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**Case Report**

# Itraconazole versus steroids in post operative cases of allergic fungal rhinosinusitis: a randomized controlled trial

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## ABSTRACT

This study was aimed to compare the effect of oral steroids and itraconazole in reducing the recurrence in allergic fungal rhinosinusitis (AFRS) patients undergoing ESS. In this randomized controlled trial, 50 patients of both sexes aged between 15-60 years with AFRS were subjected to functional endoscopic sinus surgery (ESS). In the post-operative period, patients were randomly divided into 2 groups containing 25 patients each. Group A received systemic steroid followed by topical steroid. Group B received oral itraconazole. Patients were followed at the end of 6, 10 and 14 weeks after surgery. Sinonasal outcome test 22 **(**SNOT-22) Lund Kennedy endoscopic score (LKES), AEC and serum total IgE were repeated at each post-operative visit and compared with the preoperative values. Repeat NCCT nose and PNS was done at 14$^{th}$ week to look for recurrence. Statistically significant difference was seen between the two groups in AEC, LKES and SNOT-22 with group A showing more significant improvement than group B, but not in serum IgE and Lund Mackay computed tomography (LMCT) score. The group A had 24% (n=6) recurrence rate, while group B had 44% (n=11) recurrence rate. The difference in the two groups in recurrence was not statistically significant. We evaluated multiple parameters including radiological and endoscopic scores to find the difference between the two drugs and found steroid to be superior than itraconazole.

**Keywords:** AFRS, Itraconazole, Antifungal, Steroid, FESS

## INTRODUCTION

Allergic fungal rhinosinusitis (AFRS) was first reported as a distinct clinical entity in 1976.[1] AFRS is coupled with the clinical entity of fungus ball (mycetoma) as a form of non-invasive fungal sinus disease, separate from and unrelated to invasive fungal sinus pathology. AFRS is a truly unique pathologic entity, defined largely by the presence of allergic fungal mucin, which is a thick, tenacious, eosinophilic secretion with characteristic histologic findings.[2] Since its initial characterization in the 1970s, AFRS has been the subject of much debate and controversy regarding its pathogenesis, diagnosis, classification, and optimal management.

Just as the understanding of the pathogenesis of this disease is evolving, so is the treatment protocol. There has been development of multimodality treatment algorithms, with surgical therapy remaining the cornerstone for this recidivistic disease. Meticulous and complete ESS is gold standard for the surgical extirpation of polypoidal disease, all allergic mucin and fungal debris, in an attempt to restore ventilation and drainage of sinuses.[3]

The use of steroids has been established as an essential medical remedy as an adjuvant to surgery as a result of their strong effect on the extent of inflammation.[4] The purpose of maintaining the patients on steroids for a long

period is to allow the mucous clearance mechanisms time to completely clear the sinuses from remnants of fungal hyphae not removed by surgery. Although topical nasal steroid sprays are preferred over oral steroids due to the ability of topical nasal steroids to achieve an effective drug concentration at the sinonasal mucosa without associated systemic side effects.[5]

AFRS is thought to share a similar pathogenesis with allergic broncho pulmonary aspergillosis (ABPA). Given that itraconazole has been shown to be effective in the management of ABPA, it seemed like an obvious proposition to try itraconazole for refractory cases of AFRS as a possible steroid-sparing drug.[6] Keeping in mind the etiological factor, antifungal treatment (itraconazole) has been tried in patients with AFRS aimed at better control of the disease by declining the recurrence rate of AFRS. Hypothetically, antifungal therapy may aid in decreasing the fungal burden by limiting fungal regrowth after surgery, thus reducing the antigenic load and subsequent hypersensitivity response in these allergic processes.[7-9]

The medical management of AFRS lacks consensus among otolaryngologists. Hence, this study was conducted to compare the effect of oral steroids and itraconazole in reducing the recurrence in AFRS patients undergoing ESS.

## CASE REPORT

This study was a prospective, randomized controlled study conducted in the department of ENT, government medical college and Rajindra hospital, Patiala on 50 subjects undergoing FESS for AFRS. The study was conducted over a period of 2 years from July 2018 to June 2020.

The study protocol was approved by the institutional review board for ethical clearance of government medical college and Rajindra hospital and it was performed in accordance with the code of ethics of the world medical association according to the declaration of Helsinki of 1975, as revised in 2000.

Inclusion criteria included adults of both sexes aged between 15-60 years with AFRS requiring bilateral FESS. Exclusion criteria included patients with history of previous sino-nasal surgery, invasive fungal rhinosinusitis, pregnant females, history of steroid use for conditions other than AFRS, immunocompromised patients and patients with known liver disease.

After selection of study subjects, all participants were properly informed about the tests that he/she would undergo and a written informed consent was taken. The symptom score was calculated using the 5-point Likert scale. Each patient was subjected to detailed clinical examination and diagnostic nasal endoscopy (DNE). Non contrast computed tomography scan nose and PNS (axial and coronal section) was done in all patients to look for extent of the disease. Absolute serum eosinophil count (AEC) and serum total IgE levels were also done. AEC count >500 cells/ml was considered as serum eosinophilia and serum total IgE levels values >100 U/ml were considered high. Preoperatively, LKES, SNOT 22 and LMCT (Lund Mackay computed tomography) scores were noted. SNOT 22 was the primary outcome measure, and LKES and LMCT were secondary. FESS was done to remove all the polyps and sufficiently widen the natural ostia of all the effected sinuses to allow access for topical medication.

In the post-operative period, patients were randomly divided into 2 groups containing 25 patients each. The allocation of groups was randomized. It was done discreetly by the resident doctor as per instructions from the primary investigator and this information was concealed from both, the primary investigator and the operating surgeon. This information was sealed by the resident in an envelope which was opened at the end of the post-operative data collection. In group A, consisting of 25 patients, systemic steroid (Prednisolone per oral 0.5 mg/kg od) was given for one week and tapered over the next three weeks. Thereafter topical steroid (fluticasone propionate aqueous nasal spray, two puffs in each side twice daily) was continued for 11 weeks. In group B consisting of 25 patients, oral antifungal (itraconazole 200 mg bid) was given for four weeks and thereafter maintenance dose (100 mg bid for 10 weeks) was continued.

All the patients were provided standard post-operative care during the first month. In the first week, course of antibiotics and antihistamines was given, thereafter saline nasal douching was advised. Patients were followed at the end of 6, 10 and 14 weeks after surgery. At each visit, subjective and objective assessments using SNOT-22 and LKES were carried out to compare the difference in outcome between the treatment and control groups. AEC and serum total IgE were repeated at each post-operative visit and compared with the preoperative values. Repeat non contrast CT nose and PNS was done at the end of fourteen weeks to look for recurrence of disease.

The sample size was estimated based on previous study, using the formula: $n= z^2_{(1-\alpha/2)}*SD^2/(d)^2$, where n=sample size; Z=1.96; d=5; SD=16. Data was analysed using microstate statistical program and correlation frequencies were calculated. Statistical analysis was done using the chi square test with a significance level of $p<0.05$.

This study consisted of 25 patients in both groups. Group A: patients who received steroid postoperatively had mean age of 34.80±15.63 years with a range of 17-60 years. Group B: patients who received itraconazole also had 25 patients with mean age of 33.24±13.76 years and range of 19-60 years (Table 1).

Group A had male preponderance with 15 patients being males and 10 being females. Group B had female preponderance with 14 patients being females and 11 males (Table 1).

Amongst presenting symptoms, the mean Likert score was calculated for nasal obstruction, post nasal discharge, hyposmia/ anosmia and facial pain. There has been consistent decrease in the all the symptoms in the post op visits. The difference between the two groups was statistically significant in the post-operative evaluation at 14 weeks only for nasal obstruction and post nasal discharge with group A having a significant reduction than group B (p=0.020 and 0.015 respectively) (Table 2).

The mean AEC count in group A at baseline was 634.40±226.59, at 6th week it was 575.76±191.81, at 10th week was 510.28±174.00 and 385.76±132.16 at 14th week. The reduction in AEC count at individual visits compared to baseline was statistically highly significant (p=0.001). In group B, at baseline, the mean AEC values were 477.32±203.95. At 6th week, the mean AEC value was 431.40±170.66, at 10th week 407.20±150.32 and 361.80±116.66 at 14th week. The reduction of AEC counts from baseline at individual post-op visits was statistically significant (p=0.001). The difference between the two groups was statistically significant at baseline (p=0.013), post-op 6th (p=0.007) and 10th week (p=0.030) but not at 14th week (p=0.500).

The levels of serum IgE also showed a progressively decreasing trend at all post-op visits which was highly statistically significant (p=0.001). However, the difference between the two groups was not statistically significant. The mean serum IgE levels were 628.48±213.13 pre-operatively, post-operatively at 6th week was 562.84±188.25, at 10th week was 496.72±167.58 and 428.12±136.30 at 14th week in group A; and 633.08±223.29 at baseline, 569.80±194.59 at week 6, 523.88±178.07 at week 10 and 449.52±133.39 at week 14 in group B.

Subjective improvement was assessed at the last follow up visit (week 14). It was found to be similar in the two groups as the difference between the two groups was statistically not significant (p=0.95) (Figure 1).

The reduction in SNOT-22 at each post-operative visit compared to baseline was highly statistically significant (p=0.001) in both groups. On comparing the two groups with each other, the difference was significant only at 14 weeks, showing that the patients in steroid group had better reduction in SNOT-22 scores (p=0.030) (Table 3).

The LKES showed consistent reduction at each visit. There was reduction seen in LK scores post-operatively and the difference at each visit was statistically highly significant (p=0.001) in both the groups. On comparing the two groups at each visit, the difference was non-significant at 6th and 10th week but it was significant at the last visit) (p=0.011). Group A was seen to have a statistically more significant reduction than group B (Table 4).

The mean LMCT score was 14.840±6.005 pre-operatively and 0.840±1.599 post-operatively at 14th week in group A; and 11.600±5.766 pre-operatively, 1.840±3.145 post-operatively at 14th week in group B. The mean reduction in LMCT scores postoperatively was 94.34% in group A and 84.14% in group B as compared to baseline. The difference was statistically significant in both groups (p=0.001) (Table 5). However, the mean LMCT score at postoperative week 14 between the two groups was statistically not significant (Table 6).

The group A had 24% (n=6) recurrence rate, while group B had 44% (n=11) recurrence rate. The difference in the two groups was not statistically significant (p=0.546).

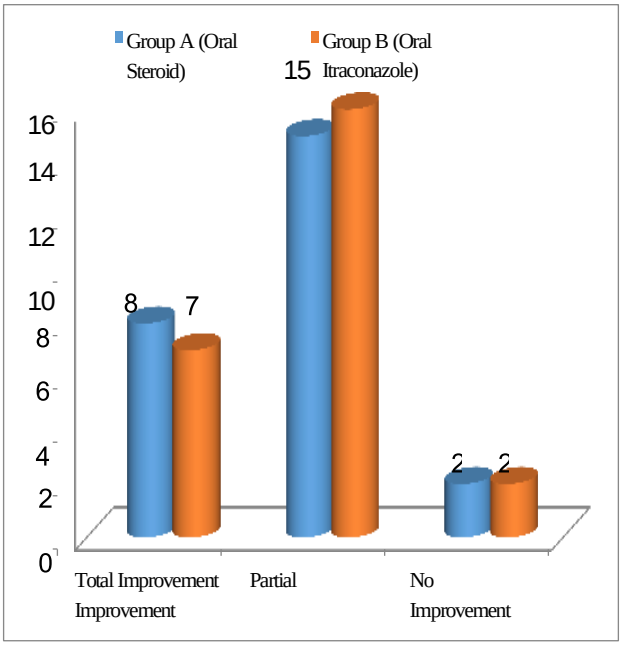


**Figure 1: Subjective improvement in symptoms in both groups.**

**Table 1: Age distribution.**

| Variables | Group A, (Oral steroid) | | Group B, (Oral itraconazole) | |
|---|---|---|---|---|
| | N | % | N | % |
| **Age (years)** | | | | |
| 16-30 | 14 | 56 | 16 | 64 |
| 31-45 | 6 | 24 | 5 | 20 |
| ≥46 | 5 | 20 | 4 | 16 |
| Total | 25 | 100 | 25 | 100 |
| Mean ± SD | 34.80±15.63 | | 33.24±13.76 | |
| **Gender** | | | | |
| Female | 10 | 40 | 14 | 56 |
| Male | 15 | 60 | 11 | 44 |
| Total | 25 | 100 | 25 | 100 |

**Table 2: Mean Likert score.**

| Variables | Group A, (Oral steroid) | Group B, (Oral itraconazole) | P value (<0.05) |
|---|---|---|---|
| **Nasal obstruction** | | | |
| Pre-op | 4.32 | 3.60 | 0.054 (NS) |
| Post op 6 weeks | 1.84 | 1.56 | 0.325 (NS) |
| Post op 10 weeks | 1.52 | 1.44 | 0.765 (NS) |
| Post op 14 weeks | 0.64 | 1.40 | 0.020 (S) |
| **Post nasal discharge** | | | |
| Pre-op | 4.04 | 3.32 | 0.067 (NS) |
| Post op 6 weeks | 1.60 | 1.44 | 0.651 (NS) |
| Post op 10 weeks | 1.36 | 1.44 | 0.807 (NS) |
| Post op 14 weeks | 0.52 | 1.36 | 0.015 (S) |
| **Hyposmia/anosmia** | | | |
| Pre-op | 2.72 | 1.68 | 0.060 (NS) |
| Post op 6 weeks | 1.20 | 1.00 | 0.586 (NS) |
| Post op 10 weeks | 1.20 | 0.92 | 0.446 (NS) |
| Post op 14 weeks | 0.72 | 1.00 | 0.426 (S) |
| **Facial pain** | | | |
| Pre-op | 2.72 | 1.68 | 0.060 (NS) |
| Post op 6 weeks | 1.20 | 1.00 | 0.586 (NS) |
| Post op 10 weeks | 1.20 | 0.92 | 0.446 (NS) |
| Post op 14 weeks | 0.72 | 1.00 | 0.426 (S) |

**Table 3: SNOT 22.**

| Variables | Group A, (Oral steroid) | Group B, (Oral itraconazole) | P value (<0.05) |
|---|---|---|---|
| **Pre-op** | 38.64 | 32.12 | 0.086 (NS) |
| **Post op 6 weeks** | 19.72 | 23.60 | 0.215 (NS) |
| **Post op 10 weeks** | 17.12 | 22.28 | 0.097 (NS) |
| **Post op 14 weeks** | 13.84 | 20.92 | 0.030 (S) |

**Table 4: Lund Kennedy endoscopy score.**

| Variables | Group A, (Oral steroid) | Group B, (Oral itraconazole) | P value (<0.05) |
|---|---|---|---|
| **Pre-op** | 7.96 | 6.68 | 0.103 (NS) |
| **Post op 6 weeks** | 3.36 | 2.56 | 0.185 (NS) |
| **Post op 10 weeks** | 2.44 | 3.00 | 0.388 (NS) |
| **Post op 14 weeks** | 1.44 | 3.64 | 0.011 (S) |

**Table 5: Comparison of LMCT scores at visit 3 from baseline.**

| Variables | LMCT score | Mean | SD | Percentage reduction | P value (<0.05) |
|---|---|---|---|---|---|
| **Group A (Oral steroid)** | Pre op | 14.840 | 6.005 | 94.34% | 0.001 (S) |
| | Post op | 0.840 | 1.599 | | |
| **Group B (Oral itraconazole)** | Pre op | 11.600 | 5.766 | 84.14% | 0.001 (S) |
| | Post op | 1.840 | 3.145 | | |

**Table 6: Comparison of LMCT score reduction between the two groups.**

| LMCT score | Mean | SD | Percentage reduction | P value (<0.05) |
|---|---|---|---|---|
| **Group A, (Oral steroid)** | 0.840 | 1.599 | 54.35% | 0.163 (NS) |
| **Group B, (Oral itraconazole)** | 1.840 | 3.145 | | |

## DISCUSSION

Over the past 2 decades, AFRS has become increasingly defined, and it is now believed to represent an allergic reaction to aerosolized environmental fungi, usually of the dematiaceous species, in an immunocompetent host.[2] Persistence of AFRS with a recurrence of sinonasal symptoms is common, particularly when eradication of allergic fungal mucin has been incomplete. Recurrence can occur even when a patient is clinically disease-free,

presumably as a result of re-exposure to fungal antigens.[10]

Treatment of AFRS is conflicting. Different treatment protocols have been adopted in the past decade to overcome recurrence of this disease. It is known that steroids whether systemic and/or topical increase the cure rates of AFRS by decreasing the recurrence with reduction of mucosal stage of the disease. Steroids are known to be the main line of treatment for AFRS. However, their prolonged use especially systemic steroid is associated with many adverse effects. In addition, there are some patients who do not respond to this treatment. So, some authors have tried to decrease the recurrence rate of AFRS by using antifungal therapy, which acts by inhibiting the fungal growth in the postoperative period with different results. Keeping in mind the etiological factor of AFRS, antifungal treatment has been tried in many patients with AFRS for better control of the disease and for less recurrence rate.[11-14] The role of antifungal treatment in the management of AFRS is still controversial, but some studies found good results with systemic use of itraconazole.

***Improvement of symptoms and patient satisfaction (Likert score)***

At the end of follow up period of 14 weeks, patients experienced significant reduction in all Likert symptom scores in both the groups. When compared between the two groups, significant improvement was seen in the steroid group than the itraconazole group at 14 weeks. Reda et al observed that in group A (local steroid), postoperatively all patients were clinically asymptomatic at the end of the first and the third month.[15] At the sixth month, five patients started to complain of nasal obstruction. In group B (local steroid plus oral itraconazole), all patients were clinically asymptomatic at the end of the sixth month postoperatively.

In study conducted by Dhote et al complete resolution of symptoms was seen more promptly in patients of group A (topical steroid plus oral itraconazole) than in group B (topical steroids).[16] Similar results were seen in our study. Patients in the steroid group showed comparatively better improvement and satisfaction in the post op period and overall treatment. However, the difference between the two groups was statistically non-significant. Rojita et al also observed similar results where both the groups had improvement of symptoms and overall satisfaction scores were also statistically non comparable.[14] It is difficult to determine which of the two: steroid or itraconazole are better in post op management of AFRS with current knowledge. Further long-term studies are needed to evaluate effectiveness of both these treatment regimens.

***Evaluation of absolute eosinophil count and serum IgE***

Eosinophilia is observed to be one of the minor criteria useful for diagnosis of AFRS.[17] In our study, the AEC and S. IgE were examined at baseline, 6th, 10th, and 14th week. We observed that the effect of steroid and itraconazole in reducing the serum IgE levels in the post-op period was similar, but steroid was superior to itraconazole in reducing AEC.

Verma et al showed that the decrease in the IgE values in group 1 (who received preop itraconazole) were significantly higher than that of group 2 (who received postop itraconazole) (p=0.003).[18] Rojita et al measured both AEC and serum IgE both preoperatively and postoperatively and found no significant difference in the two groups.[14]

***Evaluation of SNOT-22***

According to the 2012 European position paper on rhinosinusitis and nasal polyps, SNOT-22 is a good tool for assessing QOL in patients with CRS. Moreover, it can be used repeatedly and produces graphics (SNOTgrams) with SNOT-22 scores for more than a given moment in time, which clearly display the result of medicinal and surgical interventions and exacerbations over time.[19]

In group A, the difference in SNOT-22 scores at each visit compared to baseline was highly statistically significant (p=0.001). In group B as well, the difference at each visit was highly significant (p=0.001). On comparing the two groups in terms of improvement of SNOT-22 score, the difference was non-significant at baseline, 6 weeks and 10 weeks, but at 14 weeks, the difference was slightly significant which shows that patients in steroid group had better reduction in SNOT-22 scores. Verma et al showed no difference in terms of the SNOT scores obtained at 12th week (Mean difference=2.38, p=0.27) and 24$^{th}$ week (Mean difference=0.26, p=0.88) postoperatively between those who received itraconazole (group 1 and 2) and those in the control group (group 3).[18] Rojita et al all also compared the SNOT-22 scores between the two groups. 35% (10) of the patients in Group A (oral steroid) and 42% (12) in group B (oral itraconazole) were clinically asymptomatic at the end of six months and but no significant difference was noted between the two (p=0.536).[14]

***Evaluation of LKES***

Among objective measures of disease burden, radiologic and endoscopic scoring systems have been the primary foci of outcomes of research. In 1995, Lund and Kennedy, heading the staging and therapy group for chronic rhinosinusitis, proposed the LKES system based on degree of scarring, crusting, edema, polyps, and discharge.[20]

In our study, on comparing the two groups at each visit, the difference was significant at the last post-operative visit showing superiority of steroid over itraconazole. Verma et al found significant difference between the

groups receiving itraconazole and control group in terms of nasal endoscopy grades at 12th week (1.20±0.756 in itraconazole users and 1.86±1.34 among controls, mean difference=0.66, t=3.03, p=0.003), suggesting that itraconazole has a significant effect on the post-operative management in cases of AFRS.[18] However, the use of oral steroids in both cases and controls confounds the effect of itraconazole. Rojita et al compared the endoscopy scores between the steroid and itraconazole group using the Kupferberg endoscopic grading.[14] They found that the reduction in the endoscopy scores between the two groups was statistically non-significant post-operatively, suggesting that the effect of steroid and itraconazole in reducing the endoscopy scores seems to be similar in the post-operative period. There are not many studies which have examined the post-operative use of steroid and itraconazole.

***Evaluation of Lund Mackay radiological score***

LMCT score was assessed as part of diagnostic criteria of chronic rhinosinusitis according to European position paper on rhinosinusitis and nasal polyps.[19,21] Preoperative radiological scores were assessed and there was non-significant difference between the two groups which exhibits that the disease severity was equivalent in both the groups preoperatively and results were impartial. These scores were compared with LMCT scores at 14 weeks post-operative period and there was significant reduction in the scores of the two groups, however, there was no significant difference between the two (p=0.163). This shows that both steroids and itraconazole are equally effective in maintaining low CT scores in the postoperative period. Verma et al found that the LMCT scores were significantly better in group 1 (preoperative oral itraconazole) compared to group 2 (postoperative itraconazole) at 12th week (p=0.05).[18] But at 24th week postop, it was not statistically significant (p=0.21). However, in this study, all the patients were also administered oral steroids in the post-operative period, so it is difficult to comment weather the reduction in LM scores at 12th week was due to the effect of itraconazole or oral steroids.

***Evaluation of recurrence***

In our study, the recurrence rate in group A was 24% while in group B, it was 32%. Even though the recurrence rate was higher in the itraconazole group, the difference between the two groups was statistically insignificant. Rojita et al reported findings similar to our study at the end of 6 month follow up period.[14] Reda et al compared effect of itraconazole with postoperative intranasal steroid spray and reported no recurrence at the end of six months.[15] We conclude in our study that both steroids and itraconazole have almost equal recurrence rates and one cannot be preferred over the other for post-operative care after ESS. In spite of the encouraging postoperative results, a significant proportion of the patients usually present with recurrence of disease even in the early postoperative period as described by Marple et al which was ranged from 10% to nearly 100%.[22] The causes for failure after ESS are multipronged ranging from poor surgical technique on the surgeon's part and failure to comply with the postoperative instructions by the patient. A massive effort has been made in the world literature to evaluate these factors and find the best possible regimen that can reduce these recurrence rates and save the patient from multiple revision surgeries.

***Limitations***

Few limitations of our study were low sample size and shorter duration of follow up. This study was done for a limited period of around two years so the patients were followed up for narrow window of time. Patients need to be followed up for longer duration of time in further studies to look for the effect of these drugs in long term recurrence.

## CONCLUSION

In conclusion, both steroids and itraconazole are effective in reducing the recurrence in postoperative period after ESS. Very few studies have compared steroid and itraconazole in post-op period. We evaluated multiple parameters including radiological and endoscopic scores to find the difference between the two drugs and found steroid to be superior than itraconazole. However, further studies with larger patient population are required to ascertain which of the two has better efficacy.

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