Study Title: Video-based, Patient-Focused Opioid Education in the Perioperative Period: A Feasibility Study

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Study Summary

Title	Video-based, Patient-Focused Opioid Education in the Perioperative Period: A Feasibility Study
Short Title	Perioperative patient opioid education video study
Methodology	A pilot study designed to assess the feasibility of using a novel, video-based opioid education tool for opioid naïve ambulatory surgery patients in the perioperative period.
Study Center	University of Arkansas for Medical Sciences
Objectives	To evaluate the affect that video-based opioid education has on narcotic intake after outpatient surgery.
Number of Subjects	Total N = 110
Diagnosis and Main Inclusion Criteria	Opioid naïve adult men and women undergoing outpatient surgical procedure
Study Procedures	Patients will be randomized to a video or no video prior to surgery then administered a phone questionnaire at post-op day 7, 30, and 90. The Arkansas Prescriptions Drug Monitoring Database will also be accessed for information on opioid prescription refills.
Duration of Administration	The duration of the study will be approximately 3 months, plus a single 1-hour long focus group if desired by the patient.
Primary Objective	Primary outcomes are patient satisfaction, knowledge acquisition, and the effect of the video intervention on post-operative pain control.
Secondary Objective	Feasibility of collecting data including the percentage of patients who develop chronic opioid use, percentage of patients who develop a chronic post-surgical pain disorder, and number of total days to opioid cessation.

Background and Rationale

It has been well publicized that the United States is facing an opioid crisis, with most states experiencing an alarming increase in rates of prescription opioid related deaths, now spanning almost three decades (Deyo, 2016). As this public health crisis continues to plague Americans, much attention has been directed to opioid prescribing trends. It has been shown that the rate of long-term opioid use increases to 13.5% when opiate naïve patients extend its use to eight days or longer and 29.9% when its use extends to 31 days or longer (Shah, 2017). Even one additional refill after initiation can increase odds of long-term use by 2.25 (Deyo, 2016). Coupling these tendencies with the fact that over prescribing of narcotic analgesics has been shown to occur even when these opiate naïve patients encounters even their first prescription, at ambulatory surgeries for example, increased awareness through education is paramount in working to effectively battle the opioid epidemic (Thiels, 2018).

Other than overdose deaths, complications of long-term opiate use have been well studied showing tolerance to the medication, hyperalgesia, and limited efficacy over time, just to name a few (Deyo, 2016). Therefore, opiate alternatives and non-opiate analgesic regimens that can be paired with opiates to decrease total intake should be emphasized. Acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs) are popular substitutes to opioids that should be considered for post-operative pain control (Valentine, 2015). They can be administered on a scheduled basis so that consistent therapeutic concentrations can be maintained to avoid opiate analgesics as a rescue. Ibuprofen and Acetaminophen have been shown to provide superior acute pain with combined with opioids (Memtsoudis, 2018) and to be more effective than opioids in certain chronic pain conditions (Krebs, 2018).

We now know that long term opioid use often begins with the treatment of acute pain. More specifically, many patients use opioids chronically and develop opioid use disorders after they experience their first exposure to opioids during a hospital surgical encounter (Cicero, 2014). Patients are often provided with a prescription for excessive amounts of opioids without clear instructions on usage, full disclosure of the risk and benefits, or a discussion of alternative treatment strategies for pain control (Sabatino, 2018; Theisen, 2018). Approximately 6% of patients who undergo an operative procedure have continued opioid usage at 90 days (Brummett, 2017). While many of these patients have developed chronic post-surgical pain disorders, rates of chronic post-surgical pain are increased by poorly controlled acute post-surgical pain (Gjeilo, 2014; Meissner, 2015).

Disseminating information into easily understood patient education programs that will allow patients to navigate post-operative pain management options and improve acute pain treatment could be a technique to decrease narcotic intake after outpatient surgery.

According to Shah, Hayes, and Martin (2017), starting this conversation early, prior to surgery thus prior to opioid intake is suggested. Cancer-related pain control has been shown by researchers to respond well to brief 20 minute coaching interventions on self–management (Oliver, 2001). Booklets regarding pain-relief methods have been used with proven adequate analgesia (Watt-Watson, 2017). While this work is promising, there are some limitations to the use of handouts as the primary means of patient education. While most hospital education materials are produced at a 10th grade reading level, the reading level of the average patient in the United States is approximately 8th-9th grade (Saffer, 2005). Also, approximately 22 percent of patients read at a 5th grade reading level or lower (Saffer, 2005).

In studies that have randomized patients to handouts versus video-based education, patients obtained and retained more knowledge from video-based education initiatives (Hill, 2009; Shah 2017). This conclusion holds true for instructional-based initiatives pertaining to prescription medications, preventing home falls, and adherence to pre-surgical instructions (Hill, 2009; Shah 2017). Pre-procedural video based education has also been shown to decrease anxiety among patients due to increased knowledge about the unknown (Ayasrah, 2016). Ambulatory surgery, pre-procedural patient-centered interview interventions have also been shown to decrease post procedural pain, improve surgical recovery, and increase daily activity after surgery (Pereira, 2015). In the emergency room, fifty-two patients who were being discharged with an opioid prescription were randomized to either a 6 minute animation-based video on opioid education discussing safe usage of opioids and their potential dangers or an information sheet containing the same information. In this study, the animation-based video tool was found to increase knowledge acquisition of the covered material measured by a written test by a statistically significant margin of 17 percent (Chakravarthy, 2018). This trial further illustrates the benefits of standardized video-based education over non standardized verbal education by providers and handouts. We feel that this video based style of opioid education could be better implemented throughout other phases of hospital care.

Therefore, we propose to examine the feasibility of using a novel, video-based opioid education tool for opioid naïve (patients who have not taken opioids in the 30 days pre-operatively), ambulatory surgery patients in the perioperative period. During our pilot study, our primary outcomes are patient satisfaction, knowledge acquisition, and the effect of the video intervention on post-operative pain control. This pilot study will also examine the feasibility of collecting data including the percentage of patients who develop chronic opioid use (use of opioids past 90 days), percentage of patients who develop a chronic post-surgical pain disorder, and number of total days to opioid cessation. We plan to collect this data both by patient report and from the Arkansas Prescriptions Drug Monitoring Database. This study will also allow us to assess

whether video opioid education tools are an effective means of providing information about opioid use to ambulatory surgery patients and whether the perioperative holding area is the ideal location for this education.

Study Objectives

Primary Objectives

Assess the feasibility of collection of data from both cohorts including the following metrics via phone survey:

Days to post-operative opioid cessation

Methods for post-operative pain control

Patient rated knowledge of post-operative pain control

Patient rated knowledge of post-operative opioid safety

Development of chronic post-surgical pain syndromes

Development of chronic post-surgical opioid use

Assess the feasibility of collection of data from both cohorts from the Arkansas Prescription Drug Monitoring Database including the following:

Number of post-operative prescriptions obtained

Assess the feasibility of the proposed intervention on patient satisfaction, retention of information, perceived usefulness of information, effect on pre-operative anxiety, and effect on acute usage of opioid medication via focus group.

Hypothesis

The use of patient-focused, video based opioid education about the risks and benefits, alternatives to opioid therapy, and safe use, storage, and disposal of opioids is feasible in the perioperative period. The collection of data about opioid use, patient perception of their knowledge on pain control options, patient perception of their knowledge on opioid safety, rates of post-operative chronic opioid use, and rates of chronic post-surgical pain disorders is feasible via phone interview, focus group, and access to the Arkansas Prescription Drug Monitoring Database.

Potential Impact: Understanding the feasibility of this research protocol will inform the creation of a fully powered comparative effectiveness trial to test whether applying this video intervention for opioid naïve, ambulatory surgery patients in the pre-operative holding area will decrease chronic opioid use (90 days), days to opioid cessation, and development of chronic post-surgical pain conditions.

Study Population

Eligibility waivers are not permitted. Subjects must meet all of the inclusion and exclusion criteria to be enrolled in the study. Study events may not begin until a subject has signed the informed consent for and is enrolled. The study population will be opiate naïve preoperative patients arrived and consented for ambulatory surgery.

Inclusion Criteria

- 110 men and women 18 years or older
- not chronically receiving opioid analgesics
- patients who have not taken opioids 30 days pre-operatively
- undergoing surgical procedure not requiring overnight hospital stay

Exclusion Criteria

- non-English speaking
- legally deaf or blind
- on opiate contract
- has taken oral narcotic in the past 30 days
- unable to operate a telephone

Study Design and Procedures

Study Procedure

Prior to subject enrollment, we will create a 5-10 minute opioid education video. This video will explain the risks and benefits of opioid medications and provide examples of evidence-based alternative acute pain therapies. It will also discuss safe use, storage, and disposal of opioids. This video will be based on a Centers for Disease Control and Prevention publication titled “Opioids for Acute Pain: What You Need to Know.” This video will be peer-reviewed for accuracy by a panel of medical doctors, pharmacists specializing in addiction medicine, psychologist, researchers with experience in substance using populations, and nurses, all of which are experts with advanced knowledge of opioid pharmacology and opioid use disorders.

After video creation, we will begin enrolling patients. Patients admitted for ambulatory surgery will be consented for the study in the preoperative holding area. All patients will be read the risk and benefits of the study prior to signing informed consent. After signing informed consent and discussing the risks and benefits of the study protocol, interested patients will be randomized to either receive the video intervention

or to standard of care. 100-opaque-envelopes will be filled with a piece of paper with either “video intervention” or “standard intervention” typed on them. They will be shuffled 10 times then split in half then sequentially numbered, and stored in a plastic tub. Envelopes containing the treatment allocation will be opened by the recruiting clinician on participant enrolment. To be robust, the envelopes will be truly opaque, sequentially numbered, and opened in the correct order. The clinician will not open the envelope in advance and will ensure that the envelope seal has not been broken. Patients randomized to the intervention will be shown the video in the pre-operative holding area on an iPad.

Post-Operative Data Collection and Analysis.

Patients will be contacted on Post-operative day 7, 30, and 90 and asked a series of questions (Appendix B). After completing their post-operative day 90 phone call, patients will be compensated for their time with a $20 gift card. Arkansas Prescription Monitoring Database Data will be accessed for every patient (Dr. Hayes) and will be protected and de-identified. This will provide objective data to determine whether patients have gotten additional prescriptions post operatively and whether patients are continuing opioids past 90 days.

As this a prospective preliminary collection with plans for a more detailed longitudinal study in the future, no net sample size or statistical power has been planned, however the goal is to enroll 110 subjects. Data collection will continue in an ongoing, prospective, open-ended manner, which depends on participant willingness to continue in the study over several months.

Analysis of data will be undertaken with the help of SPSS version 22 software (IBM) using parametric and non-parametric tests of significance dependent on the variables being tested. Univariate and multivariate regression models will be applied using the same software to determine variables that correlate best with differences in studied variables.

Focus Group Structure and Content.

Patients who are randomized to the video group will also be notified that they are eligible to participate in one of two focus groups. These will be scheduled after all patients have been enrolled in the study and all 7 day follow up calls are completed. Patients will receive a $50 gift card in compensation for completing the interactive focus group. The two focus groups of patients from the treatment arm will be held on the 10th floor of the Winthrop P. Rockefeller Cancer Institute and will last approximately 1 hour each (Basch, 1987). We will use the information from this focus group to ensure that this information is correctly delivered to and consumed and retained by patients. We

will also use this information to assess timing for the intervention in the pre-operative holding area and assess whether patients feel that there is a better time for this information to be delivered.

Analysis of Qualitative Data Gathered from Focus Groups.

All focus group discussions will be audio recorded. We will compile and review notes and transcripts collected from the phone interviews to generate written summaries of the factors that impact acceptability and feasibility of the video intervention. We will pursue a rapid analysis (e.g., Sobo et al., 2006) of focus group data to ensure quick translation of patient feedback to actionable suggestions for developing the study protocol and finalizing the video intervention. We will listen to all focus group audio recordings and will compile all interview and observation notes. This data will be used to generate a summary of patient recommendations for adaptations to video content and final study video delivery methods. This generated summary will be presented to study team and stakeholders.

Removal of Subjects from the Study

Patients can be taken off the study at any time at their own request, or they may be withdrawn at the discretion of the investigator for safety, behavioral, or administrative reasons. The reason(s) for discontinuation will be documented and may include:

- Subject withdraws consent
- Subject is lost to follow up. If the investigator is unable to contact the subject for follow up phone calls the subject will be considered “lost to follow up”

Risks

The only potential risk to study participants is the potential for loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below.

Potential Benefits

Patients provided with education video could be at lower risk for opioid addiction. As well as the knowledge gained from the study could potentially benefit patients in the future.

Data Management

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number (Appendix A). The key to the code will be kept in a locked file in the principal investigator's office. Only principal and sub-investigators will have access to the code and information that identifies the subject in this study. At the conclusion of the study, the data will be permanently deidentified, then destroyed after seven years.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

The formal consent of each subject, using the IRB-approved consent form, will be obtained before that subject is submitted to any study procedure. All subjects for this study will be provided a consent form describing this study and providing sufficient information in language suitable for subjects to make an informed decision about their participation in this study. The person obtaining consent will thoroughly explain each element of the document and outline the risks and benefits, alternate treatment(s), and requirements of the study.

The consent process will take place in a private preoperative bay, and subjects may take as much time as needed to make a decision about their participation. Participation privacy will be maintained and questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. This consent form must be signed by the subject or legally authorized representative (only if applicable), and the individual obtaining the consent. A copy of the signed consent will be given to the participant, and the informed consent process will be documented in each subject's research record.

Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator. It should also be noted that when an amendment to the protocol substantially alters the study deign or potential risk to the patient, a revised consent form might be required.

The amendment protocol, and if required the amended consent form, must be approved by the IRB prior to implementation.

Record Retention

All study records will be retained in accordance with applicable institutional and applicable regulatory requirements.

Obligation of Investigators

The principal investigator is responsible for the conduct of the clinical trial at the site in accordance with applicable regulatory requirements. The principal investigator is responsible for personally overseeing the treatment of all study subjects. The principal investigator must assure that all study site personnel, including sub-investigators and the other study staff members, adhere to the study protocol and all applicable regulations and guidelines regarding clinical trials both during and after study completion.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

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Appendices

Appendix A: Coded Identifier List

Video-based, Patient-Focused Opioid Education in the Perioperative Period: A Feasibility Study

Code Identifier	Patient Name	DOB	Phone number	Date of Surgery
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Appendix B: Follow up Phone Interview Questions

Video-based, Patient-Focused Opioid Education in the Perioperative Period: A Feasibility Study

Day 7 post-op phone call:

1. Are you still taking opioids?
2. With your surgery day being day 0 and today being day 7, what day was your last opioid taken?
3. What methods other than opioids did you use to control your post-operative pain?
4. On a scale of 1-10 with 1 being not at all informed and 10 being very informed, rate your knowledge of post-operative pain control prior to surgery.
5. On a scale of 1-10 with 1 being not at all informed and 10 being very informed, rate your knowledge of post-operative pain control after surgery.
6. On a scale of 1-10 with 1 being not at all informed and 10 being very informed, rate your knowledge of opioid safety including safe use, storage, and disposal of opioids prior to surgery
7. On a scale of 1-10 with 1 being not at all informed and 10 being very informed, rate your knowledge of opioid safety including safe use, storage, and disposal of after surgery
8. On a scale of 1-10 with 1 being not at all improved and 10 being very improved, how you feel your hospital experience improved your knowledge of post-operative pain control.

Day 30 post-op phone call

1. Are you currently taking opioids?
2. When was your last opioid taken?
3. Are you experiencing any pain from your surgery?
4. On a scale of 0-10 with 0 being pain free and 10 being the worst pain imaginable, how would you rate your current post-surgical pain?

Day 90 post-op phone call:

1. Are you currently taking opioids?
2. When was your last opioid taken?
3. Are you still experiencing any pain from your surgery?
4. On a scale of 0-10 with 0 being pain free and 10 being the worst pain imaginable, how would you rate your current post-surgical pain?

Appendix C: Focus Group Interview Discussion Outline

Video-based, Patient-Focused Opioid Education in the Perioperative Period: A Feasibility Study

1. How do you feel about the timing of the educational video? Is there a better time this information could be provided prior to surgery (e.g.: in clinic)?
2. Did you like the way the information was conveyed in the video?
3. What information should be added to the video?