordinator to ensure the study data's quality and accuracy.

Aim 2: Prospectively compare the safety of using fentanyl/midazolam or ketamine/midazolam for sedation during IR procedures.

Hypothesis: Ketamine/midazolam sedation will result in fewer and less severe side effects compared with fentanyl/midazolam.

Rationale: Fentanyl/midazolam is associated with respiratory compromise and depression of blood pressure (6). During inpatient IR procedures, respiratory compromise occurs in roughly 1% of cases and is associated with higher hospitalization costs, longer hospital lengths of stay, and higher rates of ICU admission, mechanical ventilation, and death (24). In contrast, ketamine is not associated with cardiopulmonary depression but may cause nausea and hallucinations, which are typically transient (25). Administering ketamine in combination with midazolam mitigates these effects and reduces post-analgesia agitation (26).

Side effects from sedation will be assessed objectively through documenting vital signs, including oxygen saturation and blood pressure, subjectively through the post-procedure modified Heidelberg peri-anesthetic questionnaire, and by documenting adverse events,

IRB NUMBER: 24-1149

including need for reversal medications, need for supplemental oxygen during and after the procedure, and administration of anti-emetic medications. It is possible that by achieving better intra-procedural analgesia, procedure-related complications may be reduced. For example, by reducing patient talking and movement, pneumothorax may be less likely. Procedural adverse events, including pneumothorax and bleeding, will be documented according to the SIR standards of practice adverse event classification (27).

Design and Statistical Evaluation: Procedures performed on patients enrolled in the study will be documented in a secure database using REDCap. The lowest and highest intra-procedural blood pressure and oxygen saturation will be recorded by the study coordinator. Respiratory compromise will be defined as the administration of naloxone or flumazenil, nonmechanical or cardiopulmonary resuscitation, or endotracheal intubation during or immediately following the IR procedure (24). All analgesia- and procedure-related adverse events will be recorded. Post-procedure administration of reversal agents, anti-emetics, and benzodiazepines will be recorded. Patient-reported nausea and hallucinations will be documented through the modified Heidelberg peri-anesthetic questionnaire (**Appendix 2**). The fentanyl/midazolam and ketamine/midazolam groups will be compared in the frequency of adverse events using Fisher's exact tests.

Sample

All patients 18 years of age and older undergoing image-guided procedures who are eligible for fentanyl/midazolam or ketamine/midazolam will be recruited. Potential study participants will be identified from the Interventional Radiology daily schedule, which changes over the course of the day with new referrals for inpatient procedures. A study coordinator will be on-site to assist in identifying patients and assuring eligibility in collaboration with IR physicians. The study coordinator will assist in patient enrollment and consent.

Subjects will be randomized to receive fentanyl/midazolam or ketamine/midazolam using SPSS. Patients will be unaware of which regimen they ultimately receive.

Our initial study will focus on image-guided bone biopsy, lung biopsy, and abscess drainage. We previously conducted a prospective non-randomized quality improvement registry study of procedures performed with midazolam, fentanyl and/or ketamine, starting two months before and ending two months after the granting of deep sedation privileges to IR physicians at CAMC. During the study period, 298 cases were performed: 24 with minimal sedation (either fentanyl or midazolam alone), 178 with fentanyl/midazolam sedation, and 96 with ketamine/midazolam sedation. Deep sedation was associated with significantly lower intra- and post-procedure pain scores. The benefit was evident for biopsy procedures and drainages but not venous access cases. The data were recently published in the *Journal of Vascular and Interventional Radiology* (12).

The consensus among experts is that intra-procedural pain scores should not exceed 4/10 (8). For bone biopsies, we observed a 2-point reduction in maximum pain score for biopsies performed with ketamine/midazolam compared to fentanyl/midazolam. To detect a mean difference of 2 with a standard deviation of 3 at 80% power, the required sample size is 37 subjects per group. For lung biopsy, ketamine/midazolam was associated with a reduction of 1.9 points with a standard deviation of 3.7; power calculation demonstrates that 60 patients per group would be required to detect this difference with 80% power at an alpha level of $p<0.05$. For percutaneous drainage, ketamine/midazolam was associated with a reduction by 3.3 points with a standard deviation of 3.9; power calculation demonstrates that 29 patients per group would be required to detect this difference with 90% power at an alpha level of $p<0.05$.

IRB NUMBER: 24-1149

The study will occur from March 1, 2025 to June 30, 2026. A total of 252 patients will be enrolled: 37 per sedation group for bone biopsy, 60 per group for lung biopsy, and 29 per group for percutaneous drainage. Eligible patients scheduled to undergo interventional radiology procedures, including lung biopsy, bone biopsy, or drainage, will be randomized into one of two sedation groups: (1) fentanyl/midazolam or (2) ketamine/midazolam. A stratified randomization approach will be used to ensure equal distribution of sedation regimens across the three procedure types. Patients will first be categorized based on their planned procedure type. SAS 9.4 will be used to create a randomization schedule to assign patients to one of the two sedation groups within each procedure category (lung biopsy, bone biopsy, or drainage). This approach ensures that each procedure type has an approximately equal number of patients receiving fentanyl/midazolam and ketamine/midazolam.

Upon enrollment, each patient will be assigned a unique study ID. A research coordinator (or designated study team member) will access the randomization sequence and assign the patient to their sedation regimen. To minimize selection bias, treating providers and proceduralists will not be involved in the randomization process. Sedation will be administered per standard dosing protocols, with adjustments made at the discretion of the interventional radiologist based on clinical judgment.

All randomized patients will be analyzed according to their assigned group following an intention-to-treat (or per-protocol, if applicable) approach. Any deviations from the assigned sedation regimen will be documented, along with the rationale for the change.

Inclusion Criteria

- 18 years or older
- Planned to undergo image-guided bone biopsy, lung biopsy, or percutaneous drainage
- Eligible to receive fentanyl/midazolam or ketamine/midazolam sedation

Exclusion Criteria

- Having taken an opioid agonist-antagonist within 5 days
- Having eaten foods within 6-8 hours
- Allergy to ketamine, fentanyl, or midazolam
- Officially deemed as lacking capacity
- Prisoner
- Hypotension precluding fentanyl/midazolam
- Respiratory failure precluding fentanyl/midazolam
- Uncontrolled hypertension precluding ketamine/midazolam
- Condition for which hypertension would be a concern (aortic dissection, myocardial infarction, etc.)
- Pregnant or lactating (contraindication to ketamine/midazolam)
- Schizophrenia (contraindication to ketamine/midazolam)

Procedures/Protocol

- Explanatory variables
    - The independent variables are the type of sedation the patient receives (fentanyl/midazolam vs. ketamine/midazolam). The dosages of the medications will be recorded. Patient gender, age, and weight will be recorded in the REDCap database (see data collection tool), as these may contribute to the effectiveness of sedation. The patient's pre-procedure laboratory values, including the CBC, INR, and comprehensive metabolic panel will be recorded, because preexisting metabolic abnormalities may contribute to the safety and efficacy of sedatives, and a patient's baseline clotting function may contribute to complications such as hemorrhage. Any

IRB NUMBER: 24-1149

history of opiate use will be noted from the patient chart and recorded. The complete list of variables to be collected can be found in **Appendix 3**.

- Response variables
    - The primary response variable to be measured in this study is the peri-procedure Numeric Rating Scale pain score. Maximum pain score will be recorded immediately before, during, and after the procedure. Additionally, patients will be given a modified patient survey regarding sedation during recovery, and responses will be recorded. Other variables to be recorded include the patient's maximum and minimum systolic and diastolic blood pressure during the procedure, minimum oxygen saturation during the procedure, the total procedure duration (calculated as the procedure "time out" to the patient exiting the room), and any complications. Complications will be scored by the performing physician and may include procedure-related complications (e.g., hemorrhage or pneumothorax), or sedation-related complications (e.g., respiratory compromise). Post-procedure laboratory values, including a comprehensive metabolic panel, CBC, and INR, will be recorded because sedatives can cause changes in laboratory values.
- Confounding variables
    - Weight, age, procedure duration, and history of opiate use are all variables that may interfere with the safety and efficacy of fentanyl/midazolam and ketamine/midazolam. By carefully noting these variables, statistical analysis can assess their relative contribution to effects. The influence of confounding factors will be adjusted for using the PSMATCH procedure in the SAS statistical software with a 1:1 propensity score matching with a greedy nearest neighbor matching algorithm with a caliper of 0.1 standard deviations. It is possible that after the procedure, some patients may refuse to participate in the post-sedation survey. A study coordinator will be on-site and assist in completing the survey to ensure optimal response rates.
- Treatments under study
    - We will study ketamine/midazolam versus fentanyl/midazolam sedation for bone and lung biopsy and percutaneous drainage. Study enrollment, the procedure, and all follow-ups will be conducted on the day of the procedure. Procedures will be performed by IR physicians in CAMC's Interventional Radiology unit, under CT, CT fluoroscopy, ultrasound, and/or fluoroscopic guidance. Procedural sedation will be given by the IR physicians. Patients will be randomized to receive fentanyl/midazolam or ketamine/midazolam. In the fentanyl/midazolam group, 0.5–1 mg midazolam and 25–50 mcg of fentanyl will be given intravenously, with additional doses of 0.5–1 mg midazolam and 25–50 mcg fentanyl given as needed every 5–10 minutes. In the ketamine/midazolam group, 1–2 mg midazolam will be given as an initial intravenous bolus, followed by 30–50 mg of intravenous ketamine, with 10–20 mg ketamine administered as needed every 10–15 minutes intravenously, with a maximum dose of 2 mg/kg of ketamine. Vital signs will be monitored and documented per department protocol. Supplemental oxygen will be administered as needed to maintain oxygen saturation >90%.
    - Sedative medications (ketamine, fentanyl, and midazolam) are routine, standard-of-care medications, stored securely in the IR peri-procedural and procedural rooms' Omnicells. The inventory is maintained by the CAMC Memorial Pharmacy team. This is routine operations.
    - Randomization of participants:
- Follow-up: Pain scores and sedation survey responses will be collected at the time of the procedure, in the procedure room and in the post-procedure recovery space. This will ensure maximal response rate. Standard-of-care post-procedure telephone calls are made to every patient who undergoes a procedure in interventional radiology by a procedural area nurse. In our prospective non-randomized registry study, only a third of patients answered these phone calls, limiting any analysis that could be done on patient responses. Therefore, this will not be collected as part of the study.
- Standard of care: Abscess drainage and lung and bone biopsy are image-guided procedures routinely performed as standard of care. Procedural sedation is also standard of care, with both fentanyl/midazolam and ketamine/midazolam sedation routinely performed in our unit. Fentanyl/midazolam sedation is the

IRB NUMBER: 24-1149

most common standard practice across the US. However, ketamine/midazolam sedation is the most common sedation protocol in our unit currently.
- Study implementation: We will hire a study coordinator to assist in subject enrollment and data collection. The coordinator will be on-site and present during procedures to document pain scores and collect the post-procedure survey responses.

Data Collection/Instrumentation

- The primary outcome measures are pain scores and sedation survey questionnaires. Pain scores will be assessed on the Numeric Rating Scale of 0 to 10. The sedation survey is a modified version of a validated anesthesia questionnaire (see attached). The survey is anticipated to require 10 minutes to complete. Responses will be recorded in REDCap by the study coordinator on the day of the procedure.
- On the day of each procedure, the study coordinator will assess the following variables in the electronic medical record and store the data in the REDCap database: patient age, gender, date of procedure, type of procedure, pre-procedure laboratory values (e.g., CBC, comprehensive metabolic panel, INR), maximum and minimum systolic and diastolic blood pressure, total dosages of ketamine, midazolam and/or fentanyl, procedure-related adverse event, sedation-related adverse event, and total duration of the procedure. See **Appendix 4** for the REDCap data collection tool.
- Data will be de-identified and archived to protect patient confidentiality. Subjects will be assigned an anonymous REDCap identifier and protected information (name, date of birth, medical record number, and visit ID) will be deleted from the master file after the final publication of the data is accepted.
- An enrollment and screening log will be maintained on a secure interventional radiology internal Teams site that can only be accessed by authorized personnel.

Data Analysis

- Software: Study randomization and data analysis will be performed using SAS 9.4 by a Biostatistician (to be named).
- Statistical tests: Categorical data, such as the frequency of adverse events, will be assessed using Fisher's exact tests. Continuous data, such as pain scores, responses on the sedation survey, laboratory values, and blood pressure, will be assessed using Mann-Whitney U tests or Student's t-tests. Propensity score matching (1:1) will be conducted with the PSMATCH procedure in SAS using a greedy nearest neighbor matching algorithm with a caliper of 0.1 standard deviations.
- Interim analysis: Because fentanyl/midazolam and ketamine/midazolam sedation are both standard of care, we do not anticipate any stopping rules.
- Quality control: The study PI will review the finalized dataset and verify that missing data are not collectable. Out-of-range data will be verified in the patients' charts.

III. Human Participants

Participant Population/Recruitment Method(s)

The study coordinator will be on-site in Interventional Radiology at CAMC's Memorial Hospital. S/he will review the daily schedule with the IR physicians and identify any patient planned to undergo bone or lung biopsy or percutaneous drainage. Chart review by the IR physician and the IR nurses will ascertain whether the patient is a candidate for fentanyl/midazolam and ketamine/midazolam. Upon arrival in the peri-procedural space, the study coordinator and IR physician will approach the patient and discuss the study. If the patient agrees to participate, s/he will sign consent. The patient will not be aware of which sedation regimen is administered.

Vulnerable Populations

The study does not include vulnerable populations, such as children, pregnant/lactating women, prisoners, and patients who cannot consent.

Benefits

There are no direct benefits to the participants. Regardless of participating in the study, they may receive either ketamine/midazolam or fentanyl/midazolam. The primary benefits of this study are indirect. By validating that ketamine/midazolam is safe and more effective than fentanyl/midazolam sedation, the study may motivate IR units across the country to transition to ketamine/midazolam sedation, potentially improving the lives of thousands of patients.

Risks and Discomforts

The primary discomfort to the patient would be not knowing what medications are being given for sedation, as this is a single-blinded study. There is also a risk of loss of confidentiality, though this risk will be minimized with careful data storage and de-identification.

Consent Process

Consent will be obtained by the study coordinator and IR physician performing the procedure and sedation. We will explain that fentanyl/midazolam sedation is the most commonly performed sedation in IR throughout the US, but we are studying if ketamine/midazolam (which is our standard practice in our unit) provides greater comfort to patients. There is no waiting period per se; consent will be obtained immediately prior to the procedure in the peri-procedure space.

Consent will be sought under circumstances that minimize the possibility of undue influence. Specifically, we will explain that patients will receive sedation regardless of participating in the study. We will provide the subject with sufficient information specific to procedural sedation, and the opportunity to ask questions and have those answered. We will present the information in a language and level that is understandable to the participant. Consenting will occur in the IR peri-procedure area, which has private, curtained spaces for procedural consenting and healthcare discussions.

Waiver of Documentation of Consent:

Not applicable.

Waiver/Alteration of Consent/Assent Request

Not applicable.

Waiver or Alteration of HIPAA Authorization

HIPAA Authorization is requested for screening of patients only. HIPAA Authorization will be obtained for collection of patient data.

Privacy and Confidentiality

Study enrollment and consenting will take place in the IR unit's peri-procedure space. The unit has six recovery bays with curtains dividing the bays, providing privacy. It is in this space that procedural consent is signed.

All data will be stored in REDCap, a secure database. Any individual granted access to the database will be required to undergo training and seek authorization. The database is password-protected and encrypted. Ultimately, the data will be de-identified at the conclusion of the study. The electronic medical record will only be accessed on the day of the procedure - in the course of the standard of care assessment of the patient for the IR procedure, and for data collection - and at the study conclusion when the PI looks over data to ensure quality.

Costs to Participants

IRB NUMBER: 24-1149

All subjects will undergo interventional radiology procedures as part of their standard of care medical care. Procedures are performed with procedural sedation, which is covered by insurance as part of the standard of care. The participant will be responsible for co-pays and deductibles associated with routine care billable to the insurance carrier. No additional costs to patients are anticipated.

Payments/Gifts to Participants

None.

Debriefing

Once all patients have been enrolled and the data analyzed, we can share the study findings with participants if they wish.

Intervention

If any allergic reactions to the sedatives administered in the study are encountered, the patients will be appropriately treated and the allergy documented in the electronic medical record.

Investigator Qualifications

Dr. Deipolyi is board-certified in IR/DR by the American Board of Radiology. She obtained an MD/PhD in 2008 from the University of California, San Francisco School of Medicine and Neuroscience Graduate Program, and completed a diagnostic radiology residency and interventional radiology fellowship at Massachusetts General Hospital in 2014. She is an associate professor with appointments in the Departments of Surgery and Radiology, with 10% protected time to dedicate to this project. She was previously awarded several grants and completed a prospective human study regarding the immunological effects of radioembolization of breast cancer metastases. This prospective project involved investigational tissue biopsy and blood specimen collection, ultimately leading to the publication of the data in the journal, Radiology. She was recently awarded an internal foundation grant, the Maier Foundation grant, for prospective randomized evaluation of ketamine/midazolam and fentanyl/midazolam sedation. The grant provides funds for a study coordinator and statistician.

Other Study Personnel

Dr. Michael Korona, MD, is an IR physician and colleague of Dr. Deipolyi. He is credentialed in both fentanyl/midazolam and ketamine/midazolam sedation and will also be performing the biopsies, drainages, and sedation. He will also be consenting participants. He is CITI-trained and has an IMEDRIS account. The study coordinator and Biostatistician are to be named.

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IRB NUMBER: 24-1149

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