

**COMPARING THE EFFICACY OF ALKALINE NASAL DOUCHES VERSUS
DECONGESTANT NASAL DROPS IN POST OPERATIVE CARE AFTER SEPTAL
SURGERY**

¹Ruta Shanmugam, *²S.Amrutha, ³V.U.Shanmugam, ⁴R.Mariappan and ⁵Balaji Swaminathan

^{1*}Professor and HOD, Dept of ENT, Rajah Muthiah Medical College, Annamalai University, Annamalai nagar, Chidambaram.

²Post graduate, Dept of ENT, Rajah Muthiah Medical College, Annamalai University, Annamalai nagar, Chidambaram.

³Professor, Dept of ENT, Rajah Muthiah Medical College, Annamalai University, Annamalai nagar, Chidambaram.

⁴Professor, ⁵Reader, Dept of ENT, Rajah Muthiah Medical College, Annamalai University, Annamalai nagar, Chidambaram.

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ABSTRACT

To compare the efficacy of alkaline nasal douches and decongestant nasal drops following nasal septal surgery. This was a prospective, randomised, single-blind pilot study. Twenty patients were included in each arm of the study undergoing elective nasal septal surgery. The primary outcome measure was nasal congestion. Secondary outcome measures were nasal discharge and facial pain. This study does not show any statistically significant difference between the two treatment groups. Symptoms of nasal congestion ($P = 0.258$), facial pain ($P = 0.413$), nasal discharge ($P = 0.417$) were analysed before conclusion. No statistical significant differences were noted on analysing the post operative complications in either group. In this study, both nasal douches and decongestant nasal drop were well tolerated. Both treatments provided good postoperative relief from nasal congestion, nasal discharge and facial pain as days progressed. The post operative examination of the nose among these patients revealed no significant complications in either of the study arm.

Keywords: Nasal septal surgery, Nasal douches, Nasal drops.

1. INTRODUCTION

Septal surgery is a common procedure performed in ENT practice. The commonest indication for undergoing this operation would be nasal blockage. This symptom could be inherited or secondary to a nasal trauma. Septal surgery will be in the form of septoplasty or submucosal resection. Patients who have had such operations invariably will develop mucosal swelling, crusting and nasal discharge in the post operative period. These symptoms can last from few days to several weeks following the operation. To counter these problems patients are advised various forms of treatments. These could be in the form of nasal alkaline douches, nasal decongestants and or both. Nasal alkaline douches have been a longstanding treatment for sinonasal

disease. It has been practised in India for centuries as part of the purification routines performed in preparation for yoga⁶. Nasal irrigation with saline seems to reduce nasal and rhinosinusal dryness, facilitating the clearing of thick mucus and crusts in patient's affected by rhino sinusitis³. In addition to these properties, because of their effects of moisturisation, humidification and reduction of swelling, they have been tried after surgery for rhino sinusitis⁷. Nasal saline douches have been recommended in the immediate post operative period to clear the blood clots and crusts¹⁰. Nasal drops in the form of decongestants like ephedrine nasal drops and steroids like Betamethasone sodium phosphate 0.1% have been tried and tested with success⁹. Decongestant nasal drops (0.1% Xylometazoline hydrochloride) are potent sympathomimetic drugs which exert their effect by vasoconstriction of the mucosal blood vessels which in turn reduces oedema of the nasal mucosa. The purpose of this work is to provide data on which to

*Corresponding author **Dr. S.Amrutha**, Post graduate, Dept of ENT, Rajah Muthiah medical college, Annamalai University, Annamalai nagar, Chidambaram

design a study to compare the efficacy of the above two methods, and to assess the feasibility and likely utility of such a study.

2. MATERIALS AND METHODS:

This study will be conducted on patients of 18 to 50 years age group of either sex presenting with nasal obstruction/nasal blockage for septoplasty or submucosal resection at the Department of Otorhinolaryngology at Raja Muthiah Medical College Hospital during the study period from October 2013 to September 2015.

Eligibility Criteria:

Patients undergoing elective nasal septal surgery were enrolled into the study. Exclusion criteria were the patient being under the age of 18 years, patients unable or unwilling to give consent and those patients with relative contraindication for using nasal drops. Patients with haemostatic disorders were also excluded from the study.

Intervention:

Patients will be informed of the trial during preoperative assessment visit. Written information regarding the trial will be provided at this time and informed written consent will be obtained from those willing to take part. The trial is planned to be done as prospective, randomised, study.

Patients will be divided into two random sample groups by numbering them in series and taking odd numbered patient group as group A and even numbered patient group as group B. Patients undergo either septoplasty or submucosal resection in the hospital following which 20 patients in **Group A** are assigned to use **nasal douches** in the postoperative period for 14 days and 20 patients in **Group B** are assigned to use **nasal decongestant** (1% xylometazoline) drops in the postoperative period for 14 days. Patients will be monitored during their post operative period of 14 days. If he/she gets discharged early, the recipe and method of administration of these drugs will be meticulously instructed orally and legibly printed handouts will be handed to them.

The recipe for alkaline nasal douche was given in printed format. Each time of use it was prepared fresh by taking one mug of warm tap water and dissolving half a teaspoon of table salt and quarter teaspoon of sodium bicarbonate. Patients were advised to pour a little of this mixture into cupped palm and sniff it through both nostrils, one at a time. They were advised to use a whole mug three times a day for 2 weeks. Patients with nasal drops were advised to use two drops, three times a day for 2 weeks². The participants were given the leaflet about the position of the head and neck on inserting the drops. This group of patients were prescribed xylometazoline hydrochloride 0.1% drops on discharge.

Outcome Measures:

Our primary outcome measure was the nasal congestion in the post operative period. Patients were asked to record the severity of nasal blockage experienced each day on a graduated horizontal visual analogue scale, with a range of 0–10, 0 being no blockage and 10 representing total nasal obstruction. The scores were recorded each day for 14 days.

Our secondary outcome measures were facial pain and nasal discharge. Patients were asked to record the severity of these symptoms on a visual analogue scale each day for the 14 post operative days, on a scale ranging between 0 and 10, 0 being no problems and 10 being the worst experience. Visual analogue scores are validated for assessing the severity of pain [7] and have been used previously to record the nasal symptoms⁹. The nasal cavities were examined using nasal endoscope at 2 weeks to assess the degree of discharge, oedema, crusting and scars or adhesion formation. All recruited patients were examined by the same surgeon to avoid any bias.

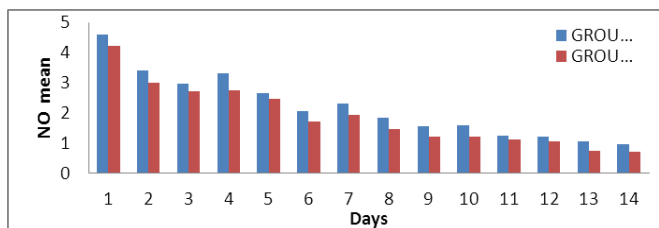
3. RESULTS:

Forty patients were enrolled in the trial with twenty patients in each group. Data was collected on all patients in the post operative period for 14 days. In Group A 10 patients were males and 10 females while in group B, 11 patients were males and 9 females, with no significant difference between two groups in gender ($p=0.752$). The mean age of the patients were 25.95 years with a range of 16–39 years, again showing no significant differences in the two groups ($p=0.234$).

Primary outcome:

a. Nasal obstruction

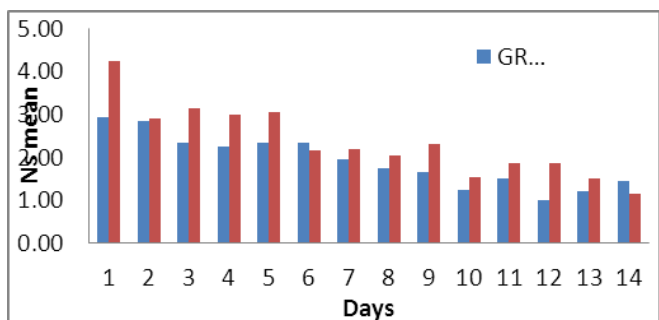
No statistically significant differences ($p=0.258$) were found between two groups in relieving nasal obstruction, although mean VAS of Group A patients was 2.193 and mean VAS of Group B patients was 1.57, suggesting slightly better relief of nasal obstruction with nasal decongestants.



Secondary outcome:

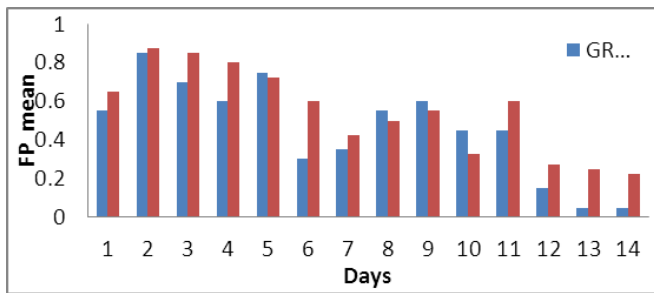
a. Nasal discharge

No statistically significant difference was found in decreasing nasal discharge post operatively between two groups with p value of 0.417. However, statistically significant difference was observed in the first post operative day with p value of 0.016 implying better control of nasal discharge with douching.



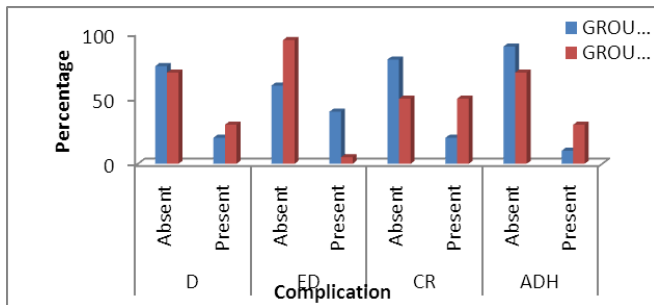
B. Facial pain:

Another secondary outcome measured was facial pain. No statistical difference was found in relieving post operative facial pain in both groups with p value of 0.413, although on day 6,13,14 some significant differences have been noted showing better relief with nasal douching.



DNE EXAMINATION

On 14th post operative day ,diagnostic nasal examination was done and discharge, edema, crusting, adhesions were documented on both groups .Mean scores were computed and no significant differences were noted between the two groups in case of nasal discharge (p=0.723) and adhesions(p=0.114).However significant differences were noted with significant decrease in mucosal edema with decongestants(p=0.008) and significant decrease in nasal crusting with douching(p=0.047).



Adverse events

No adverse events occurred among the patients in either group during the study period.

4.DISCUSSION

Interpretation of our study

Age

In our study , age of the patients enrolled were between 18-50 years, mean age being 25.75.. No significant difference was noticed while comparing the both groups in terms of age related statistical data.

This study group is comparatively younger than the study group of Vinod Prabhu [11] et al whose mean age was 44.4 years with a range of 21-68 years. But in both the studies, no significant difference were noted between two arms of trial in terms of age.

SEX

With regard to gender comparison between two groups of our study, group A had 10 males(50%) and 10 female patients(50%) while group B had 11 male (55%) and 9 female patients(45%), again showing no significant difference proportions between two arms of the trial(1:1.1). In the study by Vinod Prabhu et al [54], among the 40 patients in the study ,he had 32 males and 8 females.15 males were enrolled in group A and 17 males in group B and no significant difference were noted(0.429).

Primary outcome

Nasal obstruction

Primary outcome of our study was nasal obstruction and we found that there was no statistical significance between the two modalities of treatment. No statistically significant differences (p= 0.258)were found between two groups in relieving nasal obstruction, although mean VAS of Group A patients was 2.193 and mean VAS of Group B patients was 1.57 ,suggesting slightly better relief of nasal obstruction with nasal decongestants. In previous trials as in the one by Vinod Prabhu [54] ,no significant differences (p=0.3) were found in relief of nasal congestion between nasal saline and nasal decongestants in post operative septal surgery patients.

Secondary Outcome:

Nasal Discharge:

No statistically significant difference was found in decreasing nasal discharge post operatively between two groups with p value of 0.417. The significant difference was not consistently noted over the 14 day post operative period although mean VAS of Group A patients was 1.918 and that of Group B patients was 2.35,suggesting more decrease in post operative nasal discharge with nasal douching. This observation is in contrast to the previous study of Vinod Prabhu [54] in which consistent but insignificant differences (p=0.098) were noted in favour of decongestant drops over saline.

Facial Pain:

Another secondary outcome measured was facial pain. No statistical difference was found in relieving post operative facial pain in both groups with p value of 0.413, although on day 6,13,14 some significant differences have been noted showing better relief with nasal douching. In comparison, mean VAS of Group A was 0.457 and that of Group B was 0.635,with mean standard deviation ranging from 0.479 to 1.37. This observation was previously reported in studies of Vinod Prabhu et al [54] in which no significant difference (p=0.932) was noted in relief of post operative facial pain with nasal decongestants or nasal douches.

Our study design

Our study was purposely designed to include only septal surgery patients to maintain the uniformity with regards to nasal inflammation. We therefore avoided bias that would be

incurred from differences in nasal inflammation that would have occurred in the post operative period.

We used the visual analogue scale for scoring as it is widely used, easily understood by many patients and readily reproduced on successive presentations. All the recruited patients were evaluated on 14th post operative day by myself and findings were recorded in standard form after examination with a nasal endoscope. By doing this we have overcome the observational bias in this study.

Limitations of our study

1)Our study was limited for not evaluating patients undergoing other nasal surgery.

2)Compliance and tolerability of the patient with the treatment was not assessed.

3)The small, insignificant but consistent differences that we observed would suggest that a further, larger study would be justified .

5.CONCLUSION

Both the alkaline nasal douche and the decongestant nasal drops improved nasal symptoms well in our study. There was no statistically significant difference between the two arms of treatment. Bimodal treatment in the form of nasal decongestant drops and saline douches may be beneficial. There is scope for future trials along this line of management.

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