TITLE:
Postoperative Pain Control in Septum and Sinus Surgery

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Protocol and Statistical Analysis Plan

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TITLE

Postoperative pain control in septum and sinus surgery: A novel approach

STUDY OVERVIEW

Rationale/Background:

The purpose of this study is to investigate if a new protocol of post-operative pain management in sinus/septum surgery patients will lead to less opiate use in the first week. Current prescribing practices for septum and sinus surgery of the ENT private practice group that is included in this study includes as needed 325 mg acetaminophen and as needed acetaminophen/hydrocodone, usually 7.5 mg/325 mg. If it can be demonstrated that use of scheduled 650 mg acetaminophen drastically decreases postoperative opiate use in the first week, thought could given to reducing the number of opiates prescribed, or even eliminating opiate use all together.

Pain control in the postoperative period following septum and/or sinus surgery is controversial, as there is no consensus statement regarding current guidelines to direct clinical practice. Our study would look to demonstrate that scheduled doses of acetaminophen as opposed to reactionary as needed acetaminophen would control post-operative pain to the point where narcotics would not be necessary.

Objectives/Endpoints:

Primary objective: to investigate if postoperative pain control with scheduled acetaminophen alone versus as needed acetaminophen will lead to decrease use of opiates in the first week of the postoperative period

Secondary objective: To investigate if postoperative subjective pain scores are different between the control arm of acetaminophen as needed with as needed hydrocodone/acetaminophen versus scheduled acetaminophen with oxycodone as needed

Methodology:

The study methodology will be conducted as follows. Patients will be identified for the study who present day of for previously scheduled sinus/septum surgery. After consent is obtained by information sheet, patients will be randomized into one of two different study arms. The randomization will occur using a patient randomization sheet provided by the Beaumont Biostatistician Office.

One arm of the study will be given instructions to take acetaminophen 325 mg every 6 hours ***as needed*** to control postoperative pain and will be given a prescription for no more than 3 days of 7.5 mg/325 mg acetaminophen/hydrocodone with instructions to take this medication as needed every 4 hours for breakthrough pain. This is the current prescribing practices of the otolaryngologists included in the study. The study arm of the study, which is also a prescribing practice being used at Beaumont Farmington Hills, will be given instructions to take 650 mg acetaminophen only ***on a scheduled basis of every 6 hours*** and will be given no more than 3 days of 5 mg oxycodone with instructions take this medication for breakthrough pain only every 4 hours. The patients will be given these specific opiate strengths as they are equal morphine equivalents. All patients will have clear instructions on how to use the medication with instructions clearly imprinted on the medication bottles.

Scripts will be written by the consent provider prior to discharge from the hospital, per randomization.

The two arms of the study will then be given a survey at the first postoperative visit, approximately 1 week plus or minus 3 days, with questions regarding total amount of opiates taken as well as postoperative subjective pain scores. If patients are unable to follow up in the aforementioned time frame, a phone survey will be conducted by the principle investigator.

Risks and Benefits:

There are no risks to the patients undergoing this study, as both protocols used are accepted means of controlling postoperative pain, and both groups are given similar medications, albeit with different instructions. Additionally, there are no benefits to those enrolled, both financial and clinically.
Eligibility Criteria:

1) Undergoing primary sinus surgery, primary septum surgery, or primary sinus/septum surgery
2) 18 years of age or older
3) Male or female
4) No known allergies to or contraindications to the use of acetaminophen, hydrocodone, or oxycodone
5) Patients discharged to home after surgery

Data Analysis:

The data collected will be analyzed in order to determine the total amount of opioids used between the two groups. Analysis will also look into any characteristic differences between the two groups and whether post-operative pain scores differed subjectively. The results will be used to, hopefully, show that opioids in the post-operative period following sinus/septum surgery are not needed, and that pain control can be accomplished using scheduled Tylenol.

The hope of this study is to produce a journal-worthy article that would be accepted for publishing, in terms of data dissemination.

Sample Size:

Tentatively, 200.

Data Safety Monitoring Plan:

Study does not involve greater than minimal risk.

Summarize Existing Study Data:

A study published by Gray et al in 2018 found that most all otolaryngologists prescribe opiates in the postoperative period and that there was no significant difference in prescribing practices between geographic regions or practice setting. They did, however, find that there was a significant difference in adjuvant pain management strategy between academic centers and private practice physicians.

A study published in 2019 by Harvard University found that almost 95% of patients undergoing sinus surgery were prescribed an opiate postoperatively. Of those patients, 91.4% got the prescription filled, and 73.1% reported taking no opiates at their first follow up appointment. Given these findings, one has to wonder if opiates should even be prescribed in the postoperative period and wonder where those unused opiates went. Another study published in 2018 by Wayne State University found that the mean opioid prescription length in a cohort of 570 surgeons was 5.4 days, which brought into question whether recent legislation limiting opioid prescription length to 5 days would have an impact, if at all, on prescription length. This again brings into question whether legislature will truly affect prescribing practices of otolaryngologists and whether or not giving patients an alternative to opiates would be a more efficacious route. Another study published in 2013 by University Hospital Jena looked at pain control for postoperative day one in patients undergoing primary endoscopic sinus surgery and found that patients reporting significant pain were typically younger and that their pain management was insufficient with a routine of acetaminophen and piritramide.

References:

Gray, ML, Fan, CJ, Kappauf, C, et al. Postoperative pain management after sinus surgery: a survey of the American Rhinologic Society. Int Forum Allergy Rhinol. 2018; 8: 1199– 1203.

Sethi, R. K., Miller, A. L., Bartholomew, R. A., Lehmann, A. E., Bergmark, R. W., Sedaghat, A. R. and Gray, S. T. (2019), Opioid prescription patterns and use among patients undergoing endoscopic sinus surgery. The Laryngoscope, 129: 1046-1052. doi:10.1002/lary.27672

2019-259
09/20/19

Arianpour, K., Nguyen, B., Yuhan, B., Svider, P. F., Eloy, J. A., & Folbe, A. J. (2018). Opioid Prescription Among Sinus Surgeons. *American Journal of Rhinology & Allergy*, *32*(4), 323–329. https://doi.org/10.1177/1945892418773578

Patient Questionnaire

Patient code : _____

Date : _____

Demographics

Gender: Male Female Rather not specify

Age: _____

The following questions are about pain related to your surgery that you experienced during the first 7 days after your operation. Please fill out this survey to the best of your ability.

Q1. On this scale, please indicate the **least** pain you had in the first 7 days:

0 1 2 3 4 5 6 7 8 9 10

no pain worst pain possible

Q2. On this scale, please indicate the **worst** pain you had in the first 7 days:

0 1 2 3 4 5 6 7 8 9 10

no pain worst pain possible

Q3. How often were you in **severe** (e.g. requiring break-through pain medication) pain in the first 7 days?

Please circle your best estimate of the percentage of time you experienced severe pain:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

never in severe pain always in severe pain

Q4. How often did you take acetaminophen (Tylenol)?

As needed Every 6 hours

Q5. How many opiate narcotics did you take in total?

_____ Did not fill prescription

IRB NUMBER: 2019-259
IRB APPROVAL DATE: 10/31/2019

Q6. Did you use any other forms of pain medication, over the counter or prescribed?

Yes No

Q7. If you answered “yes” to Q6, which medication(s)?

Q8. Do you take pain medication, including narcotics, for any other medical conditions?

Yes No

Thank you for your time and feedback

Statistical Analysis Plan

Demographic and outcome data will be stratified by study arm and summarized using mean (SD) or median (IQR) for continuous data and compared using a t-test or Mann-Whitney U test. Categorical data will be summarized using frequency (percent) and compared using Fisher's exact test