The Journal of Laryngology and Otology
October 1995, Vol. **109**, pp. 941–944

Effect of Beconase nasal spray on olfactory function in post-nasal polypectomy patients: a prospective controlled trial

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Abstract

Numerous studies have postulated the possible benefit of corticosteroids on olfaction in patients with nasal/sinus disease. Twenty-nine patients with bilateral nasal polyps were included in our study using strict selection criteria to reduce other aetiologies of olfactory dysfunction. The University of Pennsylvania Smell Identification Test (UPSIT) was performed pre-operatively on the right and left nostrils separately. Following intranasal polypectomy the patients received a six-week course of beclomethasone nasal spray (Beconase) to one nostril only, with the other acting as a control. The UPSIT scores were again obtained for each nostril separately. Wilcoxon Signed Rank test revealed no statistically significant difference in UPSIT scores between treated and untreated nostrils (p = 0.31; power 70 per cent; ES = 0.47). We conclude that topical beclomethasone does not improve olfaction following nasal polypectomy.

Key words: Nasal polyps; Smell

Introduction

In ENT practice, nasal polyposis is one of the commonest causes of the loss of olfaction (Scott, 1989). While nasal obstruction is presumed to be the prime cause of anosmia in these patients, it does not always follow that surgical polypectomy returns olfaction to normal. Numerous reports describe the recovery of olfaction using systemic corticosteroids. Hotchkiss (1956) described improvement in olfaction in 30 patients with nasal polyps on oral prednisolone. Fein *et al.* (1966) reported improvement in smell function in nine patients treated with systemic steroids. Goodspeed *et al.* (1986) reported an improvement in six out of 20 patients with nasal/sinus disease. Taylor (1973) noted an improvement in the sense of smell on Adrenocorticotrophic hormone (ACTH) injections. Jafek *et al.* (1987) described two cases of 'steroid-dependent' anosmia, a rare syndrome of inhalant allergy, nasal polyps and anosmia. All these studies looked at small numbers of patients and were uncontrolled.

The prescription for topical steroid nasal sprays is widespread in patients with nasal polyposis both before, and after, surgical polypectomy. The safety of long-term topical nasal steroid therapy is well established in the literature (Harris *et al.*, 1974; Holopainen *et al.*, 1982). Evidence of the role of topical steroids in improvement of olfaction is scanty and controversial. Scott (1989) reported amelioration of general nasal symptoms without concomitant improvement in olfaction with Beclomethasone dipropionate (BDP) or flunisolide. Brown *et al.* (1977) reported an improvement in olfaction in 15 out of 169 patients with perennial rhinitis. Tarlo *et al.* (1977) reported an improvement in two out of 12 hyposmic patients with perennial rhinitis. Neuman and Toshner (1978) reported improvement of smell in eight out of 15 children with perennial allergic rhinitis having subjective smell impairment. Scott *et al.* (1988) reported seven patients with nasal/sinus disease and showed improvement in olfactory test scores in five of them on flunisolide topical therapy. Some authors like Tarlo *et al.* (1977) and Brown *et al.* (1977) suggested the preliminary use of a short course of systemic steroids to improve the olfactory recovery with topical steroids. All these trials were uncontrolled and the results are inconclusive.

The aim of the present study was to quantitatively assess the effect of Beconase nasal spray on olfaction after nasal polypectomy.

Materials and methods

Olfactory testing technique

We used the University of Pennsylvania Smell Identication Test (UPSIT) which is a standardized forced choice 'scratch and sniff' (Doty *et al.*, 1984a,b).

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Accepted for publication: 4 June 1995.

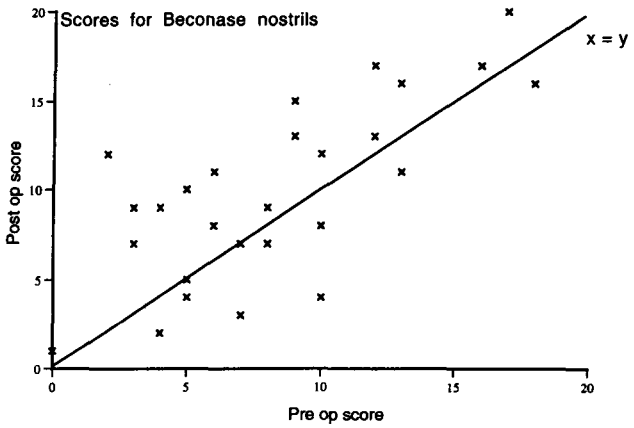

FIG. 1

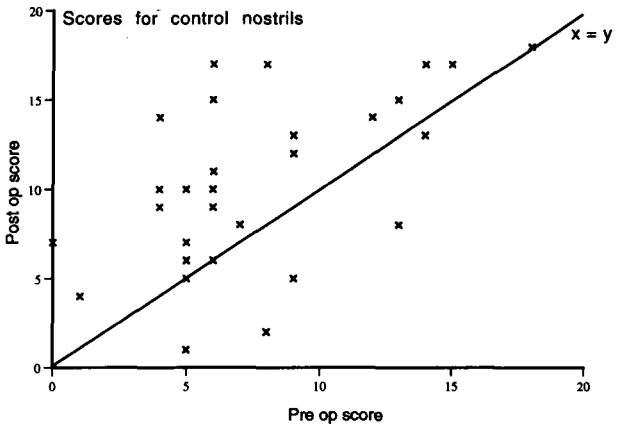

FIG. 2

FIGS 1 and 2 show the UPSIT score values for the 29 patients involved in the study. The values include the scores for the right and left nostrils separately both before, and after, nasal polypectomy. Values above x = y show post-operative improvement.

The test is commercially available (from Sensonics Inc., Haddon Heights, NJ, USA). It has a high test-retest reliability (six-month interval; r = 0.918; $p<0.001$) (Doty *et al.*, 1984b). The test consists of four booklets containing 10 odorants apiece, one odorant per page. The patient's task is to provide one of the four indicated answers, even if no smell is perceived. A correct answer gives a score of one. Two booklets of the UPSIT were administered to each nostril by one of the authors who released the stimuli under each patient's nose and recorded the responses. The nostril contralateral to the one being tested was tightly sealed by pressure applied by the test administrator. Scores were recorded, the maximum score was 20 per nostril. Booklets one and two were always used for the right nostril and booklets three and four for the left. Although UPSIT was designed to test both nostrils simultaneously, the use of two booklets per nostril has been approved by the University of Pennsylvania Smell and Taste Centre and applied in previous research (Doty *et al.*, 1992).

Patients. Twenty-nine patients with nasal polyps were included in the study. Their ages varied from 34 to 75 years with a mean of 51.5 years. Five patients were female. All patients included satisfied the following selection criteria.

The exclusion criteria were: (1) gross mechanical obstruction of the nasal airways secondary to any cause other than nasal polyposis; (2) any other concomitant intranasal surgical procedure except antral washouts; (3) a history of head trauma or exposure to toxic chemicals; (4) symptoms of neurological or psychiatric illness; (5) previous neurosurgery.

The inclusion criteria were: (1) bilateral nasal polyps; (2) informed consent to participate in the study.

Design of the trial. Eligible patients underwent pre-operative UPSIT in both nostrils as described above. Following intranasal polypectomy Beconase nasal spray was prescribed: two puffs, twice a day, into one nostril only. This nostril was randomly chosen with the other acting as a control. The patient was given two bottles of Beconase spray and was instructed to use it regularly for six weeks. The patient was then reviewed. Patients were excluded from the trial at this stage if: (1) histopathology revealed anything other than benign nasal polyps; (2) patients had any gross mechanical nasal airway obstruction.

None of our patients required exclusion at this stage. The patients then underwent post-operative UPSIT as described for pre-operative UPSIT.

Results

The UPSIT score values for the 29 patients involved in the study are displayed graphically (Figures 1 and 2). The values include the scores for the control and Beconase nostrils separately both before, and after, nasal polypectomy. The pre-operative score is plotted against the post-operative score.

The score changes in both nostrils were calculated. Data for the score change in the control nostril was labelled as C1 as opposed to C2 data representing

TABLE I

	Control nostril	Beconase nostril
No. of cases showing increase in post-operative UPSIT scores	21	18
No. of cases showing decrease in post-operative UPSIT scores	5	9
No. of cases showing no change in UPSIT scores	3	2
Total	29	29

https://doi.org/10.1017/S002221510013172X Published online by Cambridge University Press

TABLE II

	Mean	Median	Range	SD
C1 data	2.7	3	−6, 11	4.3
C2 data	1.9	2	−6, 10	3.4
C3 data	−0.8	−1.0	−8, 7	3.7

the score change in the nostril receiving Beconase. The score difference between paired C1 and C2 data was also calculated and labelled as C3 (where C3 = C2 −C1). The number of improvements and deteriorations in the UPSIT scores in both the control and Beconase nostrils are displayed in Table I. The mean, median, range and standard deviations for C1, C2 and C3 data are displayed in Table II.

The Wilcoxon Signed Rank Test was used for statistical analysis of the score change data (C1, C2 and C3) and revealed p = 0.31, 95 per cent Confidence Interval (CI) (−2.5, 0.5). The result is therefore insignificant for any UPSIT score change either way as a result of Beconase treatment. At our sample size of 29 the power of the study is 70 per cent (ES = 0.47) using for estimation the method described in Armitage (1987).

Discussion

Our results show that the use of Beconase nasal spray after nasal polypectomy does not have an impact upon olfaction as measured quantitatively using the UPSIT test (p = 0.31 at a power of 70 per cent). Whether systemic corticosteroids could be more effective in this situation remains to be proven by a proper, randomized, double-blind, placebo-controlled trial.

Compared with other methods including threshold olfactometry (Cain, 1989) and T & T olfactometry (Toyota *et al.*, 1978), UPSIT is much easier to administer, less time consuming and has high reliability. The use of two booklets for each nostril enables one nostril to act as a control for the other. The numerical score given by UPSIT facilitates statistical analysis.

Previous studies including Pederson *et al.* (1976) have shown that at least four weeks treatment is required before results of therapy for nasal polyps can be assessed. It is also well known that the first two weeks after surgery is bound to be a period when crusting and oedema are subsiding. In our study we started the Beconase treatment immediately post-operatively. Although the preceding statement might argue against early commencement of Beconase, we think that by giving the spray continuously for six weeks we have given the patients at least four weeks effective treatment which is as long as required.

In our study we have opted to use one nostril as a control for the other. Clearly an obvious alternative would have been a double cohort study. We preferred the former study design because of the anticipated difficulty in controlling the large number of variables which affect the sense of olfaction. Among these factors are age, sex, smoking habits and above all concurrent medications including steroids that are not uncommonly used concurrently for asthma in patients with nasal polyps. We have eliminated this difficulty by choosing our design. In doing so however we have exposed another potential bias which is related to drug compliance. We endeavoured to ensure that the patients have in fact used the spray regularly by asking them. Alternatively, compliance might have been verified by weighing the spray bottles.

The procedure of using one nostril as a control to the other is one that has to be applied with caution. Strict exclusion criteria have to be applied to avoid asymmetric mechanical airway obstruction skewing the results. It could be argued that the nasal cycle would make one nostril a poor control for the other. However, Doty and Frye (1989) found that olfactory threshold values did not change significantly between the extremes of the engorgement cycle for either side of the nose.

Systemic steroids may be more effective than topical steroids in relieving nasal polyp symptoms because of problems of obtaining even distribution of a spray in the presence of polyps. Seemingly successful polypectomies may be less successful in allowing ventilation of the olfactory region. Further studies relating site of polyposis to olfactory dysfunction and subsequent recovery are therefore required.

Acknowledgements

The authors are very grateful to Mr Peter Kelly, Senior Lecturer in Medical Statistics, University of Newcastle-upon-Tyne for his advice about statistical analysis in this study.

The authors would also like to express their thanks to Tracy Jackson of the ENTER Foundation, North Riding Infirmary for typing this manuscript.

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