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A prospective randomized study to assess the efficacy of post-operative nasal medication after endonasal surgery

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Abstract

Post-operative nasal medications are commonly used following routine septal or turbinate surgery but their efficacy in removing blood clots, improving the sensation of a patent airway and promoting healing are unknown. This prospective randomized trial of patients undergoing septal and/or turbinate surgery assessed the efficacy of three commonly used nasal medicines, 0.5 per cent ephedrine hydrochloride nasal drops, betamethasone sodium phosphate (Betnosol®) nose drops and alkaline nasal douches, in producing the sensation of a patent airway in the 14 days following surgery. Ninety-seven patients were randomized into the three treatment groups and a control group who received no nasal medication. Patients assessed their nasal patency by means of a visual analogue scale (VAS) and any complications of treatment were recorded. Statistical analysis of the 76 complete sets of results using the Mann-Whitney U-test showed that there was a significant difference in the distribution of all of the treatments for each of the time intervals ($p<0.05$). Glass rank biserial correlation coefficients were all small ($rg<0.085$) but the most significant differences were between ephedrine and the control group at two hours, two, seven and 10 days (0.02, 0.054, 0.057, 0.085 respectively), alkaline nasal douches being most significant at four and 14 days (0.06 and 0.0722 respectively).

Key words: Nose, surgery; Drug therapy

Introduction

Septal and turbinate surgery constitutes a significant part of the workload of the general otolaryngologist. Many surgeons routinely use one of a wide variety of nasal medications post-operatively after the removal of packs or dressings over the following weeks although no evidence exists for their efficacy. These medicines may act by encouraging clearance of blood clots and crusts from the nose, preventing the nasal mucosa from drying, reducing post-operative swelling, encouraging healing and generally giving the patient a subjective impression of a patent nasal airway.

This prospective randomized study of patients undergoing endonasal surgery at the Whittington Hospital aimed to assess the efficacy of three commonly used nasal medicines, 0.5 per cent ephedrine hydrochloride nasal drops, betamethasone sodium phosphate 0.1% (Betnosol®) nose drops and alkaline nasal douche, in achieving a subjective sensation of a patent nasal airway. Any adverse reactions of the treatments were documented at the time of review.

This trial did not include the use of nasal toilet or inhalations following surgery but the authors recognized their role in the post-operative management of patients undergoing septal or turbinate surgery.

Materials and method

Ninety-seven consecutive patients admitted to the Whittington Hospital for septal and/or turbinate surgery between July 1993 and July 1994 were randomized into four groups by random numbers opened from closed envelopes. Patients less than 16 years or more than 65 years, those requiring nasal splints or repacking of the nose due to haemorrhage, and those on systemic drugs or nasal medicines which may affect the nasal airway patency were excluded. Patients underwent septoplasty, submucous resection of the nasal septum and radical bilateral inferior turbinectomy, either alone or in combination. Surgery was performed in a standard fashion. Melolite® dressings were applied to the nasal fossae following septal surgery and Bismuth iododoform paraffin paste (BIPP) impregnated ribbon gauze following inferior turbinectomy. All dressings and packs were removed the morning after surgery. The method of administering the nose drops (head down and forward position) and douches (sniffing from the palm of the hand or an egg-cup)

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TABLE I
MEAN VISUAL ANALOGUE SCORES (VAS) AND STANDARD DEVIATIONS (SD) FOR EACH GROUP

	Group 1 Alkaline nasal douche	Group 2 Betnosol® drops	Group 3 0.5% Ephedrine drops	Group 4 Control
Total number of patients treated	19	17	20	19
Mean distance from 0 on VAS (SD)				
2 Hours	6.73 (6.58)	11.4 (16.29)	14.9 (21.73)	14.5 (17.83)
2 Days	26.0 (10.07)	15.4 (16.46)	27.6 (22.41)	34.6 (24.49)
4 Days	41.5 (13.61)	34.3 (16.45)	33.4 (22.03)	45.0 (25.38)
7 Days	61.8 (15.71)	50.5 (14.03)	48.5 (25.32)	54.0 (24.17)
10 Days	72.7 (13.27)	64.5 (17.84)	62.2 (27.63)	64.5 (22.65)
14 Days	81.9 (12.66)	68.7 (21.34)	67.2 (26.82)	75.8 (20.53)

were explained in detail by one of the authors and started two hours after pack removal.

Patients were asked to mark a simple linear, open-ended, unmarked 100 mm visual analogue scale (Adams *et al.*, 1985) at two hours, two, four, seven, 10 and 14 days following pack removal. The left end of the visual analogue scale (VAS) (0 mm) represented total nasal obstruction and the right end (100 mm) total nasal patency. Patients were asked to give an average assessment of total nasal airway patency over the previous 24 hours.

Patients were reviewed in the Outpatient Clinic 14 days after surgery by one of the authors and an enquiry was made as to any adverse reactions of the treatment.

Completed forms were reviewed by the authors and the distance of the marks from the left end of the VAS measured in millimetres and entered onto a database. Statistical analysis of the non-parametric data between the treatment groups and the control was performed using the Mann-Whitney U-test and a probability of <0.05 was considered significant.

Results

Seventy-seven of the 97 cards were returned: two cards were incorrectly marked and were excluded. There were 40 male and 35 female patients with an age range from 17 to 65 years, a mean of 35.5 years and a median of 32.2 years. Thirty-one patients underwent septal surgery alone, 26 underwent septal surgery and inferior turbinectomy and 18 underwent inferior turbinectomy alone.

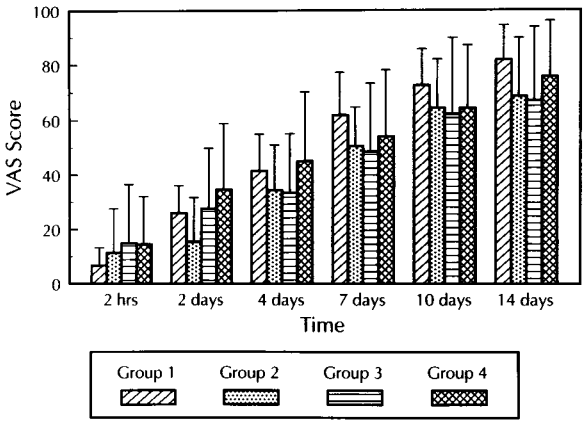

FIG. 1
Mean visual analogue scores (VAS) and standard deviations (SD) for each group plotted against time.

The mean visual analogue scores and standard deviations for each group are recorded in Table I, and plotted against time in Figure 1. There was a significant difference in the distribution of all of the treatments for each of the time intervals ($p<0.05$). Glass rank biserial correlation coefficients were all small ($rg<0.085$) but the most significant differences were between ephedrine and the control group at two hours, two, seven and 10 days (0.02, 0.054, 0.057, 0.085 respectively), alkaline nasal douches being most significant at four and 14 days (0.06 and 0.0722 respectively).

The distribution of the surgical procedures and the grade of surgeon in each group is recorded in Table II.

Comments on the treatment were recorded in only four patients. Discomfort was reported on use of ephedrine nose drops in two patients and in performing alkaline nasal douching in one patient. One patient reported a significant improvement in the sensation of nasal patency on passing a large blood clot.

Discussion

Although this trial demonstrates significant differences in the effectiveness of the tested nasal medicines against a control group, the levels of significance as determined by the Glass coefficient are small. Ephedrine was of the greatest benefit in the early post-operative period (two, seven and 10 days) and alkaline nasal douches at four and 14 days. This may reflect the different mode of action of the two preparations. Ephedrine hydrochloride is a short acting alpha-1-agonist and sympathomimetic agent which results in vasoconstriction of the nasal mucosa and reduction of the bulk of the inferior turbinates. The mode of action of alkaline nasal douches is not known but probably acts by breaking down blood clot and fibrin and moisturizing the nasal mucosa.

Little consensus exists as to the merits of any nasal regimens following routine nasal surgery. Contemporary surgical texts rarely mention post-operative nasal care and current practice relies on personal experience and tradition rather than science. For many years inhalations of the vapours of volatile oils, such as benzoin tincture compound (Friar's balsam),

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TABLE II
THE DISTRIBUTION OF SURGICAL PROCEDURE TYPE AND SURGEON GRADES BETWEEN THE GROUPS

	Type of surgery			Surgeon grade		
	Septal	Turbinate	Combined	Consultant	Registrar	SHO
Group 1 (Alkaline nasal douche)	9	3	8	4	11	4
Group 2 (Betnosol® drops)	5	2	10	2	12	3
Group 3 (0.5% Ephedrine drops)	8	6	6	1	16	3
Group 4 (Control)	9	7	3	3	10	6
Total	31	18	26	10	49	16

menthol, eucalyptus oil and camphor have been prescribed. Some departments recommend suctioning of the nasal fossae on the first post-operative day to remove blood clots and fibrin. Williams (1986) recommended warm saline sniffed through the nose 24 hours after submucous resection of the septum twice a day to clear blood clot. Maran (1986) recommended decongestant nose drops for two weeks following septoplasty. All modes of treatment are purely empirical as to date prospective trials have not been performed to investigate the effectiveness of the different regimens.

Nasal obstruction in the immediate post-operative period is not only uncomfortable for the patient but also can lead to mouth breathing, dehydration, and deterioration of lung function in patients with chronic pulmonary disease. Persistent tissue oedema and retained blood clot and exudates may also predispose towards adhesion formation within the nasal fossae which invariably results in a poor surgical outcome in operations designed to improve the nasal airway patency.

The relationship between the subjective sensation of nasal patency and nasal resistance however is by no means clear and has been the subject of much debate in the recent years. Jones *et al.* (1989) have shown that there is no correlation between nasal resistance to airflow, measured by anterior rhinomanometry and subjective nasal sensation of airflow, measured by visual analogue scale, in the normal and rhinitic patient. Furthermore, operations in the nasal fossa at the level of the nasal valve may radically reduce nasal resistance but have no effect on subjective nasal patency (Jones *et al.*, 1988; Wight *et al.*, 1988). Radical inferior turbinectomy however results in a marked increase in subjective nasal patency with a similar reduction of resistance (Wight *et al.*, 1988).

It is the subjective sensation of nasal obstruction rather than increased nasal resistance which is the patient's presenting complaint and improvement in this sensation is, in most cases, the primary aim of the operation. Certainly in the immediate post-operative period it is this symptom that is of paramount importance to the patient. Nasal receptors are found throughout the nasal cavities and via the trigeminal nerve both detect the subjective levels of inspiratory flow rate (the sensation of nasal patency) and affect the pulmonary reflexes of nasal origin. A recent study has concluded that the receptors of the nasal vestibule, which are more sensitive than those of the nasal cavum, are principally involved with the sensation of nasal obstruction and patency and those in the nasal cavum with nasal reflexes (Clarke and Jones, 1994). Anaesthesia of the receptors of the nasal vestibule results in the sensation of nasal obstruction with no changes in nasal resistance (Jones *et al.*, 1987). However anaesthesia of the nasal cavum produces the sensation of increased nasal patency (Jones *et al.*, 1986). In the immediate post-operative period there may be a combination of the increased nasal resistance and decreased sensation of nasal patency. Tissue oedema and retention of blood clots and fibrinous exudates in the nasal fossae reduces the cross-sectional area of the nasal airway. Denervation of the nasal and vestibular mucosa occurs by the combination of surgical trauma, persistent effects of local anaesthesia and the traumatic and toxic effects of nasal packing.

It would be logical therefore to manipulate the function of the nasal receptors rather than concentrating on clearing the nasal fossae of debris to improve the sensation of nasal patency in the first days following surgery. The traditional therapy of inhalation of vapours of the volatile oils cause an increase in the sensation of nasal patency by increasing the sensitivity of the nasal receptors without an improvement in nasal resistance (Burrow *et al.*, 1983). One wonders whether instillation of local anaesthetic solutions to the nasal fossae in the post-operative period would be a better approach to improve the patient's sensation of nasal patency as opposed to the current methods aimed at clearing the nasal fossae.

It is of interest that in our results the average responses to the sensation of nasal patency at the end of the 14 day period are uniformly excellent, being above 60 mm on the VAS in all groups. The reason for this may be a criticism of the design of the trial and particularly the layout of the recording card. Patients completed the assessment of visual analogue scales with the result of the previous assessments available for comparison. Therefore the readings are not completely independent and may have resulted in the steady improvement of results over the 14 day

period as the airway improved post-operatively. There should however be no bias between the groups which may have affected the outcome.

No comments from the patients in the treatment groups suggested any adverse effect of the treatments.

Conclusions

There is a statistically significant benefit achieved in the sensation of nasal patency with the use of 0.5 per cent ephedrine hydrochloride nose drops, Betnosol® drops and alkaline nasal douches when compared with a control group in the early post-operative period. Complications of the treatments are insignificant. The use of these treatments should be encouraged to both improve the sensation of nasal patency and also aid clearance of debris from the nasal fossae.

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