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Original Research Article

Efficacy of nasal irrigation of normal saline as compared to budesonide following functional endoscopic sinus surgery

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ABSTRACT

Background: Nasal irrigation following Functional endoscopic sinus surgery (FESS) appears to be a nearly universal recommendation. FESS significantly improves the symptoms of the CRS (Chronic rhino sinusitis) and the postoperative endoscopy scores. The primarily objective of our study was to study the efficacy of nasal irrigation of normal saline as compared to budesonide following functional endoscopic sinus surgery.
Methods: A total of 100 patients who underwent functional endoscopic sinus surgery were randomly divided into two groups on the basis of computerized generated random table with 50 patients in each group. In group 1 normal saline was used where as in group 2 budesonide solution was used for nasal douching. Post-operative evaluation was done using Lund Kennedy Endoscopic scoring (LKES) at the 7th and 30th postoperative day.
Results: On 7th postoperative day, we found that none of our patient in the study groups had polypoidal change. There was decrease in scores of polyposis, discharge mucosal edema, scaring and crusting in both the groups. However, the reduction of discharge in the budesonide group was more significantly decreased than normal saline group (p value<0.05). We also noted that on 30th postoperative edema, scarring and crusting was significantly decreased in budesonide group as compared to normal saline group (p value <0.05).
Conclusions: We concluded that the addition of budesonide in nasal irrigation resulted in improved scores of polyposis, discharge, mucosal edema, crusting and scarring and total score of LKES than normal saline alone.

Keywords: Budesonide, LKES, Normal saline, Nasal irrigation

INTRODUCTION

Nasal irrigation is simple, common and inexpensive procedure that has been used to treat sinus and different nasal conditions for many years as post-operative care after endoscopic sinus surgery.[1] It is also known as nasal douching or nasal toilet or nasal lavage. One of the common indications of nasal irrigation includes chronic rhino-sinusitis with and without nasal polyposis and post operative care of Endoscopic Sinus Surgery.[2] Chronic rhino-sinusitis is an inflammatory disease of nose and paranasal sinuses lasting 12 weeks or longer without resolution of symptoms. It is a substantial source of morbidity and is one of the most common reason patients visiting primary care physician. CRS is a very common condition with prevalence rates varying from 6 to 15%, nearly affecting 10% of the worldwide population.[3,4] The annual incidence of chronic rhino-sinusitis with nasal polyposis is between 1 and 20 per 1000 population in India.

Nasal irrigation following FESS appears to be a nearly universal recommendation. Many solutions that had been used as nasal irrigation are isotonic saline, hypertonic nasal saline and buffered or non-buffered solution. These solutions improve the symptoms of the CRS and the post operative endoscopy scores. However, as shown in the previous studies their efficacy was not significantly different when normal saline was used alone. So the use of normal saline following FESS is considered as first choice as normal saline is simple, harmless, and cost effective and has more patient compliance.[5]

Steroids have a definite role in chronic rhino sinusitis; however the limitation of the conventionally available steroids is that they can't be delivered properly and adequately to the entire nasal and sinus cavity.[6] Topical nasal steroids are the preferred maintenance strategy in the post-operative management of patients with chronic rhino sinusitis. So, there comes the role of budesonide nasal irrigation and hence our study aims at studying the role and compare the efficacy of nasal irrigation with normal saline as compared to budesonide.

METHODS

A prospective, comparative study was conducted at Department of ENT, Government medical college Jammu, a tertiary care patients attending Otorhinolaryngology outpatient department of Government medical college Jammu are hospital in union territory of Jammu and Kashmir.

The study was performed on all the patients attending Otorhinolaryngology outpatient department of Government Medical College, Jammu who underwent functional endoscopic sinus surgery for chronic rhino sinusitis with or without nasal polyps. Patients attending Otorhinolaryngology outpatient department of Government Medical College, Jammu from October 2021 to October 2022 were enrolled in the study. In this study we undertook 100 patients fulfilling the inclusion criteria. Sample size was calculated by keeping power of study 95% or less. In our study a total of 100 patients were included in the study. A total of 100 patients who underwent functional endoscopic sinus surgery were randomly divided into two groups (group 1 and group 2) on the basis of computerized generated random table with 50 patients in each group. In group 1 normal saline was used where as in group 2 budesonide solution was used for nasal douching.

Inclusion criteria includes patients of age 18 to 60 years, patients who underwent FESS for chronic rhino sinusitis with and without nasal polyposis. Exclusion criteria include patients not giving consent, FESS for condition other than CRS, patients listed for revision surgery.

Consent was taken from all the patients participating in the study. The objectives of the study were explained to them in detail. After consent detailed history and physical examination was done. Pre and post-operative evaluation was done using Lund Kennedy Endoscopic scoring.

After FESS all the patients were made to do nasal douching after removal of nasal pack after 3rd postoperative day. Nasal irrigation was done twice daily for 30 days either with normal saline or saline mixed with budesonide. All patients received regular follow-up evaluation by Lund Kennedy endoscopic scoring system at 7th and 30th post operative day. Data was compiled in Microsoft excel and analysed using SPSS 2I.0 version. Demographic and clinical data are expressed as the means and SDs, and other data are expressed as the means and SEMs. Unpaired t test was done to compare means of the two groups. P value of 0.05 or less was considered as significant.

RESULTS

The demography in terms of age of the patients in both the groups was similar with mean age of 34.5± 10 in group 1 as compared to mean age of 35.5±10 in group 2. Most of the patients in our study were in age group of 31-40 years as shown in table 1. Most of the patients in our study were males as compared to females as shown in Table 2. In our study out of 50 patients in group 1, 32(64%) were with nasal polyp as compared to 18 (36%) without nasal polyp. Similarly in group 2 28 (56%) were with nasal polyp and 22(44%) were with nasal polyp (Table 3).

Table 1: Age distribution of the study groups.

Age group	Group 1		Group 2	
	N	%	N	%
18-30	18	36	12	24
31-40	10	20	27	54
41-50	17	34	10	20
51-60	5	10	1	2
Total	50	100	50	100%

Table 2: Gender distribution of the study groups.

Gender	Group 1		Group 2		Total	
	N	%	N	%	N	%
Male	40	80%	32	64%	72	72%
Female	10	20%	18	36%	28	28%
Total	50	100%	50	100%	100	100%

Table 3: Distribution of cases according to diagnosis.

Diagnosis	Group 1		Group 2		Total	
	N	%	N	%	N	%
CRS with nasal polyp	32	64%	28	56%	60	60%
CRS without nasal polyp	18	36%	22	44%	40	40%
Total	50	100%	50	100%	100	100%

At 1st visit of assessment on 7th postoperative day we found that none of the patients in either normal saline group (group 1) or budesonide group (group 2) had polyposis. As shown in table 4 it is clearly evident that other parameters of Lund Kennedy endoscopic score like discharge, edema, scarring and crusting were better in group 2 as compared to group 1.

Table 4: Showing Lund Kennedy Endoscopic findings at 1st visit among study groups.

Ist visit parameters at 7th postoperative day		Group 1		Group 2		P value
		N	%	N	%	
Polyposis	Absence of polyp	50	100%	50	100%	
	Polyp in middle meatus only	0	0.0%	0	0%	
	Beyond middle meatus	0	0.0%	0	0%	
Discharge	No discharge	18	36%	25	50%	
	Clear thin discharge	15	30%	19	38%	0.03
	Thick discharge	17	34%	6	12%	
Edema	Absent	3	6%	7	14%	
	Mild	23	46%	17	34%	0.27
	Severe	24	48%	26	52%	
Scarring	Absent	48	96%	50	100%	
	Mild	1	2%	0	0%	0.36
	Severe	1	2%	0	0%	
Crusting	Absent	6	12%	5	10%	
	Mild	17	34%	25	50%	0.265
	Severe	27	54%	20	40%	

Table 5: Showing Lund Kennedy Endoscopic findings at 2nd visit among study groups.

2nd visit parameters on 30th postoperative day		Group 1		Group 2		P value
		N	%	N	%	
Polyposis	Absence of polyp	43	86.0%	49	98.0%	
	Polyp in middle meatus only	6	12.0%	1	2.0%	0.084
	Beyond middle meatus	1	2.0%	0	0.0%	
Discharge	No discharge	41	82.0%	46	92.0%	
	Clear thin discharge	9	18.0%	4	8.0%	0.137
	Thick discharge	0	0.0%	0	0.0%	
Edema	Absent	20	40.0%	34	68.0%	
	Mild	28	56.0%	16	32.0%	0.012
	Severe	2	4.0%	0	0.0%	
Scarring	Absent	4	8.0%	28	56.0%	
	Mild	23	46.0%	21	42.0%	<0.001
	Severe	23	46.0%	1	2.0%	
Crusting	Absent	0	0.0%	26	52.0%	
	Mild	33	66.0%	24	48.0%	<0.001
	Severe	17	34.0%	0	0.0%	

At 2nd visit of assessment after 1 month we found polypoidal change in 2% of the patients in the normal saline group.

There was decrease in discharge, edema, scarring and crusting in the budesonide group as compared to the normal saline group. However the improvement was more significant in the edema, scarring and crusting as evidenced by a p value of <0.05(Table 5).

At 1st visit of assessment total Lund Kennedy score was 4.5±1.0 in group 1 where as in group 2 total LKES was 3.9±0.9 and there was a statistically significant difference between the two groups(p value <0.05). Similarly at 2nd follow up total LKES score in group 1 was 2.5±1.1 as

compared to 1.2±1.2 in group 2 which again was statistically significant improvement (Table 6).

Table 6: Showing comparison of Lund Kennedy score between the study groups.

	Group 1	Group 2	P value
1ST visit LKES	4.5±1.0	3.9±0.9	0.003
2ND visit LKES	2.5±1.1	1.2±1.2	0.001

DISCUSSION

The mean age of the patients in our study was 34.5±10 years in group 1 and 35.5±10 in group 2, with maximum number of the patients in the age group 31-40 years. The results in our study were in consonance with the studies conducted by Garg et al, Chaturvedi et al and Tripathy et al.[7-9]

Similarly most of the patients in our study were males 72% as compared to only 28 % females in the literature there are a number of studies where male preponderance of the disease was found, examples include the studies conducted by Salib RJ et al Kumar J et al and Tripathy SM et al.[9-11] In our study out of 50 patients in group 1, 32 (64%) were with nasal polyp as compared to 18 (36%) without nasal polyp. Similarly in group 2, 28 (56%) were with nasal polyp and 22 (44%) were with nasal polyp. These results are in consonation with the studies done by Salib RJ et al, Deal and Kountakis, and Yoo F et al. [12,13]

After the assessment on 7th post operative day (1st visit) it was found that none of our patient in both the groups had polypoidal change. 34 % in the normal saline users and 12 % in the budesonide group had thick discharge on the 1st visit of assessment. There was a significant decrease in the amount of discharge in the budesonide group as compared to normal saline. 48% in the normal saline group and 52% of the budesonide group had mucosal edema. 2% of the patients had scarring in the 1st visit of assessment in the saline group as compared to 0% in the budesonide group. 54% of the patients in the saline group had crusting in the 1st visit as compared to 40 % in the budesonide group.

On assessing on the 30thpostoperative as shown in Table 5 polypoidal change in 2% of the patients in the normal saline group as compared to 0% in budesonide group.

There was decrease in discharge, edema, scarring and crusting in the budesonide group as compared to the normal saline group. However, the improvement was more significant in the edema, scarring and crusting as evidenced by a p value of <0.05.

Limitations

Some of the limitations of the study include small sample size, single centre study and short postoperative follow up of the patients.

CONCLUSION

Scores of polyposis, discharge, mucosal edema, scarring, crusting and total score of LKES in both groups were significantly improved in 7 days and one month after FESS. Scores of polyposis, discharge, mucosal edema, crusting and scarring and total score of LKES in group 2 were significantly better than in control group 1, one month after FESS. The side effects of the two groups were not significantly different.

We recommend the use of budesonide irrigation with normal saline irrigation in patient with CRS as it can be safely used without any major side effects. It improves endoscopic findings, prognosis and quality of life. Moreover, Off-label use of budesonide nasal irrigation deliver adequate amounts of medication to the entire post-operative nasal and sinus cavity through high pressure, high volume system which is seen an important limitation in commercially available nasal steroid spray in post-operative care of FESS.

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