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Results of perioperative steroid therapy for the treatment of patients with sinonasal polyposis during surgery

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Background: When chronic rhinosinusitis brought on by sinonasal polyposis is taken into account, the expenses of both direct medical care and lost productivity are significant. Chronic rhinosinusitis is mostly caused by inflammation, which can be treated with a variety of drugs, such as systemic steroids, topical corticosteroids, antibiotics, and saline irrigations.

Methods: Between August 2012 and July 2013, this study was carried out in the Department of Otorhinolaryngology, Sardar Rajas Medical College and Hospital, Bhawanipatna, Orissa, India. This study examines forty patients who have sinonasal polyposis and chronic rhinosinusitis. Twenty patients had systemic steroids during surgery, whereas the other twenty patients got placebos. Operative and clinical data underwent critical data analysis.

Results: This study evaluates the impact of pre- and post-operative systemic steroids on surgical outcomes for patients receiving ESS for the treatment of CRSwP. It is a double-blind, placebo-controlled trial. We used both objective and subjective measures of success. Finding out how steroid use influenced these measures of subjective and objective well-being was the main goal of the study.

Conclusion: Adjuvant steroids, which are given during surgery, can also help prevent postoperative issues such as scarring, synechiae formation, postoperative crusting, and recurrence.

Keyword: Sinonasal, polyposis, adjuvant steroid, and treatment, ESS

Introduction

The chronic rhinosinusitis brought on by sinonasal polyposis results in a marked increase in the expenses of direct medical care as well as missed work days. The pathophysiology of Chronic Rhinosinusitis (CRS), a disorder that can be treated medically in a number of ways, is heavily influenced by inflammation. This group includes systemic steroids, antibiotics, and saline irrigations. It is impossible to cure every patient or manage every symptom, not even with the most potent medicine. This is a regrettable fact of life. Endoscopic sinus surgery (ESS) has been

shown to help patients with both their symptoms and quality of life when medication therapy has failed to control their symptoms.

Our facility, the Upgraded Institute of Otorhinolaryngology at Madras Medical College, is located in Chennai and performs close to a thousand endoscopic sinus surgery (ESS) procedures annually. For patients with Chronic Rhinosinusitis with Sinonasal polyposis (CRSwP), most surgeons will recommend polypectomy, complete ethmoidectomy, and middle meatal antrostomy, though there is some disagreement as to whether or not this is the best

or most appropriate surgical technique. This can be performed with or without a sphenoidotomy or frontal sinusotomy. Nonetheless, when it comes to the medication regimen given pre- and post-operatively to patients undergoing ESS for CRSwP, as well as the management of these patients, there is a conspicuous lack of consistency and guidelines 4.

For example, some surgeons advocate preoperative systemic steroids because of the advantages they provide after surgery. These advantages include decreased blood loss, polyp load, and edema. Steroids administered during surgery are generally believed to have several potential advantages that improve recovery and results. These advantages include a decrease in scarring and postoperative edema as well as a suppression of intrinsic inflammatory illness. A vast range of potential side effects, from minor ones like gastrointestinal irritation to serious ones like osteonecrosis of the femoral head, have been thoroughly documented for systemic steroids. All of these consequences are pertinent to the ongoing discussion. Gastrointestinal discomfort is among systemic steroids' most frequent negative effects. For this reason, some surgeons recommend systemic steroids before to, during, and following surgery, while others do not. Focusing on particular surgical outcomes⁷ that happened during the procedure itself as well as subjective and objective outcomes that happened during the short and intermediate postoperative periods was the goal of the design of the placebo-controlled study that was created to assess surgical outcomes.

Examining the subjective and objective effects of endoscopic sinus surgery (ESS) in treating chronic rhinosinusitis and sinusitis with pneumonia (CRSwP) in patients who have received peri-operative systemic corticosteroids is the main goal of this research. One instrument used to assess patient-reported experience is the Lund-Sinus McKay Symptom Questionnaire (SSQ). To provide a numerical representation of the degree of advancement, the Lund-Kennedy Endoscopy Scale (LKES) is employed. This allows us to break down the study's primary

objective into its three subgoals, which are detailed below.

Materials and Methods

Between August 2012 and July 2013, this study was carried out in the Department of Otorhinolaryngology, Annai Medical College And Hospital, Kanchipuram, Tamil Nadu, India. This study examines forty patients who have sinonasal polyposis and chronic rhinosinusitis. Twenty patients had systemic steroids during surgery, whereas the other twenty patients got placebos. Operative and clinical data underwent critical data analysis.

The study involved patients with a diagnosis of CRSwP. Patients in this subgroup of the population with Chronic Rhinosinusitis are infamously challenging to treat; following surgery, symptoms in both the objective and subjective domains often reappear. For this subset of patients, some surgeons may also use systemic steroids prior to, during, or following surgery.

Inclusion criteria

1. The chance to participate in the study was extended to adult patients (over the age of 18) who were scheduled to receive ESS for the treatment of their ailment.
2. The maximum age was 60.

Exclusion criteria

1. Age 18 years
2. Age of at least 60
3. People with Type 3 Diabetes
4. Hypertensive patients
5. Individuals with mucociliary problems and immunocompromised state were excluded.
6. The study excluded patients with allergic fungal rhinosinusitis (AFRS).

A randomized, placebo-controlled study was designed to assess how systemic steroids administered during surgery affected CRSwP patients' ability to recover. After a patient's eligibility for the trial was established, the patient was randomized to receive systemic steroids or a placebo for seven days before surgery and for fourteen days afterward before the steroids were

weaned down gradually. 30 milligrams were used as the dosage, and it was taken once a day with breakfast. The mild dosage utilized in this study was predicted to provide enough clinical activity, and any possible short-term side effects were considered to be tolerable. The multivitamin pills that served as the placebo and the actual medication had the identical outside appearance. Patients maintained taking the medication for two weeks following surgery. Following surgery, the patients and the placebo group received topical steroids. Six months of post-operative surveillance were spent.

First, details regarding the operation's complexity and the state of the sinonasal mucosa were acquired. Two more significant outcomes in terms of postoperative information were identified: objective data from nasal endoscopy and subjective assessment of the disease's effect on the patient.

It was noted how long it took and how much blood loss was anticipated. Prior to surgery, the state of the turbinate and nasal mucosa was also considered. A three-point rating system was used to make this assessment. After that, the surgeon estimates the number of sinuses opened and the extent of the disease removed.

Results

This study evaluates the impact of pre- and post-operative systemic steroids on surgical outcomes for patients receiving ESS for the treatment of CRSwP. It is a double-blind, placebo-controlled trial. We used both objective and subjective

measures of success. Finding out how steroid use influenced these measures of subjective and objective well-being was the main goal of the study.

Preoperative systemic steroids are frequently used by patients undergoing ESS for the treatment of CRSwP, with the rationale being that they will facilitate surgery. Reduced tissue stress, improved vision, and less blood loss are all beneficial outcomes. The goal of this study was to provide more data in an area where "best practices" are frequently arbitrary and uneven. The findings of this study demonstrate that surgical technical difficulty varies and that this variation has therapeutic significance.

Table 1: Duration of Surgery

Test	Minimum	41
	Maximum	121
	Median	61
Control	Minimum	56
	Maximum	131
	Median	56

Preoperative, intraoperative, and postoperative steroids have significantly reduced surgical blood loss. The average blood loss in the active group was 128 milliliters, compared to 164 milliliters in the placebo group. Table 1 indicates that the surgical procedure's overall efficiency might have been significantly impacted by the bloodless field. The table below shows that 64% of the placebo group and just 28% of the surgical test group suffered significant blood loss..

Table 2: Data on the Blood loss

Test/control		Frequency	Valid %	Cumulative %
Test	Valid	100	15	75.0
		200	5	25.0
		Total	20	100.0
Control	Valid	100	7	35.0
		200	13	65.0
		Total	20	100.0

These differences might have improved the test group's operating efficiency because they were deemed to be clinically significant. The notable

amelioration of sinonasal polyposis in these patients is indicative of the anti-inflammatory properties of steroids. It should be emphasized

that the greatest degree of illness clearance was only achievable in cases where steroids were administered perioperatively. The maxillary,

ethmoid, frontal, and sphenoid sinuses of every patient in the test group were all clear of disease.

Table 3: Number of Sinuses opened

Test/control		Frequency	%	Valid Percent	Cumulative %
test	Valid	10	20	100.0	100.0
control	Valid	4	11	55.0	55.0
		6	7	35.0	35.0
		8	2	10.0	10.0
		Total	20	100.0	100.0

The surgeon expressed dissatisfaction with the disease clearance observed in the remaining patients in the placebo group. Only the maxillary and ethmoid sinuses could be accessed by surgeons due to inadequate lighting and severe bleeding. The relationship between variables including surgical time, blood loss, mucosal health, and disease clearance should also be emphasized. Compared to the placebo group, the test group's median score for facial discomfort was much lower. There would also be a difference in the nasal drainage median score.

There are four members of the experimental group and eight members of the control group. The only symptom score where there is no discernible difference between the test group and the placebo group is the median score for headache. There are four individuals in the active group and five in the placebo group. This could be the outcome of multiple headache-causing variables coming together. Furthermore, the total symptom score shows a statistically significant difference between the groups.

Table 4: Data on Recurrent polyps

Test/control		Frequency	Percent	Valid %	Cumulative Percent
test	Valid	Absent	18	90.0	90.0
		Mild	02	10.0	10.0
		Total	20	100.0	100.0
control	Valid	Absent	16	80.0	80.0
		Mild	4	20.0	20.0
		Total	20	100.0	100.0

The risk of recurrence was assessed at six months. After two years, a follow-up endoscopic examination may increase its value. Table 4 indicates that the placebo group had a higher recurrence rate, which can be attributed to the disease's incomplete eradication.

Discussion

Patients with both sinonasal polyposis and chronic rhinosinusitis are treated with endoscopic polypectomy. This has been repeatedly and conclusively shown over many years. However, there has long been debate over the appropriate

usage and dosage of corticosteroids. This study centers on this controversy. Systemic steroids were administered in this trial using oral prednisolone tablets. Prednisolone, a glucocorticoid, is contained in the equivalent of around 100 mg in a depot injection. Take 30 mg of prednisolone orally every day for three weeks. Regrettably, no controlled dose-effect studies are currently available.

As to Lildhol, if systemic steroids are given for a short period of time, medicinal polypectomy can be just as successful as snare-based polypectomy. This investigation also supports the previous

assertion. For patients with severe illnesses, using steroids before to endoscopic surgery can significantly enhance surgical outcomes. The study has demonstrated this. The low likelihood of significant adverse effects may be outweighed by the treatment's potential advantages in patients with advanced illness.

Based on existing literature, intranasal steroids appear to be the most effective treatment for sinonasal polyposis. As of right now, a minimum of sixteen randomized, controlled studies (RCTs) have shown a noteworthy improvement in comparison to placebo. Not every patient responds well to topical steroid therapy. This might occur from the spray not being able to circulate evenly throughout the nasal passages due to a severely blocked nose. This is the real gold mine for endoscopic polypectomy.

While systemic and intranasal steroid therapy may not totally eradicate polyps, it will definitely reduce their size and mucosal inflammatory activity, which will facilitate surgery. We shouldn't expect any impact on polyps in the middle meatus, though, as just a small portion of spray reaches there. These critical areas must be opened during surgery to guarantee that the sinuses receive enough air. In this trial, fewer sinuses were surgically opened in the placebo group than was predicted; however, this effect was not observed in the prednisolone group. The surgeon noted that the discrepancy was caused by technical restrictions, particularly with regard to sight and bleeding, rather than by the absence of disease in the sealed sinuses. A statistically significant difference between the two groups was seen in the surgical examination of the sinonasal mucosa; the placebo group had considerably more cases of friable and inflamed mucosa than the test group.

Controlled studies have shown that using topical steroids after polyp ectomy surgery lowers the chance of polyp recurrence. However, the effects are only transient in cases of severe inflammation. The information acquired and examined in this study allows for the drawing of numerous conclusions pertinent to the research objectives. First off, by curing the illness, improving the health of the sinonasal mucosa,

and lowering bleeding during the surgery, pretreatment with systemic steroids seems to be able to make surgery easier. Because of this, there is sufficient evidence within the framework of evidence-based care to suggest that systemic steroids be administered prior to surgery to all patients undergoing ESS for CRSwP.

Second, systemic steroids are a superior postoperative treatment for symptoms such as headache, facial pain, nasal discharge, loss of smell, nasal obstruction, and overall discomfort. Third, if the goal of these patients' sinus surgery is to eventually develop an endoscopically healthy sinonasal cavity, then early post-operative systemic steroid administration leads to shorter-term improvements in sinus health. Thus, in the practice of surgeons who provide intensive postoperative care for patients post-ESS, including debridement and medical therapy based on the endoscopic findings, there is evidence to support the use of systemic steroids in the postoperative period to optimize the initial endoscopic appearance of the cavities.

Conclusion

Finally, using adjuvant steroids before surgery can reduce the incidence of postoperative complications such as crusting, synechiae formation, and scarring. This lessens the possibility of a recurrence as well.

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Nil

References

1. Anand VK. Epidemiology and economic impact of rhinosinusitis. *Ann OtoRhinoLaryngology Suppl.* 2004;193:3-5.
2. Bhattacharyya N. The economic burden and symptom manifestations of chronic rhinosinusitis. *Am J Rhinol.* 2003;17:27-32.
3. Michael Gleason, Scott Brown's *Otorhinolaryngology, Head and Neck Surgery*, Edition 7. Volume 2;1554-1555.

4. Kennedy DW, Shaman P, Han W, Selman H, Deems DA, Lanza DC. Complications of ethmoidectomy: a survey of fellows of the American Academy of Otolaryngology-Head and Neck Surgery. *Otolaryngol Head Neck Surg.* 1994;111:589-599.
5. Catalano PJ. Minimally invasive sinus technique: what is it? Should we consider it? *Curr Opin Otolaryngol Head Neck Surg.* 2004;12:34-37.
6. Chiu AG, Kennedy DW. Disadvantages of minimal techniques for surgical management of chronic rhinosinusitis. *Curr Opin Otolaryngol Head Neck Surg.* 2004;12:38-42.
7. Sindwani R, Wright ED, Janzen VD, Chandarana S. Peri-operative management of the sinus patient: a Canadian perspective. *J Otolaryngol.* 2003;32:155-159.
8. Gosepath J, Mann WJ. Current concepts in therapy of chronic rhinosinusitis and nasal polyposis. *ORL J Otorhinolaryngol Relat Spec.* 2005;67:125-136.
9. Jorissen M. Postoperative care following endoscopic sinus surgery. *Rhinology.* 2004;42:114-120.
10. Rowe-Jones JM, Medcalf M, Durham SR, Richards DH, Mackay IS. Functional endoscopic sinus surgery: 5 year followup and results of a prospective, randomised, stratified, double-blind, placebo controlled study of postoperative fluticasone propionate aqueous nasal spray. *Rhinology.* 2005;43:2-10.
11. van Camp C, Clement PA. Results of oral steroid treatment in nasal polyposis. *Rhinology.* 1994;32:05-09.
12. Boksenbaum M, Mendelson CG. Aseptic necrosis of the femoral head associated with steroid therapy. *JAMA.* 1963;184:262-265.
13. Lund VJ, Mackay IS. Staging in rhinosinusitis. *Rhinology.* 1993;31:183-184.
14. Lund VJ, Kennedy DW. Staging for rhinosinusitis. *Otolaryngol Head Neck Surg.* 1997;117:S35-S40.
15. Meltzer EO, Hamilos DL, Hadley JA, *et al.* Rhinosinusitis: Establishing definitions for clinical research and patient care. *Otolaryngol Head Neck Surg.* 2004;131(Suppl 6):S1-62.
16. Kennedy DW. Functional endoscopic sinus surgery. Technique. *Arch Otolaryngol.* 1985;111:643-649.
17. Gliklich RE, Metson R. Techniques for outcomes research in chronic sinusitis. *Laryngoscope.* 1995;105:387-390.
18. Bhattacharyya N. Clinical and symptom criteria for the accurate diagnosis of chronic rhinosinusitis. *Laryngoscope.* 2006;116(Suppl 7):1-22.
19. Vleming M, Middelweerd MJ, de VN. [Good results of endoscopic paranasal sinus surgery for chronic or recurrent sinusitis and for nasal polyps.] *Ned Tijdschr Geneesk.* 1993;137:1453-1456.
20. Kennedy DW, Wright ED, Goldberg AN. Objective and subjective outcomes in surgery for chronic sinusitis. *Laryngoscope.* 2000;110:29-31.
21. Metson RB, Gliklich RE. Clinical outcomes in patients with chronic sinusitis. *Laryngoscope.* 2000;110:24-28.
22. Senior BA, Kennedy DW, Tanabodee J, Kroger H, Hassab M, Lanza D. Long-term results of functional endoscopic sinus surgery. *Laryngoscope.* 1998;108:151-157.
23. Rosenfeld RM. Clinical research in otolaryngology journals. *Arch Otolaryngol Head Neck Surg.* 1991;117:164-170.
24. Sackett DL, Rosenberg WM. On the need for evidence-based medicine. *J Public Health Med.* 1995;17:330-334.
25. Erin D. Wright, MDCM, M Ed, Sumit Agarwal, MD. *The Laryngoscope journals.* 117; November 2007 Supplement; 1-28.
26. Sackett DL, Richardson WS, Rosenberg WM, Hayes RB. *Evidence-based Medicine: How to Practice and Teach EBM*, ed2. London: Churchill Livingstone; c2000.