Designing an outcomes-based study of disability, depression, and patient satisfaction for patients with chronic rhinosinusitis

Sample
Statement of the problem:

Chronic rhinosinusitis (CRS) is an inflammatory disease affecting the tissue of the nasal passage. CRS patients display two or more of the following cardinal symptoms: reduction in sense of smell, facial pressure or pain, nasal obstruction, and nasal discharge\(^1\). Although 14.2% of adults in the United States will develop CRS, the underlying cause of the disease is not well understood\(^2\). CRS is associated with significant reduction in quality of life, loss of productivity, and high healthcare costs\(^1\). Patients can opt for medical treatment or surgery to alleviate symptoms. The overall purpose of our current study is to determine how surgical or medical treatment impacts patient quality of life and disease severity, as measured by the Rhinosinusitis Disability Index and Patient Health Questionnaire; however, we do not understand how patient healthcare satisfaction affects baseline quality of life, or whether initial patient satisfaction correlates with quality of life improvement after treatment. In this project, we gather and analyze data from Press Ganey patient satisfaction surveys, Rhinosinusitis Disability Index scores, and Patient Health Questionnaire-2 scores to determine how disease-related disability and depression relate to baseline patient satisfaction. In addition, we will compare quality of life outcomes for patients originally treated by medical management with those who underwent surgery. Future expansions of this project may include administering patient surveys to collect information on stress levels and anxiety, which will provide a broader picture of what factors influence patient satisfaction. These outcomes can be used to provide more accurate recommendations for treating the debilitating symptoms of CRS.
**Literature review:**

Current research indicates that nasal inflammation in patients with CRS can be caused by a number of factors, including allergic reactions, deviated septum, and immune system cells\(^3\). CRS can present with or without nasal polyposis. In patients without nasal polyps, higher expression of the interleukin-22 receptor indicates the role of innate immunity in inducing CRS symptoms\(^4\). Researchers have observed both up- and down-regulation of Toll-like receptors (TLRs), receptor proteins that contribute to the innate immune system’s inflammatory response, in the mucous of CRS patients\(^5\). Medical treatment of CRS includes saline irrigations and corticosteroids\(^2\).

In the absence of significant improvements with medical management, CRS patients can opt for surgery. Surgical techniques such as paranasal sinus balloon catheter dilation have been used to relieve CRS symptoms, although further studies are needed to confirm the efficacy of this approach\(^6\). Endoscopic sinus surgery is the most common surgical technique used to treat CRS, and significant quality of life improvements have been seen post-surgery when patients were evaluated using the Sino-Nasal Outcome Test (SNOT-22)\(^7\). Recent studies have focused on identifying outcome differences between patients treated medically and those treated surgically. When the Brief Smell Identification Test (B-SIT) was used to assess olfaction outcomes in CRS patients treated by medical management and by surgery, both experimental groups showed comparable improvements\(^8\); however, endoscopic sinus surgery was shown to be more effective in reducing three of the four cardinal CRS symptoms: facial pressure, nasal discharge, and nasal obstruction\(^1\).

Different metrics have been used to assess quality of life for patients with CRS, and to analyze compounding factors that influence treatment outcomes. Patients with depression display...
lower quality of life scores prior to sinus surgery, but experience significant post-operative improvement in quality of life\textsuperscript{9}. Similarly, cognitive dysfunction is linked to decreased quality of life for CRS patients\textsuperscript{10}. Depression scales have been shown to accurately predict patient satisfaction post-surgery, independent of other measures of improvement\textsuperscript{11}. In this project, correlation between depression, patient satisfaction, and quality of life will be determined for patients with CRS.

\textbf{Activities and timetable:}

Since 2013, 202 patients have been enrolled in a CRS study. Patients with CRS have been treated by endoscopic sinus surgery or by standard medical management. In addition, surgical patients who have undergone endoscopic sinus surgery for conditions other than CRS have been included as control subjects. In the fall, I worked on collecting patient encounter numbers (CSNs) from patients' medical records, which were used to obtain Press Ganey scores for patient satisfaction analysis.

Patients completed two surveys to assess quality of life: the Rhinosinusitis Disability Index and the Patient Health Questionnaire-2. This spring, with a focus on care provider and overall assessment domains, we compiled Press Ganey data for all patients enrolled in the study and drafted a proposal for a paper based on these data. I conducted a broad literature review on patient satisfaction and disease severity studies to facilitate this process. The paper proposal has undergone several revisions since January. I also gathered information on potential anxiety and stress surveys, which will be used to collect further data about patients’ mental health and wellbeing.
Over the summer, we hope to integrate our data with data from the Oregon Health & Science University to obtain a larger n size. We will use the PHQ-2 score to determine a patient’s risk for depression, with a value of 3 or greater indicating moderate risk. RSDI scores provide information on disease-related quality of life and disability experienced by patients with rhinosinusitis. I will help organize and analyze data points that have previously been collected from the RSDI and PHQ-2. Using bivariate analysis, we will compare these data to determine statistically significant correlations. Specifically, we will look at how disability index scores influence patient satisfaction, and whether risk of depression influences patient satisfaction independent of disease-related disability. This analysis should take 1–2 months. Our findings will be compiled into a paper for a national meeting in addition to journal submission; revising this paper will take an additional month. We hope to have the paper completed by the end of the summer.

Long-term, we want to compare quality of life outcomes for CRS patients treated with endoscopic surgery and those treated with medical management. Additional post-operative data will allow us to more adequately assess outcomes for patients treated with surgery and medical management. I also hope to begin comparing more specific quality of life measurements obtained from patient surveys and looking for correlations between these measurements.

**Relationship of the proposed work to that of my mentor:**

As a surgeon and researcher, my mentor’s area of expertise is in the treatment of sinus and nasal disease, including chronic rhinosinusitis. [Name] is working on several clinical trials with CRS patients. One of these trials focuses on sleep quality and sleep disruption in patients with CRS, and how endoscopic sinus surgery might be used to relieve these issues. [Name] also
has an interest in how different surgical techniques can improve outcomes for patients with sinus disease. He is currently working on a long-term CRS quality of life study, in which patient quality of life has been evaluated through several different surveys and analyzed using various parameters. Dr. Alt also conducts basic science research on tissue samples collected from surgical patients, which are used to help identify CRS biomarkers at the microscopic level.

I will be working directly on Dr. Alt’s CRS quality of life study. My individual project will be part of the study’s broader research goal, which is to determine different factors affecting quality of life for patients with CRS.

**Relationship of the proposed work to my future goals:**

I plan to apply for medical school, where I hope to do further work in the area of translational research. Specifically, I am interested in how various quality of life metrics can be used to analyze the effects of medical treatment on patients with chronic diseases. This project will help familiarize me with designing an outcomes-based study, conducting ethical human subject research, asking and answering scientific questions, and processing data obtained.

Although my background in basic science research has taught me a great deal about study design, working with Dr. Alt has given me the opportunity to learn more about the clinical implementation of medical research. Through this project, I will gain valuable skills that I believe will help prepare me for a career in medicine, and for future work in the area of translational research. I will come away with a better understanding of IRBs, informed consent, statistical analysis, and different techniques for quantifying quality of life.

This coming summer, I will have the chance to work on communicating our findings in a manuscript that will be submitted to a national meeting in addition to the top rhinology journal.
International Forum of Allergy and Rhinology. I will learn more about what makes a paper successful, how to present my research, and the paper review process. This work will be useful in applying to medical schools, where research and publication experiences are greatly valued.

References:


