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Original Research Article

Comparative Study on the Efficacy of Irrigating the Postoperative Fess Cavities [B/L Nasal Polyps] with Topical Nasal Solutions of Budesonide and Betamethasone

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Conflict of interest: Nil

Abstract:

Nasal polyps are benign lesions arising from the mucosa of nasal sinuses (commonly at the outflow tracts of one or more sinuses) or from the mucosa of nasal cavity. Having an uncertain etiology and a tendency to recur, they form a challenging disease to be treated. The present study compares the efficacy of irrigating the postoperative fess cavities with betamethasone and budesonide nasal douche in symptomatic relief, pain score and condition of sinonasal mucosa. A total of 30 subjects with Chronic Rhinosinusitis with nasal polyps were included in the final analysis with 15 subjects receiving Budesonide nasal douche and 15 subjects receiving Betamethasone nasal douche. The median 6 month post-operative SNOT score was 5 (IQR 4 to 6) in Budesonide group and 5(IQR 5 to 6) in Betamethasone group**,** with no statistically significant difference between the two groups (P value 1.00). Within each group there was statistically significant decline in the VAS score from baseline to 1 month. (P value 0.001) On comparing Modified Lund Kennedy Endoscopic grading at 6 months, Budesonide group, 2 (13.3%) participants were grade 2, 11 (73.3%) participants was grade 4 and 2 (13.3%) participants were grade 6. In Betamethasone group, 2 (14.3%) participants were grade 2 and 12 (85.7%) participants were grade 4. It was concluded that nasal irrigation of post FESS sinus cavities with diluted solutions of either budesonide or betamethasone is equally effective in providing symptomatic relief and in preventing recurrence of nasal polyps.

Keywords: Budesonide, Betamethasone, nasal douche, nasal polyp.

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Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) shows inflammatory changes in nose and paranasal sinuses.[1]

Treatment of NP involves a combination of medical and surgical treatment depending on individual case assessment. The advent of topically administered corticosteroids has improved the treatment of NP. Topical Corticosteroids form the mainstay of conservative therapy in NP as both a primary treatment and to prevent recurrence

The Functional Endoscopic sinus surgery is essential for adequate topical drug access. Devices delivering large volume with positive pressure allow better distribution to sinus mucosa. [2]

Glucocorticoids have proven to be effective in reducing the symptoms of nasal polyps. Comparison of beclomethasone dipropionate nasal spray and betamethasone nasal drops were studied and it helped in reducing polyp size and rhinitis symptoms [3] Beclomethasone diproprionate, flunisolide and budesonide sprays have been proven to delay recurrence of nasal polyps after surgery[4]

Objectives

1. To compare the efficacy of irrigation of post-operative FESS cavities with diluted solutions of budesonide and betamethasone.
2. To compare the outcomes in terms of symptomatic relief (SNOT22), VAS(pain scale) and status of mucosa seen on Diagnostic nasal endoscopy(Modified Lund Mackay endoscopic grading).

Methods:

A total of 30 patients aged 18-75 years with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) admitted to the ENT ward in tertiary care centre were included in the study

Inclusion criteria:

1. All cases of chronic rhinosinusitis with B/L nasal polyposis undergoing FESS within the age group 18-75 years.
2. All cases of chronic rhinosinusitis with recurrent nasal polyposis undergoing revision FESS.

Exclusion criteria:

- Patients of chronic rhinosinusitis without nasal polyps.
- Patients aged less than 18 years and aged more than 75years.
- Patients with trauma or tumors of nose, PNS.
- Patients with acute invasive fungal sinusitis
- Patients of chronic rhinosinusitis with complications.
- Patients who refuse to do nasal douching.

Patients diagnosed as Chronic Rhinosinusitis with nasal polyp based on clinical examination, DNE,CT and having failed maximal medical therapy with minimal or no relief in symptoms and requiring Functional Endoscopic Sinus Surgery who were ready to perform nasal irrigation with Budesonide or Betamethasone and frequent follow up after surgery were recruited for the study with their consent.

A detailed medical history and clinical examination as per pre-designed and pre-tested proforma was obtained from all cases. Diagnostic Nasal endoscopy and Radiological examination of Paranasal sinuses (CT PNS) were done to confirm the diagnosis. Pre-operative Sino nasal outcome test (SNOT) 22 scores was obtained to assess the severity of the patient's symptoms. Preoperative Visual Analogue Scale (VAS) to assess the severity of pain and Preoperative Modified Lund-Kennedy Endoscopic grades of nasal polyps were also obtained to assess the status of sinonasal mucosa. These parameters were taken as baseline for a given patient. Lund Mackay CT scores were also obtained preoperatively. Functional Endoscopic Sinus Surgery was performed depending on the extent of the disease as noted by CT scan and on table assessment by the surgeon. Nasal douching was started from 8th day postoperatively once daily.

Nasal douche was prepared with 200ml of NS mixed with 1 respule of Budesonide (0.5mg/2ml) in group 1 and 200ml of NS was mixed with 1 ampoule of Betamethasone sodium phosphate (4mg/1ml)in group 2 in a squeeze bottle. Patients were trained to perform nasal douching before discharge from the hospital.

Patients were randomized into two groups using simple random technique [chit method]. Group1 received Budesonide with NS Nasal solution and Group 2 received Betamethasone with NS solution. Following surgery, the Post-operative FESS cavities of Group1 were irrigated with 200ml NS with 1 respule of Budesonide[0.5mg/2ml] and Group2 were irrigated with 200ml NS +1 Ampoule of Betamethasone[3mg/1ml].

Nasal douching was done once daily starting from the day of splint removal(8th postoperative day).Patients were followed up and evaluated for Post-operative SNOT score at the end of 1 and 6 months post-surgery. Postop VAS, Modified Lund Kennedy endoscopic scores were obtained at 1month, 3 month, 6 months post- surgery.

Statistical Methods:

SNOT total score, VAS Total score (pre and post-operative) grading of polyps DNE were considered as primary outcome variables. Study group (Budesonide Vs Betamethasone) was considered as primary explanatory variable.

All age, SNOT total score, VAS Total score (pre and post-operative) variables were checked for normal distribution within each category of study group variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For normally distributed age parameter the mean values were compared between study groups using Independent sample t-test (2 groups). For non-normally distributed SNOT total score, VAS Total score (pre and post-operative) parameters, Medians and Interquartile range (IQR) were compared between study groups using Mann Whitney u test (2 groups). The change in the non-normally distributed quantitative variables was compared within each group by Wilcoxon Signed Rank Test. Categorical outcomes were compared between study groups using Chi square test /Fisher's Exact test (If the overall sample size was < 20 or if the expected number in any one of the cells is < 5, Fisher's exact test was used.)

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Results:

A total of 30 subjects were included in the final analysis. With 15 subjects receiving Budesonide and 15 subjects receiving Betamethasone. The mean age of the participants in Budesonide group was 45 ± 12.44 and in Betamethasone 42.67 ± 13.82, with no statistically significant difference (P value 0.631)

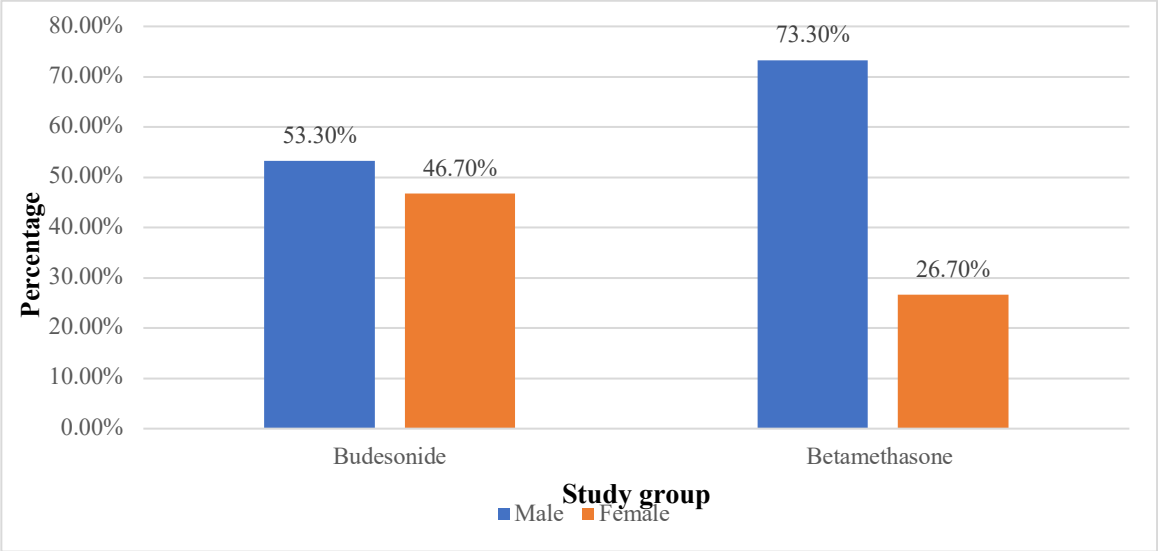

Figure 1: Clustered bar chart of comparison of group with gender (N=30)

In both the study group, the proportion of males was higher than females, with no statistically significant difference between two groups. (P value 0.256) The median duration of disease was 30 months (Inter quartile range 12 to 48) in budesonide group and it was 24 months (Inter quartile range 12 to 48) in betamethasone group, with no statistically significant difference between the two groups (P value 0.90).

Table 1: Comparison of SNOT score between the two intervention groups at different time period (N=30)

Parameter	Group		P value (Mann Whitney U test)
	Budesonide Median (IQR)	Betamethasone Median (IQR)	
Pre-operative SNOT score	41 (29, 46)	40 (32, 46)	0.803
Post-operative SNOT score at 1 month	6 (5, 7)	6 (6, 6)	0.290
Post-operative SNOT score at 6 Months	5 (4, 6)	5 (5, 6)	1.000

The median pre-operative SNOT score was 41 (IQR 29 to 46) in group 1 and 40 (IQR 32 to 46) in group 2**,** with no statistically significant difference between the two groups (P value 0.803). The median 1 month post-operative SNOT score was 6 (IQR 5 to 7) in group1 and 6 (IQR 6 to 6) in group 2, with no statistically significant difference between the two groups (P value 0.290). The median 6 month post-operative SNOT score was 5 (IQR 4 to 6) in group 1 and 5(IQR 5 to 6) in group 2**,** with no statistically significant difference between the two groups (P value 1.00).

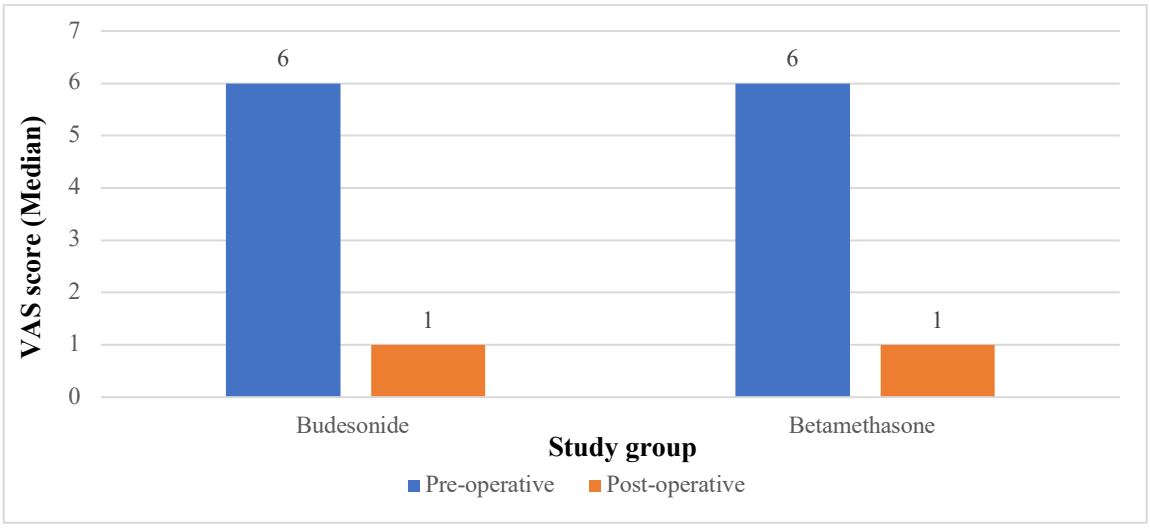

Figure 2: Comparative bar chart of VAS total score between the two groups at different follow up periods (N=30)

Within each group there was statistically significant decline in the VAS score from baseline to 1 month. (P value 0.001)

Table 2: Comparison of PRE-OP CT SCORE (LUND MACKAY) Total score 24 between the two groups (N=30)

Parameter	Group		P value (Mann Whitney U test)
	Budesonide Median (IQR)	Betamethasone Median (IQR)	
CT score (Lund MacKay)	18 (15, 23)	22 (18, 24)	0.185

The median (Lund MacKay) score was 18 (IQR 15 to 23) in group1 and 22 (IQR 18 to 24) in group 2 with no statistically significant difference between the two groups (P value 0.185).

Table 3: Comparison of groups using MODIFIED LUND KENNEDY ENDOSCOPIC GRADING at 1 month total score 12 (N=30)

Grading of polyps 1 month total score 12	Group	
	Budesonide (N=15)	Betamethasone (N=15)
GRADE 2	15 (100%)	13 (86.7%)
GRADE 4	0 (0%)	2 (13.3%)

*No statistical test was applied- due to 0 subjects in the cells

Table 4: Comparison of groups using MODIFIED LUND KENNEDY ENDOSCOPIC GRADING at 3 months (N=29)

Grading of polyps 3 months	Group		Chi square	P-value
	Budesonide (N=15)	Betamethasone (N=14)		
GRADE 2	11 (73.3%)	9 (64.3%)	0.277	0.599
GRADE 4	4 (26.7%)	5 (35.7%)		

In group 1, 11 (73.3%) participants were grade 2 and 4 (26.7%) participants were grade 4. In group 2, 9 (64.3%) participants were grade 2 and 5 (35.7%) participants were grade 4. The difference in the proportion of Grading of polyps DNE 3 months between study group was statistically not significant (P value 0.599).

Table 5: Comparison of groups using MODIFIED LUND KENNEDY ENDOSCOPIC GRADING at 6 months (N=29)

Grading of polyps 6 months	Group	
	Budesonide (N=15)	Betamethasone (N=14)
GRADE 2	2 (13.3%)	2 (14.3%)
GRADE 4	11 (73.3%)	12 (85.7%)
GRADE 6	2 (13.3%)	0 (0%)

*No statistical test was applied- due to 0 subjects in the cells**.** In group 1, 2 (13.3%) participants were grade 2, 11 (73.3%) participants were grade 4 and 2 (13.3%) participants were grade 6. In group 2, 2 (14.3%) participants were grade 2 and 12 (85.7%) participants were grade 4.

Table 6: Comparison of group with results at the end of 6 months (N=30)

Results	Group	
	Budesonide (N=15)	Betamethasone (N=15)
Improved	14 (93.3%)	14 (93.3%)
Lost to follow up	0 (0%)	1 (6.7%)
Recurrence	1 (6.7%)	0 (0%)

*No statistical test was applied- due to 0 subjects in the cells.

In budesonide group, 14 (93.3%) participants were reported in improved and 1 (6.7%) participant was reported in recurrence. In Betamethasone group, 14 (93.3%) participants were reported in improved and 1 (6.7%) participant was reported lost to follow up. In budesonide group, 1 (6.6%) participant had postop bleed which was managed successfully with anterior nasal packing for 24hrs, 1 (6.6%) participant underwent revision FESS at 6 months and 13 (86.67%) participants were asymptomatic. In Betamethasone group, 1 (6.67%) participant was lost to follow up and 14 (93.33%) participants were asymptomatic.

Discussion:

The study included 30 patients of CRSwNP who remained symptomatic despite maximal medical treatment and required surgical intervention in the form of Functional endoscopic sinus surgery. The study comprised of 2 groups of 15 patients each. Group 1 was budesonide group and Group 2 was

betamethasone group. Group 1 had 8(53%) males and 7(46%) females. In Group 2, 11(73%) were males and 4(26.7%) were females. In both the study groups proportion of males was higher than females. The mean age of the participants in budesonide group was 45+_12.44 and in betamethasone group 42.67+_13.82. Median duration of disease was 30 months in Group 1 and 24 months in Group 2.

Patient related outcome measures like SNOT22, VAS and modified LK endoscopic grading system has been used in the study to know the impact of CRSwNP on physical, emotional and functional domains of an individual. SNOT 22 scoring system was used to assess the severity of symptoms preoperatively, and postoperatively at 1month and 6months. They were categorized into 3 groups. Mild being defined on ths SNOT22 as 8-20, moderate as 20-50 and severe as more than 50. Preop scores observed in budesonide group ranged from 41(maximum) to 29(minimum) and 46(max) to 32(min) in Betamethasone group.

Median preop SNOT22 score was 41(IQR 29-46) in budesonide group and 40(IQR 32-46) in Betamethasone group. The medians 1 month post-operative score was 6(IQR 5-7) in Budesonide group and 6 in Betamethasone group. The median 6 months post-operative SNOT22 score was 5(IQR 4 to 6) in budesonide group and 5(IQR 5 to 6) in Betamethasone group. This showed that there was significant improvement in the quality of life in both the groups with no significant difference between the groups. (p value-1)

In our study, Modified Lund Kennedy endoscopic grading system was used to assess the status of sino-nasal mucosa pre operatively and postoperatively at 1, 3 and 6 months. The median preoperative DNE score was 6(IQR 6 to 8) in Budesonide group and 6(IQR 6 to 7) in Betamethasone group which was statistically insignificant.

Postoperatively MLK endoscopic grading was performed. At 1 month, in budesonide group, all the 15(100%) participants were grade 2. In betamethasone group, 13(86.7%) participants were grade 2 and 2(13.3%) participants were grade 4.

At 3months, 11(73.3%) participants were grade 2 and 4(26.7%) participants were grade 4 in budesonide group, 9(64.3%)participants were grade 2 and 5(35.7%) participants were grade 4.(p value 0.59) At 6 months, 2(13.3%) participants were grade 2, 11(73.3%) were grade 4 in budesonide group. In betamethasone group, 2(14.3%) participants were grade 2 and 12(85.7%) participants were grade 4. In budesonide group, 14 (93.3%) participants were improved with recurrence reported in 1 participant. In betamethasone group, 14(93.3%) participants had improved sinonasal mucosa and 1 participant lost to follow up.

In our study, Pain severity in the patients was assessed using Visual Analogue Scale with scores ranging from 0- 10 preoperatively and postoperatively. 0 represented no pain at all and 10 being worst pain imaginable. The median pre-operative VAS score was 6(IQR 6 to 7) in budesonide group and 6(IQR 6 to 8) indicating moderate pain in both the groups preoperatively.

The median 6th month postoperative VAS score was 1(IQR 1 to 2) graded as mild pain in budesonide group and 1(IQR 1 to 1) graded as mild pain in betamethasone group showing reduced pain in both the groups postoperatively.

The Lund Mackay CT score was performed preoperatively. Maximum score was 23 and minimum was 15 in budesonide group, maximum score was 23 and minimum score was 15 in betamethasone group. The median CT SCORE was 18(IQR 15 to 23) in budesonide group and 22(IQR 18 to 24) in betamethasone group.

Overall, 14 (93.3%) participants improved symptomatically in both the groups. In budesonide group, one patient had postop bleed, 1 patient underwent revision FESS and 13(86.67%) participants symptomatically improved. In Betamethasone group, 1(6.67%) participant was lost to follow up and 14(93.3%) participants improved symptomatically.

In the study conducted by Huang et al scores of polyposis, mucosal edema, secretions and total score of Lund Mc Kay scoring system; VAS scores of nasal blockage, hyposmia and rhinorrhea; and SNOT-22 results in both groups were significantly improved 3 months after ESS. [5]

In the study by Gabriela Ricci Luz-Matsumoto et al it was concluded that 1% compounded budesonide drops improved the Lund–Kennedy endoscopic score with fewer adverse events than betamethasone cream, particularly at higher doses (1000 μg).

In the study done by Kothiwala et al showed decrement in SNOT-22 scores and endoscopy scores in case nasal cavity in comparison to control nasal cavity were compared by student ‘t’ test and found to be statically significant [7]

In the study done by David et al SNOT-20 scores were significantly lower with BNI ($p < 0.05$). On subgroup analysis, SNOT-20 scores were significantly improved with BNI for patients with eCRS and Samter's triad ($p = 0.04, 0.03$).[8]

In a study conducted by Tae Wook Kang et al[9] concluded that Nasal irrigation with budesonide is an effective postoperative treatment for chronic rhinosinusitis with polyposis and asthma, in reducing the need for oral steroid intake and also to prevent the recurrence.

A Study by Dawson [10] concluded that daily betamethasone nasal irrigation is an efficacious treatment modality with no changes in morning serum cortisol levels and negligible changes in 24-hour urinary free cortisol levels and hence considered viable and safe treatment option for chronic rhinosinusitis patients following functional endoscopic sinus surgery.

Study by Neubauer et al [11] compared the efficacy of fluticasone nasal spray and budesonide respule via mucosal atomized device after FESS in CRSwNP in a randomized controlled trial concluded that Patients treated with budesonide after ESS for CRSwNP had greater improvement in SNOT-22 and Lund Kennedy scores compared to fluticasone at 6 months.

Conclusion

This study was undertaken to compare the efficacy of budesonide and betamethasone nasal irrigation in CRSwNP patients following FESS surgery. SNOT 22 scale was applied preoperatively and postoperatively in both the groups. It was found that preoperatively 80% of the participants had moderate and 20% had severe symptoms according to the grading of SNOT scale and at the end of 6 months 93.3% of patients were symptomatically better as indicated by grade 1 SNOT (mild problem). In budesonide group one patient had recurrence and in betamethasone group 1 patient lost to follow up.

VAS pain scale was applied to assess the pain severity. Preoperatively median VAS sore was 6 in both budesonide and betamethasone group which indicated moderate pain. Following the nasal irrigation, Median postoperative VAS scores at the end of 6 months in both the budesonide and betamethasone groups were found to be 1 indicating mild pain. Modified Lund Kennedy grading of nasal polyps was applied to know the status of sinonasal mucosa pre and postoperatively in both the budesonide and betamethasone nasal irrigation groups. In budesonide and betamethasone groups, polyps were found beyond the middle meatus with thick secretions and edema. At the end of 6 months, in budesonide group, 2 (13.3%) patients had mild edema and thin secretions with no polyps, 11(73.3%) patients had thick secretions with minimal edema and polyps limited to middle meatus, 2(13.3%) patients had severe edema, thick purulent secretions and polyps beyond the middle meatus. In betamethasone group, 2(14.3%) patients had minimal edema and thin secretions with no polyps, 12(85.7%) patients had thick secretions , minimal edema and polyps limited to middle meatus and one patient was lost to follow up. Hence, irrigation of post FESS sinus cavities with diluted solutions of either budesonide or betamethasone is equally effective in providing symptomatic relief and in preventing recurrence of nasal polyps.

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