Title: Quantifying Narcotic Use in Outpatient Otolaryngology Procedures

Brief: Patient Narcotic Requirements After Outpatient Otolaryngology Procedures

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PROTOCOL OUTLINE AND GUIDELINES

1. PROTOCOL INFORMATION
Quantifying Narcotic Use in Outpatient ENT Procedures

2. PRINCIPAL INVESTIGATOR'S INFORMATION
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3. STUDY PERSONNEL

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4. STUDY INFORMATION
Study will be conducted in the Loma Linda University Medical Center affiliated clinic for Otolaryngology-Head and Neck Surgery.

5. OBJECTIVE
Opioid medication is routinely given for pain control after surgery. However, this has not been well studied with regards to the efficacy, and amount of medication that is required. Therefore the objective of this study is to quantify the efficacy of already standard practice.

Approximately 200 patients will be enrolled in this study. The rationale and goal for this study is to provide a guideline for future patients undergoing similar procedures.

6. INCLUSION / EXCLUSION CRITERIA
Inclusion criteria: Adult patients between the ages of 18 and 89 years of age undergoing the following outpatient procedures at a Loma Linda University Health associated surgical facility: septoplasty, unilateral or bilateral functional endoscopic sinus surgery, rhinoplasty/vestibular stenosis repair, tympanomastoidectomy, tympanoplasty, total or partial thyroidectomy, parathyroidectomy, parotidectomy.

Exclusion criteria: Patients under 18 years old; patients who are admitted after planned outpatient surgery; those allergic to Hydrocodone or NSAIDS; pregnancy; patients with chronic medical conditions including hepatic/renal disease, sickle cell anemia

7. SUBJECT RECRUITMENT & SCREENING
We plan to recruit about 200 patients for this study over the course of one year. We expect a high rate of participation as we are continuing with our usual practice for prescribing pain medication after surgery.

Subjects will not be selected or excluded based on gender, ethnicity/race, native language or specific vulnerabilities. All patients who meet inclusion criteria will be

assessed and determined for candidacy for participation. Recruitment will take place on the morning of surgery and a screening questionnaire will be used for screening and as part of data collection should the patient agree to participate. Since we are continuing our standard treatment, no extraordinary risks are involved. The patient may opt out of the study at any time.

8. INFORMED CONSENT PROCESS

The primary investigator or one of the physician study personnel will obtain consent at the time of recruitment during the clinic visit or on morning of surgery. We will explain to the patient that participation in this study is entirely voluntary and that it will not change clinical management. If patient is unable to consent for himself or herself, we will exclude them from the study.

9. STUDY DESIGN

a. Background

While it is routine practice to give analgesic medication after any surgical procedure to provide adequate pain control for patients, the abuse of prescription medications has recently become the fastest growing drug problem in the United States. More people died from prescription drug overdoses in 2014 than in any year on record with the majority of drug overdose deaths, more than 60%, involving an opioid. From 2000 to 2014 nearly half a million people died from drug overdoses, and based on the 2014 data, about 78 Americans die every day from an opioid overdose. The most common drugs involved in prescription opioid overdose deaths include Methadone, Oxycodone (such as OxyContin®), and Hydrocodone (such as Vicodin®), and it was also these three drugs that has the highest rate of opioid overdose death in 2014.

Given the potential for narcotic abuse, as well as its impact on health care and societal cost, we wish to quantify baseline pain medication needs in patients who undergo outpatient ENT surgeries. Based on published data on postoperative pain and anecdotal experience, patients may not require as much narcotic medication as we have been prescribing. By providing patients with appropriate pain expectations and counseling, a clear regimen for pain control, and non-narcotic alternatives such as NSAID, we could likely decrease the amount of prescribed narcotic medication by 25-50%.

b. Literature review

Other than septoplasty and tonsillectomy, very little has been studied to determine the appropriate amount and regimen for pain control after routine outpatient ENT procedures. One of the most comprehensive studies looking at postoperative pain in ENT procedures demonstrated that predictors of poor pain control after surgery includes preoperative pain, anatomic site, and higher pain catastrophizing scores. However, this study only looked at post-surgical pain up to 4 days after surgery and included a variety of ENT procedures including tonsillectomy, which is known to be an exceedingly painful procedure. Not only was the pain regimen utilized not common to what is used in the United States, this study did not separate inpatient versus outpatient procedures.

In another study looking specifically at patients who underwent parotidectomy, it was demonstrated that on a scale of 1-10 (10 being the worse imaginable pain), the mean pain score was only 3 on POD 1 with a range of 1 to 6. While this study did quantify the number of pain pills used on each day following surgery, it was unclear what the actual pain regimen was. What they did demonstrate very well was that post-surgical pain after parotidectomy is for the most part mild and at worst moderate. Similarly, in a study comparing open total and partial thyroidectomy with robotic total and partial thyroidectomy, pain after thyroid surgery was demonstrated to be only mild with the pain regimen that consisted of acetaminophen, tramadol and diclofenac. For those who had open surgery, the mean visual analog scale (VAS) score (from 1-10) on postsurgical day 1 was only 3.59 and 3.48 for total and partial thyroidectomy, respectively. While the study design suggested that all patients were admitted after surgery, this also was not clear. Interestingly, pain literature overall shows that treating pain under a VAS score 3 is not helpful and likely unnecessary and is definitely not recommended to require narcotic use. However, patients commonly take the prescription given by their surgeon with little to no education or understanding of pain thresholds or narcotic side effects. Anecdotally, many patients will state they did not use their narcotics as directed because they did not need them or that it did not help decrease the pain they were experiencing. Other patients seemingly take the medications as prescribed without question even though they were not experiencing pain.

Overall, these studies suggest that certain ENT procedures may not be very painful for patients, thus begging the question of how much narcotic medication is actually needed for adequate pain control. An additional question that should be addressed is at what point does pain need to be treated and if so, does it require a narcotic medication? According to Gerbershagen and colleagues, a cut-off point of greater than or equal to 4 was determined to be the appropriate pain level to be considered moderate to severe where patients may benefit from analgesic therapy. A rating of less than 4 was considered to be tolerable pain. In a study of over 10,000 patients who underwent various types of surgeries, not only were patients asked their pain level, but they were also assessed whether this pain was tolerable. More than 50% of patients with a reported pain level of 4-6 reported pain as tolerable thus not requiring additional treatment. This study advised against adhering to a strict guideline of simply treating pain when greater than or equal to 4 and suggested clinicians to ask patients whether they desire to receive medication in order to prevent overtreatment and possibly unnecessary treatment. In a follow up study to determine at what point on the Numeric rating scale (NRS) should a patient be given a narcotic medication, only at an NRS of greater than or equal to 8 did more than 50% of patients desire to have an opioid medication for pain control. Interestingly, there were 314 patients in this study who had an ENT procedure and only 20 reported a desire to have opioid medication on POD 1 when patients were assessed. Ultimately, the conclusion from this study is that the NRS is not reliable to predict whether a patient requires narcotic medication, and again suggests that the patient's preference for additional therapy should be assessed instead of following a rigid guideline for pain management.

With this data and the implications of this topic in mind, the goal of this study is to quantify the amount of narcotic medication needed for adequate pain control for some of the most common outpatient ENT procedures. By providing a guideline and having

patients manage their own pain level, this could provide a truer assessment of patient needs based on their preference.

c. Design:

The study will be a prospective randomized study, and patients will be recruited before surgery. They will then be given an envelope assigning them to Group 1 or Group 2 pain regimen (see below). The patient will be prescribed both Hydrocodone/acetaminophen and Ibuprofen as described below, and instructed to follow the directions for their assigned group. They will be given other medications related to the procedure as needed.

Following surgery, the patient will be discharged with the medications prescribed and asked to fill out a data sheet from post-operative day 1 (POD) to POD 7, recording their pain level three times per day as well as pain medication usage for each day. On follow up, the data sheet will be collected, marking the completion of patient participation. Patient data will then be analyzed for: the procedure that they underwent, pain level on each day after surgery, and amount of narcotic usage. The statistician will be blinded to which regimen the patients are on.

Pain regimen:
Group 1:
1) First line: Hydrocodone/acetaminophen 5mg/325mg every 6 hours as needed for pain control
2) Second line: Ibuprofen 600mg every 6 hours as needed for pain control. Take 6o minutes after Hydrocodone/acetaminophen if pain is still not controlled.

Group 2:
1) First line: Ibuprofen 600mg every 6 hours as needed for pain control
2) Second line: Hydrocodone/acetaminophen 5mg/325mg every 6 hours as needed for pain. Take 60 minutes after Ibuprofen if pain still not controlled.

10. DATA COLLECTION

Consenting patients who meet the study criteria will be provided with the following handouts: (1) an instruction sheet explaining the study; (2) a consent form for participation (to be given back to the attending or resident physician); (3) the assigned study group with instructions, as described above; (4) a data sheet, where the patient will record the data after surgery.

Beginning on the night after surgery, the patient will record the following: (1) pain level at morning (0800), midday (1300), and night (2000); (2) time when medication is taken, which medication is used, pain level when medication is taken. All of the data mentioned will be recorded daily until POD 7 or the first follow-up appointment (whichever comes first). At this time, the attending will collect the patient questionnaire and data sheet and store them in a secure location. If the patient forgets to bring the data sheet, the clinic will provide a self-addressed envelope for the patient to mail in the data.

11. LABELING & STORAGE OF DATA & SPECIMENS

Subjects will be identified by medical record number only, and all study materials will be kept in a locked drawer or on a secure, password protected desktop computer at the Otolaryngology clinic at the Faculty Medical Office (FMO) or Orange Tree Lane Otolaryngology(OTL) clinic. Every effort will be made to protect patients' private information and the only information gleaned from the electronic medical record will be demographic information for the purposes of the study.

Aside from the medical record number, which will be kept secure, no identifying information will be used. All forms related to Privacy of Medical and Research Records information / medical records, Medical Release forms, HIPAA compliance/authorization forms will be signed by the patient and copies given to them if requested as patients are enrolled in the study.

12. DATA ANALYSIS

Data will be analyzed by investigator at the conclusion of the study with descriptive statistics reported as means with 95% CIs. For comparison between the treatment groups, Student's t test and Fisher's exact test will be used as appropriate, with statistical significance defined as $P < .05$.

For comparison of multiple surgical groups, single-factor analysis of variance will be used and the following independent variables evaluated as factors for reported pain scores and opioid usage: age, sex, prior opioid use, liver or kidney disease, chronic pain, tobacco, alcohol, marijuana, benzodiazepine, surgery type, surgery length, and revision surgery. Univariate linear regression and multivariate linear regression will be used to determine factors most predictive of higher reported pain scores and/or opioid consumption.

13. RISK AND INJURY

Patients in this study will receive standard outpatient pain regimens, which are already in practice, with no changes. There is no additional risk, as we are using the same medications that we currently use and are within the standard of care. All patients receiving pain medications are given printed prescription warnings from the pharmacy. The only specific risk could be the unintended disclosure of HPI if the research protocols are not followed; however, standard research protection steps will be taken.

14. BENEFIT(S)

Patient will receive no benefit in addition to that received from the current standard of care.

15. COMPENSATION

No compensation will be offered in exchange for participation in our study.

16. CONFIDENTIALITY

No patient identifiers will be used in this study. Medical record will be used to gather demographic information only. All study information will be kept secure in either a locked drawer or password protected hard-drive. No patient information will be shared or distributed at any time.

17. REFERENCES:

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