PROPHYLACTIC BUDESONIDE NASAL SPRAY AFTER POLYPECTOMY

S.K. Gulati[1], Karan Sharma[2], Gurinder Kaur Shergill[3], Rajeev Kumar[4]

ABSTRACT : *This double blind study compared the effect of budesonide nasal spray with placebo, in the prophylaxis of nasal polyp recurrence after avulsion. 38 cases were given budesonide nasal spray and 25 placebo for 3 months after polypectomy. Follow up of 9 months revealed budesonide treated patients to have significantly lower recurrence rate as compared to the placebo. Interestingly patients with recurrent nasal polyposis benefitted much more from topical budesonide treatment as compared to ones with no previous history of polypectomy.*

INTRODUCTION

Allergic nasal polyp is a benign smooth pedunculated swelling of nasal mucosa arising mainly in the ethmoidal region. Excision of polyp usually produces no cure, as it fails to correct the factors favouring regrowth of hyperplastic tissues. The problem of recurring nasal polyposis continues to harass the patients as well as the rhinologists. A large number of patients subjected to repeated polypectomy rationalizes the strong need for improvement in management.

In past topical steroids had been used intranasally with good results as shown by Pederson (1976) and Larsen (1995), the former using beclomethasone and later budesonide. Budesonide is a new generation non-halogenated glucocorticosteroid (GCS). It has high affinity for GCS receptors and therefore considerable topical potency. It is readily absorbed and is not metabolized in the respiratory mucosa. The subsequent drug at the site of application is prolonged by the binding of budesonide to mucosal tissue. It undergoes rapid systemic inactivation in liver, which is an advantage over most other GCS.

MATERIAL AND METHODS

This study was carried out on 63 patients in the Department of ENT, Govt. Medical College, Amritsar. Patients were selected as per the history and anterior and posterior rhinoscopic examination. Nasal smear examination for presence of eosinophils, radiological and haematological investigations were done in all cases. Patients were carefully examined and fully investigated to rule out pulmonary tuberculosis, peptic ulcer, psychotic disorder, recurrent epistaxis, diabetes mellitus and hypertension as these are contraindications to prolonged use of budesonide therapy. An antibiotic coverage (amoxycillin 250 mg + cloxacillin 250 mg orally) thrice a day for one week was given before surgery.

After polypectomy, these patients were divided into two groups; Group A having budesonide spray comprised of 38 patients and group B having placebo saline nasal spray comprised of 25 patients. Two puffs of 50 mg each of budesonide were sprayed into each nostril twice a day (total dose 400 mg /day) for three months after surgery.

Patients in both groups were followed up every week for one month and then every month for nine months after surgery. During follow up symptoms of nasal obstruction, sneezing, rhinorrhoea and sensation of smell were evaluated. Patency both pre-operatively and during follow-ups was measured by Gertner's (1984) plate method. Complications of budesonide spray especially dryness of nose, crusting, epistaxis or any other were evaluated.

OBSERVATIONS

Majority of patients were in age group of 21 to 35 years. Youngest being 18 and eldest 65 years. 78% were males and 56% belonged to middle socio-economic group. 60% of patients were susceptible to dust and 32% had seasonal variations. In 84% cases, duration of illness varied between 6 months and 2 years. In all cases, chief complaint was bilateral nasal obstruction. Sneezing, rhinorrhoea, post-nasal drip and hyposmia/anosmia was complained off by 70, 46, 58 and 72% patients respectively. Proptosis was

[1]Professor Incharge, [2]Senior Lecturer, [3]Senior Resident, [4]Ex-Jr. Resident, Department of E.N.T., Govt. Medical College, Amritsar

Table- I : Showing Recurrence of Polyp after Polypectomy

	Total no. of cases	Cases showing recurrence	%age
Group A (n = 38) Previous h/o polypectomy	12	3	25.00
No previous h/o polypectomy	26	19	73.08
Group B (n = 25) Previous h/o polypectomy	5	4	80.00
No previous h/o polypectomy	20	18	90.00

seen in 2 cases and six patients had history of asthma along with. Nasal smear examination for presence of eosinophils revealed its score to be more than 10% in 41% of cases; 5-10% in 32% of cases and less than 5% in rest 23% of the cases. In Group A, 32% cases had history of previous polypectomy whereas in Group B, 20% had such history (Table I).

After treatment with budesonide nasal spray (Group A), only 25% patients had recurrence in the category having previous history of polypectomy in contrast to 73% in the category having no such history of polypectomy. In group B, with placebo treatment, 80% of patients had recurrence in the category having previous polypectomy

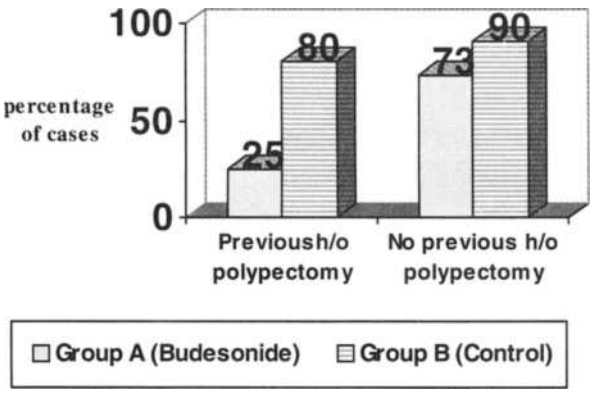

Fig. I : Showing Recurrence of Polyps in both groups with & without history of polypectomy.

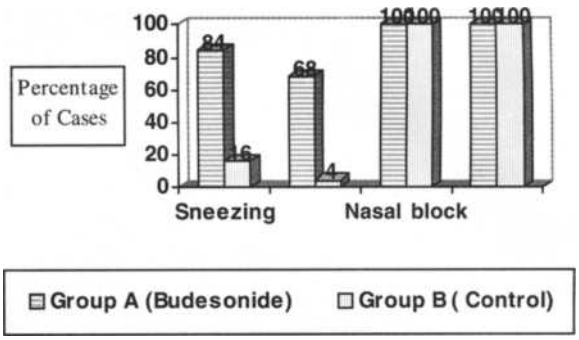

Fig. II : Showing improvement in nasal symptoms.

and 90% in patients with no such history in the past. The comparison of recurrence of polyps with and without history of polypectomy in both groups is depicted in Fig. I. Improvement in nasal symptoms of sneezing, rhinorrhoea, nasal blockade and sense of smell in both groups as depicted in Fig. II, indicate significant subjective improvement of all these pre-operative complaints. Patients having recurrence as evident from rhinoscopic examinations and Gertner's (1984) plate method for nasal patency however did not complain of nasal obstruction and instead showed significant subjective improvement. None of our patients with recurrence (as observed objectively) were operated upon for it during the follow up period.

DISCUSSION

In the present study 25% of patients in group A as compared to 80% in group B with previous history of polypectomy developed recurrence after the surgery. However in patients with no previous history of polypectomy, 73% had recurrence in trial group as compared to 90% in control group (Table I).

Hartwig (1988) in a follow up of 6 months in patients undergoing polypectomy revealed significantly lower recurrence in patients taking 400 mg daily of budesonide nasal spray as compared to placebo. Further, recurrence rate was less in those patients who had previous history of polypectomy.

Larsen (1995) found recurrence of only 17.8% in patients treated with budesonide nasal spray after polypectomy in those cases who had previous such history of surgery. Lildholdt (1995) found success rate of nasal polyp treatment with 400 mg of budesonide to be 82% as

compared to 43% in placebo group. Vendelo Johansen (1993) in a double blind study on 91 patients found 200 mg b.i.d. of budesonide nasal spray for a period of 3 months to be very effective in the preliminary treatment of small and medium sized nasal polypi. Pipkorn (1988) in 5.5 years follow-up study concluded that intranasal budesonide in dose of 200-400 mg/day is quite safe for prolonged treatment of perennial rhinitis.

From the present study, we concluded that Budesonide, a topical glucocorticosteroid had been very effective as a prophylactic treatment of nasal polyps after surgery. Significantly better effectiveness in patients with previous history of polypectomy may be as a result of persistent predisposing factors and recurring tendencies in these patients as compared to the others where recurrence itself would have been very low. Furthermore, intranasal budesonide nasal spray has advantage of being non-sedative and also its prolonged use does not lead to rhinitis medicamentosa.

REFERENCES

1. Gertner R; Pondoshin L and Fradus M (1984): A simple method of measuring the nasal airway in clinical work. Journal of Laryngology and Otology, 98: 351-355.
2. Hartwig S; Linden M; Laurent C; Vargo AK and Lindovist N (1988): Budesonide nasal spray as prophylactic treatment after polypectomy. Journal of Laryngology and Otology, 102: 148-151.
3. Larsen K; Tos M (1995): Clinical course of patients with primary nasal polyp. Acta Otolaryngol (Stockh) 114 (5): 556-559.
4. Lildholdt T; Rundcrantz H; Lindquist N (1995): Efficacy of topical corticosteroid powder for nasal polyps. Clin. Otolaryngol, 20 (1): 26-30.
5. Pederson CB; Mygind N; Sorensen H; Prytz S (1976): Long term treatment of nasal polyp with beclomethasone dipropionate aerosol. Acta Otolaryngol 82: 260-262.
6. Pipkorn U; Pukander J; Suonpaa J; Makinen J; Lindqvist N (1988): Long term safety of budenoside nasal aerosol: a 5.5 years follow-up study. Clinical Allergy 18 (3): 253-259.
7. Vendelo Johansen L; Illum P; Kristensen S et al (1993): The effect of budesonide (Rhinocor) in the treatment of small and medium sized nasal polyps. Clinical Otolaryngology, 524-527.

Address for correspondence :

Dr. Karan Sharma,
Sr. E.N.T. Consultant,39-B, Circular Road,
Amritsar – 143001