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A comparative study on the effectiveness of budesonide nasal irrigation versus normal saline nasal irrigation in post endoscopic sinus surgery patients

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ABSTRACT

Objective: Comparative studies evaluating budesonide and saline nasal irrigations for patients with polyposis/ rhinosinusitis are deficient in the current literature. This study aimed to evaluate the effectiveness of budesonide nasal irrigations compared with saline irrigations during postoperative care of patients with rhinosinusitis.

Materials and Methods: A total of 100 patients who underwent functional Endoscopic Sinus Surgery (ESS) were randomly divided into two groups (A and B) of 50 participants each (normal saline [NS] + budesonide irrigation and NS irrigation alone, respectively). Pre- and post operative evaluation was done with a 22-item sinonasal outcomes test (SNOT-22), and Lund Kennedy endoscopic (LKE scores) in second and sixth week.

Results: The condition of the patients significantly improved in both intervention arms related to SNOT-22 and LKE score at each postoperative visit (Group A: $p<0.001$, Group B: $p<0.001$). The reduction of SNOT 22 score was higher in budesonide group by 10% (mean SNOT 22 score from 33.31 to 15.84) compared to normal saline group (mean SNOT 22 score from 37.49 to 22.24). The reduction of LKEscore was higher in budesonide group by 18.69% (mean LKE score from 4.49 to 2.71) compared to normal saline group (mean LKE score from 5.02 to 4).

Conclusion: Steroid nasal irrigation is a good option in postoperative EES patients. The difference of reduction of both SNOT 22 score and LKEscore was statistically significant ($p <0.05$ and $p<0.01$ respectively) by repeated contrast test. This study is one of the few comparative studies evaluating budesonide and saline nasal irrigations in post-ESS patients.

1. Introduction

Chronic rhinosinusitis represents a significant disease burden worldwide, affecting at least 5 to 12% of the population and consequently carrying a substantial economic burden to healthcare systems, patients, and the economy from loss of productivity in the workplace.[1] The annual incidence of Chronic rhinosinusitis with nasal polyposis is between 1 and 20 per 1000 population in India. Chronic rhinosinusitis (C.R.S.) lasts for 12 weeks or more without complete resolution of the symptoms.[2] Management of chronic rhinosinusitis with nasal polyposis can be achieved by surgical removal of polypoid mucosa of all paranasal sinuses by functional endoscopic sinus surgery, followed by the use of topical steroids for suppressing the immune response either in form of spray or as irrigation. Topical steroids are the preferred maintenance strategy due to the reduced risk of potential systemic side-effects with prolonged therapy and increased concentrations applied to the diseased tissue, especially after Endoscopic sinus surgery. Topical steroid sprays may not deliver an adequate dose of the drug to the entire postoperative nasal cavity

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due to the presence of mucosal secretions, edema, crusting, and scarring. Budesonide nasal irrigation can solve this problem by delivering drugs in a high-volume high-pressure system.[3–5] However, normal saline nasal irrigation alone has been effective in few studies compared to budesonide nasal irrigation.[6–8]

Budesonide with normal saline nasal irrigation in post functional endoscopic sinus surgery patients is studied to know its additional benefit over normal saline irrigation and its control over disease recurrence and in reducing the need for revision surgery. The study aims to analyze whether the addition of budesonide to normal saline for nasal irrigation in patients subjected to functional endoscopic sinus surgery is more effective subjectively and objectively compared to normal saline nasal irrigation.

2. Materials and Methods

It is a prospective, single-blinded randomized controlled trial study. Those patients who underwent functional endoscopic sinus surgery in the Government General hospital were included in this study between January 2019-June 2020. Current study granted ethical approval by the Institutional Ethics committee at Govt. general hospital, Rajiv Gandhi Institute of Medical Sciences, Kadapa, Andhra Pradesh, India (dt. 19.01.2019)

2.1. Inclusion criteria

Patients between age 18 and 60 years, and those who undergo Endoscopic sinus surgery for chronic rhinosinusitis with nasal polyps during the study period.

2.2. Exclusion criteria

Patients who were on concomitant use of oral steroids (patients with bronchial asthma, autoimmune disorders), patients with known hypersensitivity to corticosteroid, and Immunocompromised patients.

A sample size of 100 patients was enrolled in the study and divided into two categories. Randomization was done by a computerized random number generator, at the time of his or her pre-operative visit. Ten patients were lost during follow-up. Each category had 45 patients.

Category A includes patients using Budesonide with normal saline for nasal irrigation postoperatively (2 respules of budecort (2 mg) mixed in 500 ml normal saline given twice a day with 10 ml syringe, 10 ml on each side).

Category B patients include normal saline for nasal irrigation postoperatively (10 ml of normal saline in each nasal cavity, twice daily).

Each category's outcomes were assessed using SNOT 22 score and LKE score at the second week and sixth week.

Statistical analysis: SNOT-22 score/LKE score was given in mean and standard deviation. The similarity of demographic distribution among category A and category B was tested using the chi-square test. Quantitative variables difference between Category A and Category B was assessed using an independent student t-test. Quantitative differences between Pretest, posttest 1 and posttest 2 were assessed using one-way repeated measures analysis of variance F-test/ two way repeated measures analysis of variance F-test and Posthoc multiple comparisons were conducted using Bonferroni t-test. Association between demographic variables and SNOT-22 score/LKE score was analyzed using one-way analysis of variance F-test and independent student t-test. A p-value of ≤ 0.05 was considered statistically significant, and two-tailed tests were used for testing significance. SPSS ver 22(SPSS Inc, IL, USA) and STATA (version10) software were used for statistical analysis.

3. Results

3.1. Demographics

Major age group in both categories was between 21-30 years, which was observed as 37.7% and 46.6% in group A and group B. Statistically age group wise there is no significant difference between the groups ((χ2=7.70 p=0.10 (NS)). There were 60% and 48.89% in group A, and group B were males. The similarity of gender distribution between the groups is assessed, there is no significant difference between the groups (χ2=1.12p=0.29 (NS).

Clinical diagnosis in post functional EES: C.R.S. with bilateral sinonasal polyposes noted in category A was 26(57.78%) and 24(53.33%) in category B. Left DNS with chronic rhinosinusitis with nasal polyp (CRSwNP) in 4(8.89%) and 6(13.33%)cases in category A and category B. Right DNS with CRSwNP 5(11.11%) and 4(8.89%) cases in category A and category B. CRS with right sinonasal polyposis is noted in category A was 3(6.67%), and 4(8.89%) in category B. betweenPostoperativeSNOT-22scoreandSNOT22patient's Demo graphic variablesage, in category A (F=1.32P=0.28).Still, there is a significantassociation A (t=2.02P=0.05). Female patients have reduced scores more than male patients. It was tested using one-way analysisof variance F-te stand independent studentt-test.

3.2. Association between postoperative SNOT-22 score and demographics

There is no association between the Postoperative (6th week) SNOT-22 score and patient's age in the normal saline group (F=0.20 P=0.93). There is a significant association between the postoperative (6th week) SNOT-22 score and patients' gender in Budesonide with the normal saline group. Male patients are reduced more score than female patients (t=2.07 P=0.04)(one-way ANOVA F-test and student t-test).

SNOT-22 score preoperatively, there is no significant difference between category A and category B in post functional EES patients (t=0.23 p=0.82). Postoperative (2nd week) and postoperative (6^{th} week) SNOT-22 score difference is statistically significant (t=5.9, p=0.01)(Table 1).

3.3. Comparison of mean SNOT-22 score

In the experiment group, Repeated measures one-way analysis of variance F-test shows that the mean overall SNOT-22 score is statistically significant between preoperative and posttest (6^{th} week)(F=1420.29, P≤0.001). In preoperative, they have a 60.24 score, and in postoperative (6^{th} week), they have a 15.84 score, so the difference is 44.40. This difference is statistically significant. Therefore, category A reduces more SNOT-22 score significantly. In the control group, Repeated measures ANOVA F-test shows that the mean overall SNOT-22 score is statistically significant between preoperative and posttest (6^{th} week)(F= 687.22, P ≤ 0.001). Preoperatively, they have a 60.60 score, and in postoperative (6^{th} week), they have 22.24 scores, so the difference is 38.36. This difference is statistically significant. Therefore, category B reduces the SNOT-22 score significantly but less in category B (Table 2).

3.4. Multiple comparison of SNOT-22 score

In category A, Repeated measures ANOVA F- test shows that mean SNOT-22 score difference is statistically significant between Preoperative, Postoperative (6^{th} week) (F=1420.29, p ≤ 0.001). Posthoc multiple comparisons of Bonferroni t-test show the SNOT-22 reduction score from Preoperative to 2nd week (60.24 ± 8.01 vs. 33.31 ± 6.17, respectively is 26.93), which was statistically significant (p≤ .001). After the 6th week, Budesonide with normal saline further reduces the SNOT-22 score (60.24 ± 8.01 vs. 15.84 ± 4.25, respectively, mean difference is 12.83), which was statistically significant reduction from Pretest to posttest 6th- week score (p≤0.001). Therefore, we can conclude that category A reduces the SNOT-22 score significantly (Table 3). A,Repeated measures ANOVA F- test shows that mean SNOT-22 scoredifference is statistically significant between Preoperative, Postoperative (6th week)(F =687.22,p≤0.001).

Post hoc multiple comparisons of Bonferroni t-test show the SNOT-22 reduction score from Preoperative to 2nd week (60.60 ± 6.80 vs. 37.49 ± 7.98, respectively is 23.11), which was statistically significant (p≤0.001). After the 6^{th} week, normal saline further reduces the SNOT- 22 score (60.60 ± 6.80 vs. 22.24 ± 5.91, respectively mean difference is 38.37), which was a statistically significant reduction from Pretest to posttest 6^{th} week score (p≤.001). Therefore, we can conclude that normal saline reduces the SNOT-22 score significantly but less than category B (Table 3).

3.5. SNOT-22 score during Pre-OP, PostOP-1, and PostOP-2

The mean SNOT-22 for category A was found to be 60.24 before the intervention. After the intervention, the SNOT-22 score was reduced to 33.31 scores after the 2nd week and further reduced to 15.84 scores after the 6th week. Among category B, the mean score was 60.60, 37.49, and 22.24 at the Pretest, posttest-1, posttest-2.

3.6. ANOVA of last variable as repeated measure

To ascertain whether improvement in the two groups is statistically different at all the three assessments, a 2x3 ANOVA test with the last variable as the repeated measure was applied. The significant P value of ≤ 0.001 "between groups" comparison shows that the two groups are statistically significantly different concerning the SNOT-22. It indicates that, in general, SNOT-22 of category A had been different from the category B group (Table 4)(Figure 1).

To get more details on which assessment the difference occurs between the category A and category B group, the "Within comparison" procedure was carried out. The "Assessment" comparison P-value of <0.001 shows that the mean SNOT-22 has been reduced from preOP to 6th week in both groups. To know when the changes occurred, i.e., in which assessment the change is significant, "Repeated Contrast test" was applied. The significant P value of the two comparisons, namely PreOP-2nd week, 2nd week-6th week, indicates that in both the groups and in all the three assessments, there is a reduction in the SNOT-22 score from PreOP-2nd week and 2nd week -6th week.

The comparisons between PreOP -2nd week and 2nd week -6th week shows that in category A, the SNOT-22 Reduction score has been more compared to category B. The above finding indicates that category A was more effective in reducing SNOT-22 score than category B.

3.7. LKE score

Considering LKE score in preoperative, there is no significant difference between category A and category B in post functional endoscopic sinus surgery patients (t=1.10 p=0.28). Still, in postoperative (2nd week) and postoperative (6th week), LKE score difference is statistically significant (t=9.66 p=0.001). It was calculated using a Student independent t-test.

In category A, Repeated measures one-way analysis of variance F-test shows that mean overall LKE score is statistically significantly different between preoperative and posttest(6th week)(F = 887.67, P ≤ 0.001). In preoperative, they have a 7.76 score, and in postoperative (6th week), they have a 2.53 score, so the difference is 5.05. This difference

is statistically significant. Therefore, we can conclude that category A reduces more LKE score significantly (Figure 2).

In category B, repeated measures one-way analysis of variance F-test shows that mean overall LKE score is statistically significantly different between preoperative and posttest(6th week)(F = 624.19, P ≤ 0.001). In preoperative, they have a 7.91 score, and in postoperative (6th week), they have 4.00, so the difference is 3.91. This difference is statistically significant. Therefore, we can conclude that category B reduces LKE score significantly but less reduction score than category B.

3.8. Multiple comparisons of LKE score

In category A, Repeated measures ANOVA F- test shows that mean LKESCORE difference is statistically significant between Preoperative, Postoperative (6th week)(F = 887.67, p ≤ 0.001). Post hoc multiple comparisons of Bonferroni t-test shows the LKE score reduction score from Preoperative to 2nd week (7.76 ± 0.66 vs. 4.49 ± 0.92, respectively mean difference is 3.27), which was statistically significant (p≤ .001). After the 6th week, category A further reduces the LKE score (7.76 ± 0.66 vs. 2.71 ± 0.76, respectively difference is 5.05), which was a statistically significant reduction from Pretest to post test 6th-week score (p≤ .001). Therefore, we can conclude that category A reduces the LKE score significantly. category, repeated measures ANOVAF-test shows that mean LKE score differen ceisstatistically significant between Preoperative, Postoperative (6thweek) (F=p≤0.001).

Post hoc multiple comparisons of Bonferroni t-test shows the LKE score reduction score from Preoperative to 2nd week (7.91 ± 0.60 vs. 5.02 ± 0.75, respectively mean difference is 2.89), which was statistically significant (p≤ .01). After the 6th-week, category B further reduces the LKE score (7.91 ± 0.60 vs. 4.00 ± 0.48, respectively mean difference is 3.91), which was a statistically significant reduction from Pretest to post-test 6th week score (p≤0.001). Therefore, we can conclude that category B reduces the LKE score significantly but less than category A.

3.9. Mean LKE score during preoperative, postoperative

The mean LKE score for category A was found to be 7.76 before the intervention. After the intervention, the LKE score was reduced to a 4.49 score after the 2nd week and further reduced to a 2.71 score after the 6th week. Among category B, the mean score was 7.91, 5.02, and 4.00 at the Pretest, posttest-1, posttest-2.

3.10. ANOVA with last variable as repeated measure test for LKE score reduction

The ANOVA test results are shown in Table 6. The significant P value of ≤ 0.001 "between groups" comparison shows that the two groups are statistically significantly different concerning the LKE score. It indicates that, in general, the LKE score of category A had been different from category B (Table 6).

"Within comparison" procedure was carried out between category A and category B. The "Assessment" comparison P-value of <0.001 shows that the mean LKE score has been reduced from preOP to 6th week in both groups. To know when the changes occurred, i.e., assessing the change is significant, "Repeated Contrast test" was applied. The significant P value of the two comparisons, namely PreOP – 2^{nd} week, 2^{nd} week -6^{th} week, indicates a reduction in the LKE score in both the groups and all three assessments from PreOP -2^{nd} week, and 2^{nd} week -6^{th} week.

The reduction of LKE score was statistically significantly different for the two groups. To understand which assessment, the changes differ between the two groups, the "Repeated Contrast test" was applied. The corresponding P-value of the two comparisons between PreOP -2nd week and 2^{nd} week -6^{th} week shows that in Category A, the LKE score Reduction score has been more compared to category B. The above finding indicates category A was more effective in reducing LKE score than category B

3.11. Association between postoperative LKE score and demographics

There is no association between Postoperative (6th week) LKE score and patient's age in category A. There is a significant association between Postoperative (6th week) LKE score and patient's gender in category A(t=2.02 P=0.03). Male patients are reduced more score (2.44±0.85) than female patients (2.89±0.51). It was tested using one-way analysis of variance F-test and independent student t-test. Whereas, there is no association between Postoperative (6th week) LKE score and patient's demographic variables age and gender in category B(F=0.20 P=0.93). It was tested using one-way analysis of variance F-test and independent student t-test.

4. Discussion

In the present study, age group between 21 to 30 years had the highest number of patients with chronic rhinosinusitis who underwent functional endoscopic sinus surgery. However, age group wise statistically there was no significant difference between groups. Similar results observed in other studies.[4–9] In the present study, there was male preponderance in budesonide with normal saline nasal irrigation group and female preponderance in normal saline nasal irrigation group. Similar results observed in other

studies.[6–11]

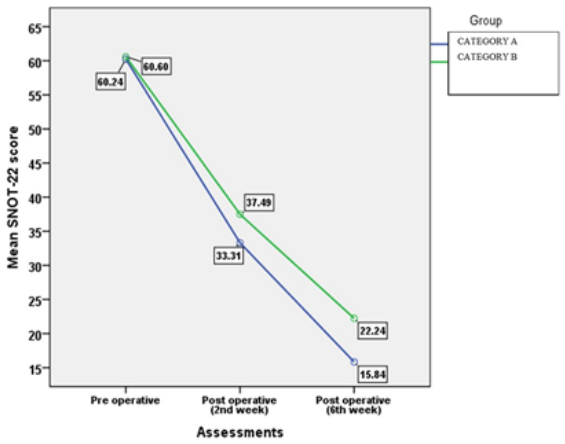

Fig. 1: The line graph shows the preoperative, postoperative (2nd week), and postoperative (6^{th} week) SNOT-22 score of category A and category B.

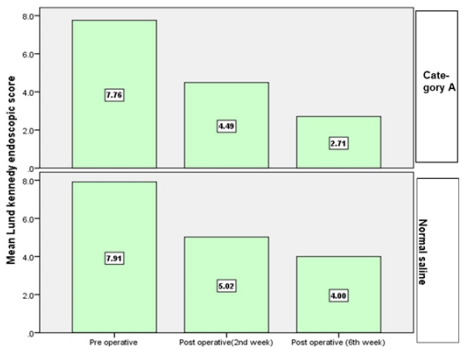

Fig. 2: Simple bar diagram compares the preoperative, postoperative (2nd week), and postoperative (6th week) LKE score among category A category B.

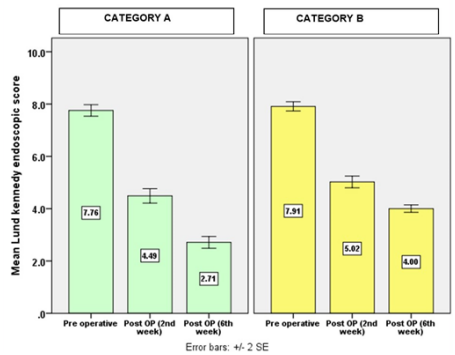

Fig. 3: Simple bar with standard error compares the patient's LKE score during preoperative, post op (2nd week), and Post O.P. (6th week) between category A and category B.

In the present study, SNOT 22 score of postoperative first visit (2^{nd} week) and postoperative second visit (6^{th} week) got reduced in both category A (Budesonide with normal saline nasal irrigation) and category B (normal saline nasal irrigation). However, the Budesonide with normal saline nasal irrigation group was superior in reducing the SNOT 22 score (from an average of 33.31 to 15.84, standard deviation 6.17 to 4.25) when compared to the normal saline nasal irrigation group (from average of 37.49 to 22.24, the standard deviation of 7.98 to 5.91). Similar findings observed in other studies by Huang et al. 2019[4] and Yoo et al. 2017,[12] Kosugi et al. 2015.[13]

Tait et al.[9] in 2018, study showed that budesonide in saline nasal irrigation resulted in clinically meaningful benefits beyond saline benefits for chronic rhinosinusitis patients.

Kosugi et al.[13] in 2015, did a Prospective uncontrolled intervention trial. Participants were assessed before and three months after budesonide nasal irrigation. 75% improved Lund Kennedy scores after high-volume budesonide nasal irrigations. They concluded that high-volume corticosteroid nasal irrigations are a good option in difficult-to-treat Chronic Rhinosinusitis control of the disease.

In a study by Kang et al.[14] in 2016, the endoscopy score improved from 7.4±4.7 before irrigation to 2.2±2.7 after six months. Nasal irrigation with Budesonide is an effective postoperative treatment for chronic rhinosinusitis with asthma, which frequently recurs, reducing the oral steroid intake.

Yoo et al.[12] in 2017 conducted a prospective study on the effectiveness of nasal irrigation in post-endoscopic sinus surgery patients. Lund Kennedy's endoscopic score was studied for three postoperative visits. Patients were instructed to rinse with a 240-mL bottle of saline, split between the two sides, at least twice a day, with encouragement to irrigate more often if desired. They concluded that the Identification of patients who may be non-compliant could benefit from increased preoperative counseling to improve adherence rates.

Xu et al.[5] in 2020, did a randomized controlled study on the short-course glucocorticoid application on patients with chronic rhinosinusitis with nasal polyps. Patients were assigned randomly in a 1:1:1 ratio to receive oral methylprednisolone, 24 mg/day budesonide nasal spray, 256 mg/day, or intranasal budesonide suspension, 1 mg/day for one week. They concluded that budesonide suspension nasal drop could significantly improve life quality and reduce the endoscopic score following short-course treatment. The treatment effect of the nasal drop was better than that of the regular nasal spray.

The limitations of the current study were the study period was one year and six months, the only small sample size could be studied. Long term benefit of intranasal steroid

Table 1: Comparison of SNOT-22 Score by student independent t test

	Group				Mean difference	Student independent t-test
	Category A		Category B			
	Mean	SD	Mean	SD		
Pre operative	60.24	8.01	60.60	6.80	0.36	t=0.23 p=0.82 (NS)
Post op(2nd week)	33.31	6.17	37.49	7.98	4.18	t=2.78 p=0.01** (S)
Post op (6th Week)	15.84	4.25	22.24	5.91	6.40	t=5.90 p=0.001*** (S)

p≥0.05 not significant NS= not significant, S= significant **p≤ 0.01 highly significant, ***p≤ 0.001 very high significant

Table 2: Comparison of mean SNOT-22 score during Preoperative, Postoperative (2nd week) and Postoperative (6th week) among category A and category B by within- group analysis

	Preoperative		Postoperative (2nd week)		Postoperative (6th week)		Mean difference	Oneway Repeated measures ANOVA F- test
	Mean	SD	Mean	SD	Mean	SD		
budesonide with normal saline	60.24	8.01	33.31	6.17	15.84	4.25	44.40	F=1420.29 p=0.001*** (S)
normal saline	60.60	6.80	37.49	7.98	22.24	5.91	38.36	F=687.22 p=0.001*** (S)

S= significant ***p≤ 0.001 very high significant

Table 3: Multiple comparison of SNOT-22 score between Preoperative, Postoperative (2nd week) and Postoperative (6th week) analysis using Bonferroni t-test

	Assessment	Score		Repeated ANOVA test score		Bonferroni t- test		
		Mean	SD	F value	P value	Comparison	MD	P value
Category A	Pretest	60.24	8.01					-
	Posttest-1	33.31	6.17	F=1420.29	P=0.001***	Pretest vs post-1	26.93	0.001
	Postttest-2	15.84	4.25			Pretest vs Post-2	44.40	0.001
Category B	Pretest	60.60	6.80			-		-
	Posttest-1	37.49	7.98	F=687.22	P=0.001***	Pretest vs post-1	23.11	0.001
	Postttest-2	22.24	5.91			Pretest vs Post-2	38.37	0.001

MD=mean difference, S= significant, ***p≤ 0.001 very high significant

Table 4: ANOVA (2 x 3) analysis with last Variable as Repeated Measure Test Results forSNOT-22 Reduction

Source of variation	F value	P- value	Repeated contrast test results		
			Assessment Comparison	F value	P-value
1) Between comparison Group	19.71	0.01	-	-	-
2)Within comparisons (a) Assessment	1941.09	0.001	Pre Vs 2nd week	1348.51	0.001 (S)
			2nd week Vs. 6th week	855.15	0.001 (S)
(b) Assessment* group	10.44	0.001	Pre Vs 2nd week	7.86	0.01 (S)
			2nd week Vs. 6th week	3.99	0.05 (S)

S= significant *p≤ 0.05 significant **p≤ 0.01 highly significant ***p≤ 0.001 very high significant

Table 5: Multiple comparisons of LKE score between Preoperative, Postoperative (2nd week) and Postoperative (6th week) analysis using Bonferroni t-test

	Assessment	Score		Repeated score ANOVA test		Bonferroni t-test		
		Mean	SD	F value	P-value	Comparison	MD	P- value
Category A	Pretest	7.76	.66					-
	Posttest-1	4.49	.92	F=887.67	P=0.001***	Pretest vs post-1	3.27	0.001
	Postttest-2	2.71	.76			Pretest vs Post-2	5.05	0.001
Category B	Pretest	7.91	.60			-		-
	Posttest-1	5.02	.75	F=624.19	P=0.001***	Pretest vs post-1	2.89	0.01
	Postttest-2	4.00	.48			Pretest vs Post-2	3.91	0.001

MD=mean difference S= significant **p≤ 0.01 highly significant ***p≤ 0.001 very high significant

Table 6: ANOVA with last variable as repeated measure test results for LKE score reduction

Source of variation	F value	P-value	Repeated contrast test results		
			Assessment c omparison	F value	P-value
1) Between comparison Group	39.77	0.01	-	-	-
2)Within comparisons (a) Assessment	1146.44	0.001	Pre Vs 2nd week	1024.34	0.001 (S)
			2nd week Vs. 6th week	187.55	0.001 (S)
(b) Assessment* group	18.18	0.001	Pre Vs 2nd week	3.85	0.05 (S)
			2nd week Vs. 6th week	4.47	0.01 (S)

To ascertainwhether improvement in the two groups is statistically different at all the three assessments, a 2x3 ANOVA test withthe last variable as the repeated measure wasapplied.
S= significant*p≤ 0.05 significant **p≤ 0.01 highly significant ***p≤ 0.001 very high significant

irrigation could not be studied due to a shorter follow-up time (postoperative second week and sixth week. Despite these limitations in the study, it is hoped that the study largely attained its objectives.

5. Conclusion

Budesonide with normal saline nasal irrigation was more effective compared to normal saline alone nasal irrigation in patients who underwent functional endoscopic sinus surgery for chronic rhinosinusitis with Sinonasal polyposis since the difference in the reduction of SNOT 22 score and LKE score among groups were higher in Budesonide with normal saline nasal irrigation. Hence to conclude, the addition of budesonide to normal saline for nasal irrigation in patients subjected to functional endoscopic sinus surgery is more effective both subjectively and objectively compared to normal saline nasal irrigation. Budesonide with normal saline nasal irrigation can be safely and effectively used in post-functional endoscopic sinus surgery patients.

6. Source of Funding

None.

7. Conflict of Interest

None.

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