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A Study on the Efficacy of Intranasal Fluticasone Spray versus Intranasal Budesonide Spray in Patients with Mild to Moderate Nasal Polyps

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ABSTRACT

Background Nasal polyps are soft, painless, noncancerous growths lining the nose or sinuses, small polyps may not cause any symptoms but larger nasal polyps lead to nasal obstruction, headache, loss of smell or taste, nasal congestion, nasal drainage, nose bleeds, pain in the face or top teeth and snoring. Management of polyposis involves combination of medical therapy and surgery. The first line treatment for nasal polyps are corticosteroid spray. **Objective** To find out the efficacy of intranasal fluticasone spray versus intranasal budesonide spray in patients with mild to moderate nasal polyps.**Method** A prospective study was conducted over six months on Nasal polyps patients receiving fluticasone and budesonide intranasal spray. Data were collected using SNOT-22 score. Statistical analysis was performed to compare scores before and after treatment. **Result** A total number of 20 patients were enrolled in the study, among them 13 were male and 7 were female. In Group A patients, fluticasone intranasal spray was given and SNOT-22 scores assessed before and after treatment (after 15 days) and then the scores were compared. SNOT-22 scores were found lower after treatment with fluticasone intranasal spray. In Group B patients, Budesonide intranasal spray was given and SNOT-22 scores were assessed before and after (after 15 days) treatment and then the scores were compared. SNOT-22 scores was found slightly lower after treatment with budesonide intranasal spray. In this study, result assessed from the data, that the efficacy of fluticasone intranasal spray was slightly better than budesonide intranasal spray in reducing the polyp size, inflammation and associated symptoms. **Conclusion** The study highlights that both intranasal fluticasone spray and budesonide spray were effective in the treatment of nasal polyps. However, intranasal fluticasone spray provides rapid relief associated with symptoms and helps in reducing the polyp size.

Keywords: Nasal polyps, SNOT-22 score, fluticasone spray, Budesonide spray

INTRODUCTION

Nasal polyps are inflammatory outgrowths of paranasal sinus mucosa caused by chronic mucosal inflammation that typically arise from the middle meatus and ethmoid region, having a characteristic appearance and a common occurrence, which affects either one or both parts of the nose openings to the ethmoidal sinuses descending between the middle turbinate and lateral nasal wall into the nasal cavity. The prevalence of nasal polyposis in the general population is around 4%. The disease is predominantly evident among the adults especially patients above the age of 20.

Nasal polyp has tendency to recur. They seem to grow due to long term swelling and inflammation in the nose from allergies, asthma or infection.

Clinical examination using rhinoscopy shows single or multiple pale, grey polypoid masses consisting of loose connective tissue, oedema, inflammatory cells, capillaries and glands. The inflammatory cells present are the eosinophils and neutrophilic cells.

Management of nasal polyps is individualized, involving a combination of observation, medical and surgical therapy. Elimination or reducing the size of the nasal polyps present is the main goal of the physicians thereby providing relief of nasal obstruction, increased sinus drainage, restore the taste and smell. Medical treatment is often started with the application of nasal steroids either as drops or sprays. Epistaxis is a rare symptom in nasal polyp. The most commonly used intranasal sprays are budesonide and fluticasone propionate.

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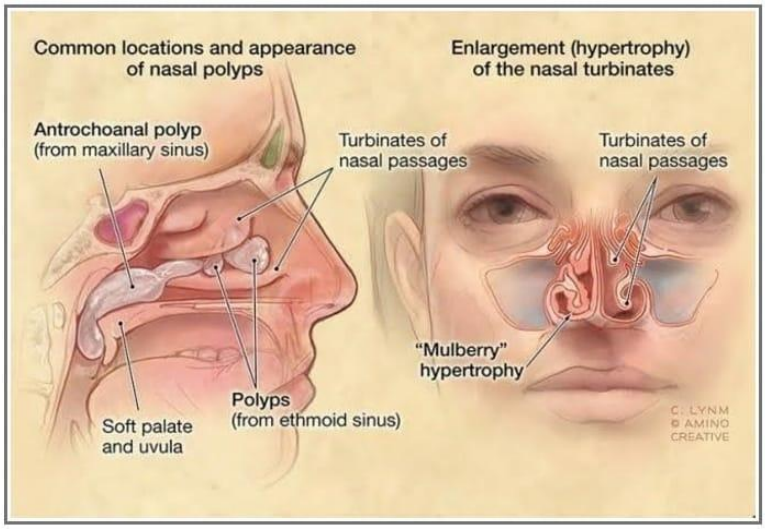

Fig.1

METHODOLOGY OF STUDY SETTING

STUDY SITE:

Hospital based study was carried out in clinically diagnosed Nasal polyp patients attending Department of ENT, Government Cuddalore Medical College and Hospital, a 1250 bedded Tertiary Care Teaching Hospital in Rural South India, Chidambaram.

STUDY PERIOD:

6 months [November 2023- April 2024].

STUDY DESIGN:

The Prospective Observational study.

STUDY TOOLS:

Predesigned PROFORMA (Data collection form)

SOURCE OF DATA:

Patients visiting the ENT-Department.

SUBJECT RECRUITMENT:

1**. TARGET POPULATION**

Patients clinically diagnosed as nasal polyps attending Department of ENT, at Government Cuddalore Medical College and Hospital, a 1250 bedded Tertiary Care Teaching Hospital in Rural South India, Chidambaram were included for study.

2. STUDY POPULATION

Patient who fulfills both the inclusion and exclusion criteria.

INCLUSION CRITERIA:

1. Patients with age more than 18 years of either sex diagnosed with nasal polyps.

2. Patients with nasal polyps, who were willing to give informed consent for the research study.

3. Patients with clinically diagnosed nasal polyps attending the ENT-Department.

EXCLUSION CRITERIA:

1.Pregnancy and lactating women were excluded.

2.Patients who are not willing to participate will be excluded.

SAMPLE SIZE:

Patients with clinically diagnosed nasal polyps attending the ENT Department during the study period. The subjects will be randomized by simple randomization in 1:1 allocation into Group A(10 patients) and Group B(10 patients). Totally 20 number of patients were included in the study.

STUDY PROCEDURE:

Written informed consent form and Information sheet in English and vernacular language (Tamil) will be obtained from the patients.

Demographic details, medical history, local examination and therapeutic management will be collected from the patients.

Group-A patients received fluticasone spray and Group-B patients received budesonide spray.

A predesigned proforma including SNOT-22 (SINO-NASAL OUTCOME TEST) collected from patients' case sheet will be used in this study. The SNOT will be graded depending upon the summation of severity of symptoms as mentioned in Predesigned Proforma.

Follow up will be done in patients with nasal polyps after treatment for 4 weeks by using SNOT-22.

The result of SNOT-22 pre and post treatment values will be compiled and analysed using suitable descriptive statistical tools (SPSS).

DATA ANALYSIS:

The data gathered will be recorded using Microsoft excel and analyzed using relevant statistical tool to provide significant results.

CONFLICT OF INTEREST:

There is no potential conflict of interest in this study.

RESULT AND OBSERVATION

DEMOGRAHIC DETAILS OF PATIENT

GENDER WISE DISTRIBUTION

A total number of 20 patients were enrolled in the study, among them 13 were male and 7 were females.

Table no. 01 Gender wise distribution

GENDER	NO. OF PARTICIPANTS	PERCENTAGE
MALE	13	65%
FEMALE	7	35%

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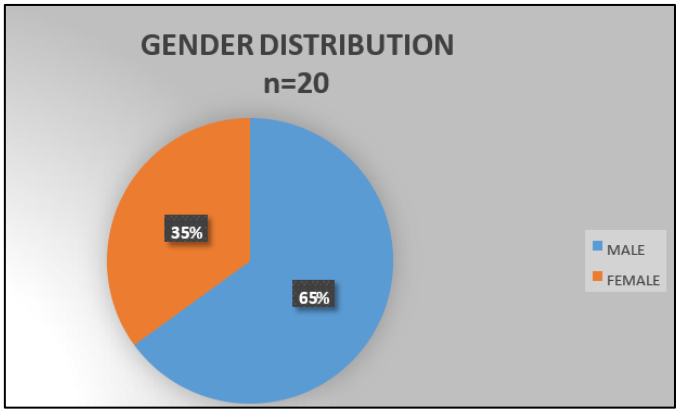

Fig no. 02 Gender wise distribution of patients involved in the study

AGE WISE DISTRIBUTION

A total number of 20 patients were enrolled in the study. Among them 1 belongs to age group of 18-25 years and 2 were 26-35 years and 7 were 36-45 years and 7 were 46-55 years and 3 were 56-65 years.

Table no. 02 Age wise distribution

PARAMETERS	NO. OF PATIENTS(n=20)	PERCENTAGE(%)
18-25	1	5%
26-35	2	10%
36-45	7	35%
46-55	7	35%
56-65	3	15%

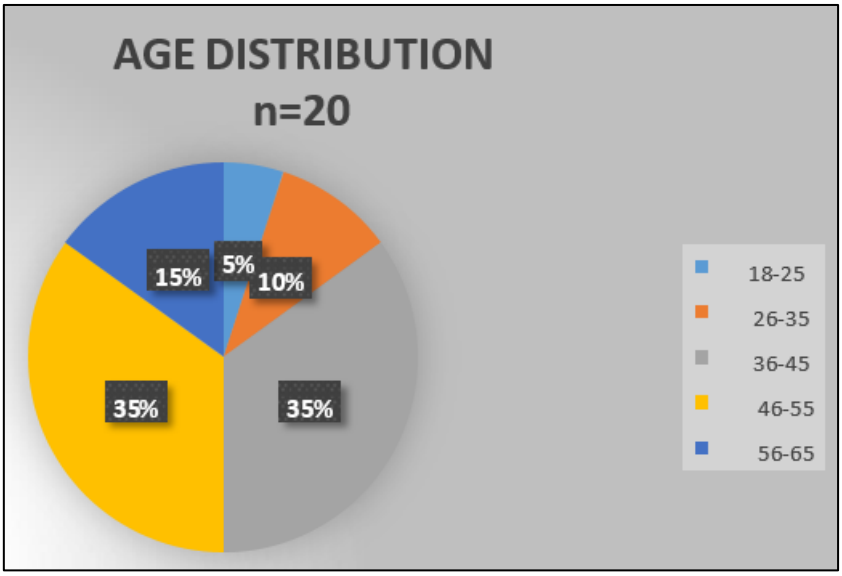

Fig no. 03 Age wise distribution of patients involved in the study

The demographic data shows that among these patients a high prevalence of nasal polyps occurred in the age group of 36-45 years (35%) and 46-55 years (35%).

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DEMOGRAPHIC PROFILE OF PATIENTS WHO RECEIVED INTRANASAL FLUTICASONE SPRAY GENDER WISE DISTRIBUTION

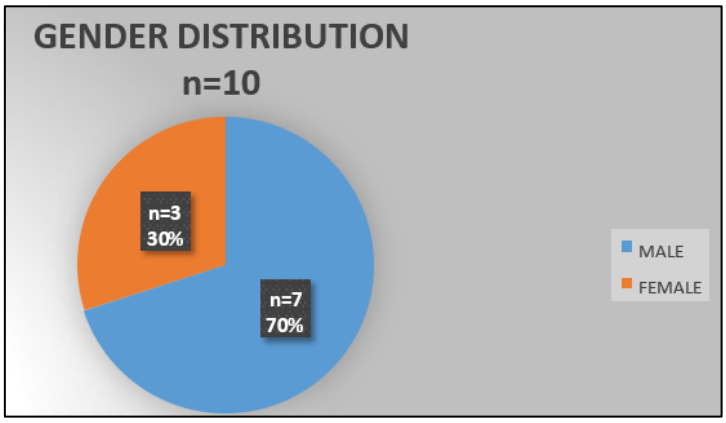

Fig no .04 Gender wise distribution of patients received intranasal fluticasone spray

AGE WISE DISTRIBUTION

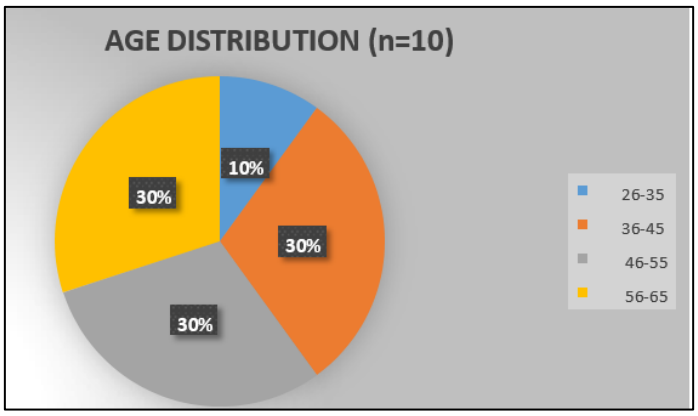

Fig no. 05 Age wise distribution of patients received intranasal fluticasone spray.

DEMOGRAPHIC PROFILE OF PATIENTS WHO RECEIVED INTRANASAL BUDESONIDE SPRAY

GENDER WISE DISTRIBUTION

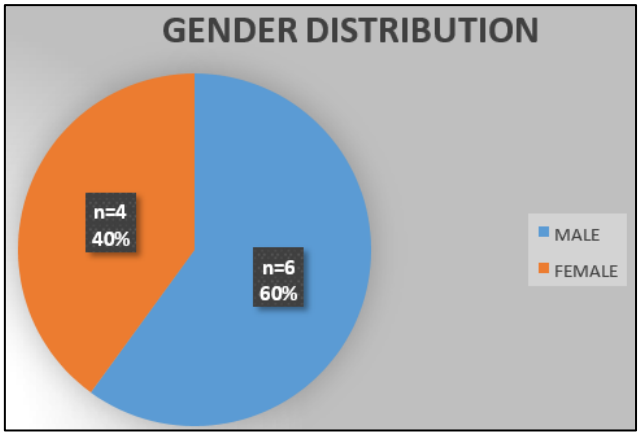

Fig no:06 Gender wise distribution of patients received intranasal budesonide spray

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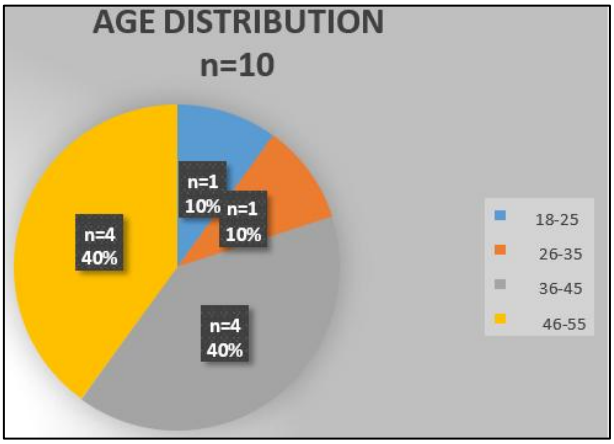
AGE WISE DISTRIBUTION



Figno:07 Age wise distribution of patients received intranasal budesonide spray

TYPES OF POLYP PRESENT IN THE PATIENTS INCLUDED IN THE STUDY

Table no. 03 Types of polyp present in the patients included in the study

TYPES OF POLYP	NO. OF PATIENTS	PERCENTAGE
Sinonasal polyposis	18	90%
Antrochoanal polyp	2	10%

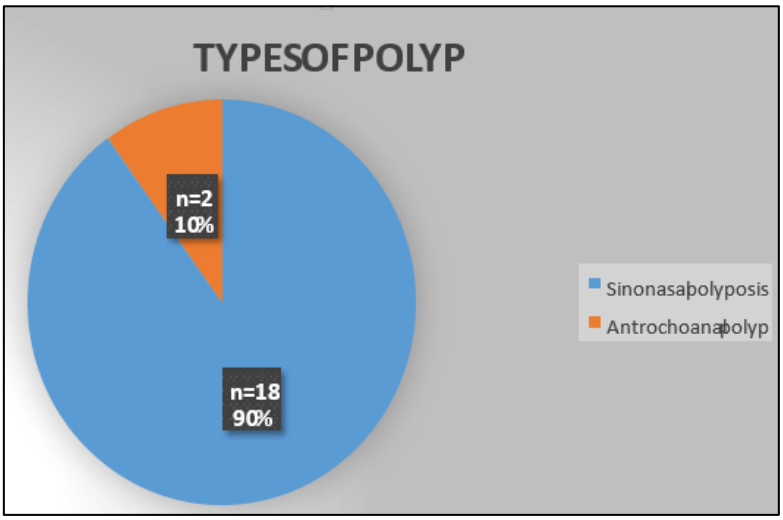


Fig no: 08 Types of polyp included in the study

LOCATION OF NASAL POLYP

LOCATION OF NASAL POLYP PRESENT IN THE PATIENTS INCLUDED IN THE STUDY

Table no. 04 location of nasal polyp present in the patients included in the study

LOCATION OF THE POLYP	NO. OF PATIENTS	PERCENTAGE
Bilateral (both)	7	35%
Left	6	30%
Right	7	35%

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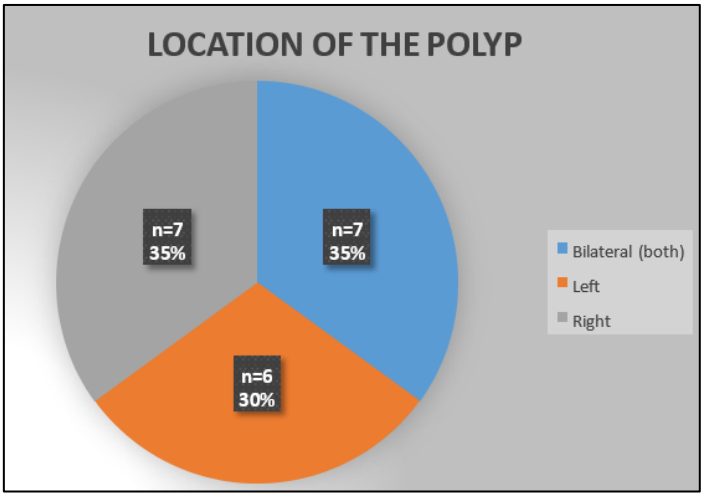

Fig no: 09 Location of the nasal polyp present in the patients included in the study.

STUDENTS 't' TEST FOR EFFICACY OF INTRANASAL FLUTICASONE SPRAY ON

PRE AND POST TREATMENT SCORES AMONG THE PATIENTS

Table No.: 05 't' test for Efficacy of Intranasal Fluticasone spray on pre and post treatment score among the patients.

Groups	Number of Patients	Mean	Standard Deviation	Mean Difference	t-value	P Value
Pre treatment	10	41.30	12.48	24.10	6.248	0.002 (P<0.01)
Post treatment	10	17.20	6.07			

In the case of pre and post treatment, Pretreatment have shown higher scores (higher mean value, 41.30) than that of Post treatment (Mean value, 17.20). The calculated 't' value (6.248) is greater than the table 't' value. Hence, Significance difference exists between the pre and post treatment groups.

EFFICACY OF INTRANASAL FLUTICASONE SPRAY ON PRE AND POST

TREATMENT SCORE AMONG THE PATIENTS

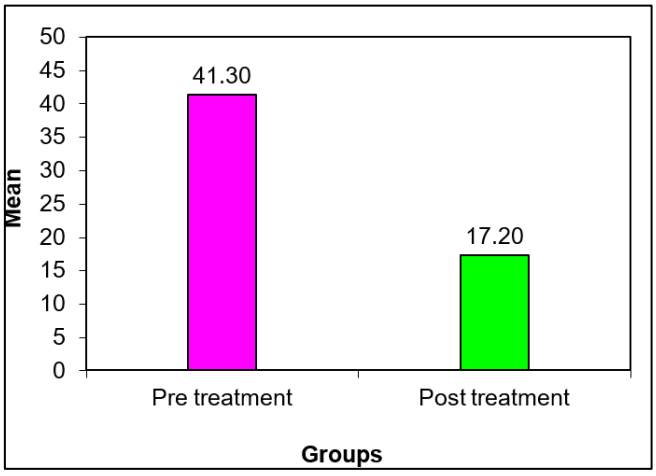

Fig no.10 Efficacy of intranasal fluticasone spray on pre and post treatment score among the patients

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 8, August 2025 ijppr.humanjournals.com ISSN: 2349-7203

STUDENTS 't' TEST FOR EFFICACY OF INTRANASAL BUDESONIDE SPRAY

ON PRE AND POST TREATMENT SCORE AMONG THE PATIENTS.

Table No. 6: Students 't' test for Efficacy of Intranasal Budesonide Spray on pre and post treatment score among the patients

Groups	Number of Patients	Mean	Standard Deviation	Mean Difference	t-value	P Value
Pre treatment	10	34.30	11.55	12.50	7.553	0.000 (P<0.01)
Post treatment	10	21.80	9.84			

In the case of pre and post treatment, Pretreatment have shown higher scores (higher mean value, 34.30) than that of Post treatment (Mean value, 21.80). The calculated 't' value (7.553) is greater than the table 't' value. Hence, Significance difference exists between the pre and post treatment groups.

EFFICACY OF INTRANASAL BUDESONIDE SPRAY ON PRE AND POST TREATMENT SCORE AMONG THE PATIENTS

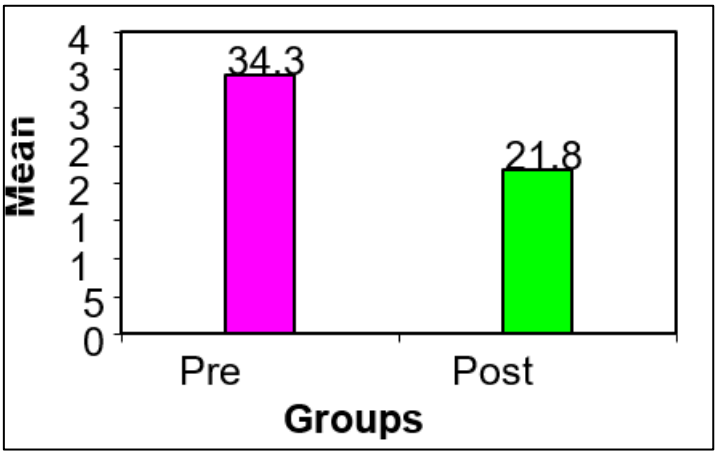

Fig No.11 Efficacy of intranasal budesonide spray on pre and post treatment score among the patients

STUDENTS 't' TEST FOR EFFICACY OF INTRANASAL FLUTICASONE SPRAY AND BUDESONIDE SPRAY ON PRE AND POST TREATMENT SCORES AMONG THE PATIENTS

Table no.07 't' test for Efficacy of Intranasal Fluticasone Spray and Budesonide Spray on pre and post treatment score and patients

PARAMETERS			Group A Fluticasone Spray	Group B Budesonide Spray	p-value (unpaired t test)
Treatment	Pre treatment	MEAN	41.30	34.30	0.000
	Post treatment	MEAN	17.20	21.80	
	MEAN DIFFERENCE		24.10	12.50	

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EFFICACY OF INTRANASAL FLUTICASONE SPRAY AND BUDESONIDE SPRAY ON PRE AND POST TREATMENT SCORE AMONG THE PATIENTS

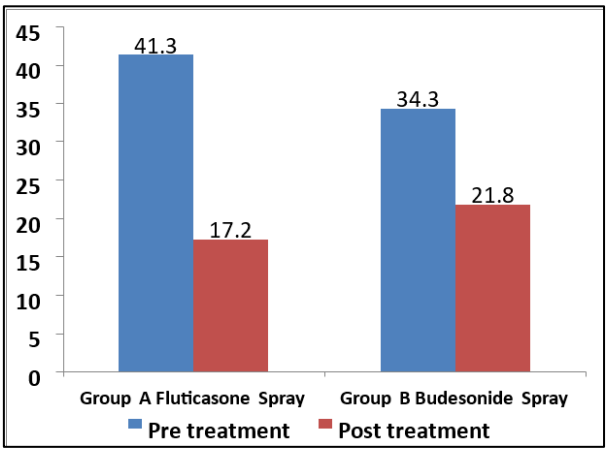

Fig No.12: Efficacy of intranasal fluticasone spray and budesonide spray on pre and post treatment score among the patients

't' TEST FOR EFFICACY OF INTRANASAL FLUTICASONE SPRAY AND BUDESONIDE SPRAY SCORE AMONG THE PATIENTS

Table no : 8 't' test for efficacy of intranasal fluticasone spray and budesonide spray score among the patients

Groups	Number of Patients	Mean	Standard Deviation	Mean Difference	t-value	P Value
Fluticasone Spray	10	17.20	6.07	4.60	1.420	0.189 (P>0.01)
Budesonide Spray	10	21.80	9.84			

In the score of Fluticasone Spray and Budesonide Spray, Budesonide Spray (21.80) scored higher mean value than that of Fluticasone Spray (17.20). The calculated 't' value (1.420) is less than the table 't' value. Hence, no significance difference exists between the Fluticasone Spray and Budesonide Spray groups.

EFFICACY OF INTRANASAL FLUTICASONE SPRAY AND BUDESONIDE SPRAY SCORE AMONG THE PATIENTS

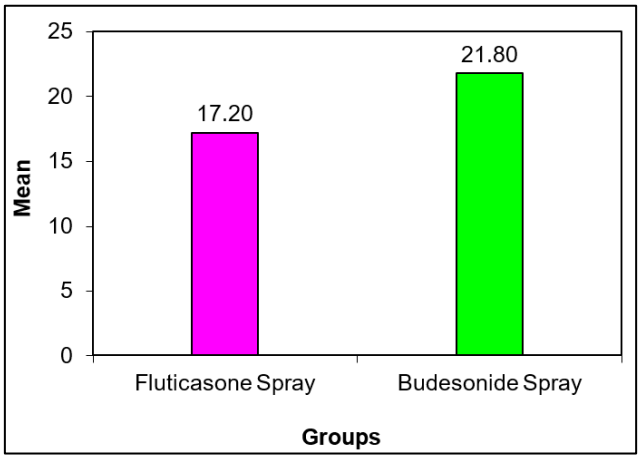

Fig no :13 Efficacy of intranasal fluticasone spray and budesonide spray score among the patients

DISCUSSION

In our study, Group A [Intranasal fluticasone spray] and Group B [intranasal budesonide spray] comprises of 10 patients each. Both Intranasal fluticasone spray and intranasal budesonide spray significantly exhibited reduced SNOT-22 scores in post –treatment periods.

Pre-treatment SNOT-22 scores in the intranasal fluticasone spray (Group A) was 41.30 (Mean score) and have reduced to 17.20 (Mean score). Similarly, Pre-treatment SNOT-22 scores in the intranasal budesonide spray (Group B) was 34.30 (Mean score) and scores have reduced to 21.80 (Mean score). The mean difference in SNOT-22 Score in Group A was 24.10 and in Group B was 12.50 (p value 0.189). When the scores of intranasal fluticasone spray were compared with that of intranasal budesonide spray; intranasal budesonide spray (21.80) scored higher mean value than intranasal fluticasone spray (17.20). The calculated `t' value (1.420) is less than the table `t' value, and hence there is no significance difference between the fluticasone spray and budesonide spray groups. Hence, fluticasone intranasal spray have higher effectiveness (low score indicate higher effective) than budesonide intranasal spray among the patients.

The study has also demonstrated that mean difference of fluticasone intranasal spray (4.60) is slightly higher than that of budesonide spray.

CONCLUSION

In our study, Group A patients received fluticasone spray and Group B received Budesonide and then SNOT-22 scores were compared between pre and post-treatment. The intranasal corticosteroid spray is found to be efficacious in reducing the symptoms and size of nasal polyp. The statistical data of the study revealed that the intranasal fluticasone spray mean difference (24.10) is higher than budesonide intranasal spray (mean difference=12.50).

There were changes in the SNOT-22 scores (Pre and Post treatment) between the two groups. The difference was statistically not significant (p value- 0.189). Hence the present study highlights that the intranasal fluticasone spray provides rapid relief associated with symptoms and helps in reducing the polyp size.

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Conflict of Interest Statement: All authors have nothing else to disclose.