



## EFFECT OF BUDESONIDE NASAL DOUCHING ON OUTCOME OF FESS: A COMPARATIVE STUDY

### Otorhinolaryngology

<b>K Satish Kumar*</b>	Assistant Professor & Consultant, Department Of Otorhinolaryngology, Head & Neck Surgery, Adichunchanagiri Institute Of Medical Sciences, B G Nagara - 571448 *Corresponding Author
<b>Nikethan G</b>	Department Of Otorhinolaryngology, Head & Neck Surgery, Adichunchanagiri Institute Of Medical Sciences, B G Nagara - 571448
<b>Raghavendra S K</b>	Department Of Community Medicine, Adichunchanagiri Institute Of Medical Sciences, B G Nagara - 571448

### ABSTRACT

Chronic rhinosinusitis is a common disease characterised by the inflammation of the nasal cavity and paranasal sinuses, with or without nasal polyps. Even after undergoing FESS inflammatory processes continue to play a significant role in chronic rhinosinusitis patients and hence the use of topical medical therapy plays a very important role.

This study aims to evaluate the efficacy of nasal irrigation with various solutions including topical steroid like budesonide in order to treat chronic rhinosinusitis patients after FESS, and compare this with normal saline and alkaline nasal solution. 60 patients undergoing FESS for CRS were randomly divided into three groups. Each group was instructed to do nasal douching with different solutions and results were recorded.

We found that topical steroids like budesonide when used as nasal irrigation solution and delivered in high volume effectively reduces the post-operative inflammation after FESS as compared to alkaline nasal solution and normal saline.

### KEYWORDS

Budesonide nasal irrigation, Chronic rhinosinusitis, FESS

### INTRODUCTION

Chronic rhinosinusitis (CRS) is a common disease characterised by the inflammation of the nasal cavity and paranasal sinuses, with or without nasal polyps<sup>1</sup>. Many times it does not respond to medical therapies causing significant morbidity impacting the quality of life<sup>2</sup>.

Functional endoscopic sinus surgery (FESS) is indicated for the treatment of chronic rhinosinusitis that is resistant to medical treatment.<sup>1,3,4</sup>

Even after undergoing FESS inflammatory processes continue to play a significant role in chronic rhinosinusitis patients and hence the use of topical medical therapy plays a very important role<sup>5</sup>. Nasal irrigation is a powerful and significant method for the management of chronic rhinosinusitis after FESS<sup>6</sup>.

The mechanism of nasal irrigation is not fully understood but saline nasal irrigation may improve nasal mucosa function through several physiological effects like direct cleaning of mucus (mucus is a potential condition for bacteria to multiply; saline dilutes mucus and helps to clear it out); removal of antigens, bacterial biofilm or inflammatory mediators (thereby alleviating the inflammation); and improving mucociliary function<sup>7</sup>.

Saline nasal irrigation in chronic rhinosinusitis after FESS has been proved to clean the nasal cavity and promote the restoration of mucosal function and is widely used<sup>3,8</sup>.

A number of studies have verified the efficacy of nasal irrigation with various solutions<sup>9</sup>. Topical nasal steroid sprays have been used post FESS but are not very effective in decreasing the post operative inflammation. This may be because the thick mucus and post operative crusting decrease the delivery of drug. Many recommend delivery of steroids by nasal irrigation in a large volume and high pressure. This technique is more effective in treating the inflammation of sinus mucosa.<sup>10</sup>

This study aims to evaluate the efficacy of nasal irrigation with topical steroid like budesonide in order to treat chronic rhinosinusitis patients after FESS and compare this with normal saline and alkaline nasal solution.

### MATERIALS AND METHODS

Participants were selected from the out patients diagnosed with CRS and nasal polyposis and undergoing FESS in Adichunchanagiri

Institute of Medical Sciences, B G Nagara. This study includes 60 patients undergoing FESS for CRS between January 2018 to January 2019.

Surgery was unilateral or bilateral, and consisted of removing all the polyps and involved sufficient widening of the natural ostia of the affected sinuses to allow convenient passage for topical medications. Patients were randomly divided into three groups, each group containing 20 patients (Group A, Group B & Group C) and were given instructions to perform nasal douching post operatively using different solutions.

Patients belonging to Group A were advised nasal douching with 500ml normal saline with 1 ampule of sodium bicarbonate (alkaline solution) for 3 weeks.

Patients belonging to Group B were advised nasal douching with 100ml saline with 1 respule of budesonide for 3 weeks.

Patients belonging to Group C were advised with nasal douching with 100ml saline alone.

Patients were instructed to perform nasal douching two times a day using their respective assigned solutions for a period of three weeks.

After a period of three weeks the patients underwent diagnostic nasal endoscopy and Lund and Kennedy endoscopic appearance scores were recorded.

Data was entered in MS excel 2016 and analysed using SPSS 20.0. Data was expressed in mean and proportion. p value less than 0.05 was considered significant.

### RESULTS

In our study a total of 32 male subjects and 28 female subjects were evaluated. In all the three Groups the maximum number of patients belong to the age group of 31-40, and minimum in patients belonging to the age group of less than 20 years.

**Table 1 : Age distribution**

	≤20 years	21-30 years	31-40 years	>40 years
Group A	3.3	8.3	13.3	8.3
Group B	3.3	8.3	13.3	8.3
Group C	3.3	8.3	15.0	6.7

**Table 2 : Sex distribution**

Sex	Male	Female
Group A	12	8
Group B	9	11
Group C	11	9
Total	32	28

**Table 3 : Comparison between Group A and Group C.**

	GROUP	N	Mean	Std. Deviation	P value
DISCHARGE	A	20	1.35	.933	0.006
	C	20	2.20	.894	
SCARRING	A	20	1.90	1.165	0.459
	C	20	2.15	.933	
CRUSTING	A	20	1.65	1.137	0.165
	C	20	2.10	.852	
OEDEMA	A	20	2.10	1.252	0.882
	C	20	2.15	.813	
POLYP	A	20	1.65	.988	1
	C	20	1.65	1.040	
TOTAL	A	20	8.65	2.601	0.046
	C	20	10.25	2.291	

The endoscopic scores of Group A and Group C were compared and it was found that there is a significant difference between the two [ $p=0.046$ ], Group A who were given alkaline nasal solution had a lesser mean endoscopic score of  $8.65\pm 2.601$  compared to that of Group C with a score of  $10.25\pm 2.291$ .

**Table 4 : Comparison between Group B and Group C**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	P value
DISCHARGE	C	20	2.20	.894	.200	.000
	B	20	1.00	.562	.126	
SCARRING	C	20	2.15	.933	.209	.000
	B	20	.75	.716	.160	
CRUSTING	C	20	2.10	.852	.191	.000
	B	20	.65	.813	.182	
OEDEMA	C	20	2.15	.813	.182	.001
	B	20	1.25	.716	.160	
POLYP	C	20	1.65	1.040	.233	.104
	B	20	1.20	.616	.138	
TOTAL	C	20	10.25	2.291	.512	.000
	B	20	4.85	2.134	.477	

The endoscopic scores of Group B and Group C were compared and it was found that there is a significant difference between the two [ $p=0.1$ ], Group B who were given budesonide nasal solution had a lesser mean endoscopic score of  $4.85\pm 2.134$  compared to that of Group C with a score of  $10.25\pm 2.291$ .

**Table 5 : Comparison between Group A and Group B.**

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	P value
DISCHARGE	A	20	1.35	.933	.209	.159
	B	20	1.00	.562	.126	
SCARRING	A	20	1.90	1.165	.261	.001
	B	20	.75	.716	.160	
CRUSTING	A	20	1.65	1.137	.254	.003
	B	20	.65	.813	.182	
OEDEMA	A	20	2.10	1.252	.280	.012
	B	20	1.25	.716	.160	
POLYP	A	20	1.65	.988	.221	.092
	B	20	1.20	.616	.138	
TOTAL	A	20	8.65	2.601	.582	.000
	B	20	4.85	2.134	.477	

The endoscopic scores of Group A and Group B were compared and it was found that there is a significant difference between the two [ $p=0.00$ ], Group B who were given budesonide nasal solution had a lesser mean endoscopic score of  $4.85\pm 2.134$  compared to that of Group A with a score of  $8.65\pm 2.601$ .

## DISCUSSION

Inflammation of the nasal and the sinus mucosa is one of the most common concerns after FESS, this can be addressed with the help of

topical steroids.<sup>11</sup> Corticosteroids like budesonide have a wide range of inhibitory activities against many cell types (example:- lymphocytes, eosinophils, mast cells, neutrophils, and macrophages) and mediators involved in allergic and nonallergic mediated inflammation (example:- cytokines, histamine, eicosanoids, and leukotrienes). In addition, corticosteroids increase the synthesis of anti-inflammatory proteins, such as lipocortin-1, secretory leukocyte protease inhibitor, and IL-10, and increase the expression of  $\beta_2$ -adrenergic receptors.<sup>12</sup>

These properties of budesonide are very helpful in reducing the post-operative inflammatory processes after FESS.

Adequate delivery of topical intranasal corticosteroids continues to be one of the most important factors for controlling sinonasal mucosal inflammation.<sup>13</sup>

However, common nasal delivery methods such as drops, sprays, aerosols, and nebulizers provide good nasal cavity contact but poor sinus delivery. An appropriate access and delivery is required to deliver topical medicine into the sinuses.<sup>14</sup> High volume irrigation improves topical medication delivery into the paranasal sinuses and this is the recommended approach for managing patients with CRS, especially those who have undergone FESS.

In this study we found that the mean score of Group A is  $8.65\pm 2.601$ , Group B  $4.85\pm 2.134$  and Group C  $10.25\pm 2.291$ .

From the above data we can say that subjects using budesonide nasal douching had mild or no post-operative inflammation and symptoms compared to alkaline nasal douching and normal saline douching and subjects using alkaline nasal solution had lesser scores compared to subjects using normal saline. Hence it can be observed that budesonide nasal douching after FESS is very efficient in reducing post-operative inflammation and symptoms compared to sodium bi-carbonate and normal saline nasal solutions.

In 2012 Snidvongs K et al, conducted a study on Corticosteroid nasal irrigations after endoscopic sinus surgery in the management of chronic rhinosinusitis and found that topical steroid therapy even though non specific is very effective in controlling post-operative symptoms after FESS.<sup>14</sup>

In 2013 Jang DW et al, conducted a study on Budesonide nasal irrigations in the postoperative management of chronic rhinosinusitis and found that the addition of budesonide nasal irrigation is beneficial in the postoperative management of patients with CRS.<sup>15</sup>

In 2017 Yoon HY et al, conducted a study on Post-operative corticosteroid irrigation for chronic rhinosinusitis after FESS and found out that, although steroid nasal irrigation would not induce adverse effects related to systemic steroid absorption, the beneficial effects of additional steroids in saline irrigation were ambiguous in regard to endoscopic score compared with saline alone irrigation.<sup>16</sup>

In 2017 Tae Wook Kang et al, conducted a study on The Effectiveness of Budesonide Nasal Irrigation After Endoscopic Sinus Surgery in Chronic Rhinosinusitis With Asthma and found out that Nasal irrigation with budesonide is an effective postoperative treatment for chronic rhinosinusitis with asthma, which recurs frequently, reducing the oral steroid intake.<sup>17</sup>

## CONCLUSION

We conclude that topical steroids like budesonide when used as nasal irrigation solution and delivered in high volume effectively reduces the post-operative inflammation after FESS as compared to alkaline nasal solution and normal saline.

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