

# Use of Sodium Chloride IP 0.65% w/v Nasal Spray for Symptom Relief in Patients after Nasal Surgery

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## Abstract

**Introduction :** The use of nasal irrigation for the treatment of nose and sinus complaints has its foundations in yogic and homoeopathic traditions. There has been increasing use of saline irrigation, douches, sprays and rinsing as an adjunct to the medical management of chronic rhinosinusitis. Treatment strategies often include the use of topical saline from once to more than four times a day.

After nasal surgery patient may suffer from various complications like nasal congestion, discharge, bleeding etc. So this study was conducted to evaluate the efficacy of Saline Nasal Spray during post-operative nasal surgery like Septoplasty, Polypectomy, Turbinectomy, Dacryocystorrhinostomy (DCR) and Functional Endoscopic Sinus Surgery (FESS).

**Objectives :** The objective of this study was to evaluate the efficacy, safety and tolerability of Saline Nasal spray during post-operative period of nasal surgery.

**Methods :** Forty patients of either sex posted for nasal surgery were enrolled in the study after obtaining informed written consent. The patients were administered Saline Nasal spray during the post-operative period 2 times in a day for 3 days. Response for the nasal symptoms and adverse events was recorded on days 3, 4, 5, 6 and 7. Additionally at the end of the therapy global impression about therapy was assessed by the patient and the doctor for efficacy and tolerability.

**Results :** Complete response for nasal congestion was seen in 79.5% patients, whereas 17.9% had partial response and 2.6% had no response. For nasal pain 90.9% had complete response, 6.1% had partial response and 3% had no response. For nasal bleeding 100% subjects had complete response. For rhinorrhoea, 88.6% had complete response and 11.4% had partial response. For loss of smell 60% had complete response, 30% had partial response and 10% had no response.

For global efficacy evaluation the doctors rated the therapy as excellent for 35% of patients, good for 62.55% and satisfactory for 2.55%. For global efficacy evaluation 10% patients rated the therapy as excellent, 77.5% rated as good and 12.5% rated as satisfactory. Not the doctors nor the patients rated the therapy as poor. For global tolerability evaluation the doctors rated the therapy as excellent for 35% of patients, good for 57.5% and satisfactory for 7.5%. For global tolerability evaluation the 25% patients rated the therapy as excellent, 60% rated as good and 15% rated as satisfactory. Nor the doctors neither the patients rated the therapy as poor.

**Conclusion :** In Indian patients Saline Nasal spray when used during the post operative nasal surgery period is well tolerated and provides significant reduction in symptoms like nasal congestion, nasal pain, nasal bleeding, rhinorrhoea and loss of sense of smell.

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## Introduction

For simple problems of the nose and the sinuses, the conventional operations using a simple head light and special ENT

instruments suffice. However, in more complicated cases, either MES or FESS is done. Whichever methods are used they are associated with post operative complication like nasal congestion, discharge, bleeding, etc.

Saline irrigation, douches, sprays and rinsing are used as an adjunct to the medical management of chronic rhinosinusitis.<sup>1</sup> Nasal saline spray (NSS) used in the treatment of rhinitis and sinusitis often contains the preservative benzalkonium chloride (BKC). Intranasal products containing the preservative BKC appear to be safe and well tolerated for both long- and short-term clinical use.<sup>2</sup>

NSS spray contains Sodium chloride IP 0.65% w/v in distilled water made isotonic and buffered and benzalkonium chloride solution IP 0.03% w/v (as Preservative). So this study was conducted to evaluate the efficacy of Saline Nasal Spray during post-operative nasal surgery like septoplasty, polypectomy, turbinectomy, dacryocystorrhinostomy (DCR) and functional endoscopic sinus surgery (FESS).

Our objective is to observe the efficacy and tolerability of Saline Nasal spray during post-operative period of nasal surgery.

## **Material and Methods**

### **Study Design**

The study was an open, prospective, observational, open label, non-comparative user study conducted in 40 patients at Department of Otorhinolaryngology, Grant Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai, India.

### **Study Subjects**

Forty patients of either sex were enrolled in the trial. Post nasal surgery the baseline demographic data and symptoms were recorded. Response for the nasal symptoms

and adverse events was recorded on day 3, 4, 5, 6 and 7. Additionally at the end of the therapy global impression about therapy was assessed by the patient and the doctor for efficacy and tolerability.

### **Interventions**

All enrolled patients received Saline Nasal spray 2 times in a day for 3 days. There was no dose titration. All patients received chemotherapeutic agents for antimicrobial prophylaxis.

### **Assessments**

The study population was evaluated for baseline demographic data (age and gender) and baseline symptoms. The nasal symptoms were assessed on a 4-point scale of 0=absent, 1 = mild, 2 = moderate and 3 = severe. Nasal congestion, nasal pain, nasal bleeding, rhinorrhoea and loss of sense of smell were the 5 nasal symptoms that were assessed.

The efficacy parameter was, symptom relief (score) from baseline analyzed by Friedman test, physician global assessment (PGA), patient global assessments (PtGA). Response was defined as absence of nasal symptom when it was present at baseline. No. and % of responders for the nasal symptoms on days 3, 4, 5, 6 and 7 were calculated. For all statistical tests, the significance level ( $\alpha$ ) was  $p < 0.05$ .

Safety assessment was made based upon the adverse events reported by the patients. Global evaluation for efficacy and tolerability was assessed by the patient and doctor independently based on a 5-point rating scale of Excellent, Good, Moderate, Fair and Poor.

### **Compliance**

Patient compliance was assessed at each visit by the investigator by open questioning about the study medication consumption.

## Statistical Analysis

Measurement data expressed as Mean and SD whereas Numbers as (No.) and percentages as (%). Chi-square test applied for patients showing improvement/cure after therapy. One-way ANOVA applied for repeat measures data for measurement data. Non-parametric data analyzed using Mann-Whitney 'U' test and Friedman test. For all statistical tests, the significance level is taken as  $p < 0.05$ .

## Results

### Patients Population

A total of 40 patients were enrolled and since there were no drop outs or loss to follow up all the patients data were analysed. Thus, data of 40 patients was evaluated. The mean age of the subject was 25.5 years of which 70% were males and 30% were female patients. The type of surgery the subject underwent are as seen in Fig. 1.

### Mean Symptom score

The mean symptom score for nasal congestion reduced significantly ( $\chi^2=118.67$ , 4 df,  $p < 0.0001$ ) from day 3 to day 7. On Day 3, the mean score was 1.7 (0.8) and on days 4, 5, 6 and 7 it reduced to 1.4 (0.9), 1.0 (0.7), 0.4 (0.6) and 0.2 (0.5) respectively. The mean symptom score for nasal pain reduced significantly ( $\chi^2=100.93$ , 4 df,  $p < 0.0001$ ) from day 3 to day 7.

On Day 3, the mean score was 1.2 (0.8) and on days 4, 5, 6 and 7 it reduced to 0.7 (0.8), 0.3 (0.6), 0.1 (0.3) and 0.1 (0.3) respectively. The mean symptom score for nasal bleeding reduced significantly ( $\chi^2=42.15$ , 4 df,  $p < 0.0001$ ) from day 3 to day 7. On Day 3, the mean score was 0.5 (0.8) and on days 4, 5, 6 and 7 it reduced to 0.2 (0.5), 0.1 (0.2), 0.0(0.0) and 0.0(0.0) respectively. The mean symptom score for rhinorrhoea reduced significantly ( $\chi^2=106.51$ , 4 df,  $p < 0.0001$ ) from

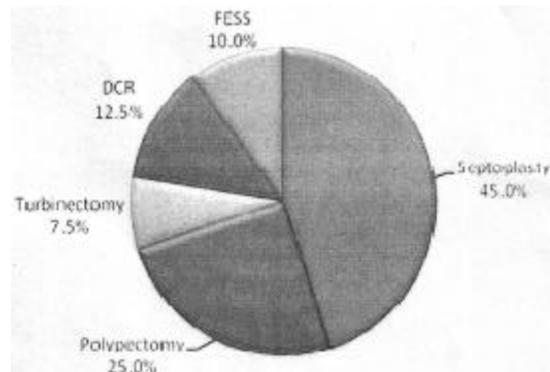


Fig. 1 : Type of nasal surgery (n=40)

day 3 to day 7. On Day 3, the mean score was 1.3 (0.8) and on days 4, 5, 6 and 7 it reduced to 1.0(0.8), 0.6 (0.7), 0.2 (0.4) and 0.2 (0.4) respectively. The mean symptom score for loss of smell reduced significantly (Friedman test:  $\chi^2=35.19$ , 4 df,  $p < 0.0001$ ) from day 3 to day 7. On day 3, the mean score was 0.7 (1.2) and on days 4, 5, 6 and 7 it reduced to 0.6 (1.0), 0.4 (0.7), 0.3 (0.5), and 0.1 (0.3) respectively.

Thus there was significantly reduction in all the nasal symptoms from the baseline after use of Saline Nasal spray.

### Response to Saline Nasal Treatment

The response to Saline Nasal spray was seen as shown in Table 1. For nasal congestion 79.5% had complete response, 17.9% had partial response and 2.6% had no response. For nasal pain 90.9% had complete response, 6.1% had partial response and 3% had no response. For nasal bleeding 100% subjects had complete response. For Rhinorrhoea 88.6% had complete response and 11.4% had partial response. For Loss of smell, 60% had complete response, 30% had partial response and 10% had no response.

### Complete Response to Saline Nasal Therapy (No. (%))

The Complete response to Saline Nasal

**Table 1 : Response to saline nasal therapy (No. (%))**

	No response		Partial response		Complete response	
	No.	%	No.	%	No.	%
Nasal Congestion (n=39)	1	2.6	7	17.9	31	79.5
Nasal Pain (n=33)	1	3.0	2	6.1	30	90.9
Nasal bleeding (n=13)	0	0.0	0	0.0	13	100.0
Rhinorrhoea (n=35)	0	0.0	4	11.4	31	88.6
Loss of smell (n=10)	1	10.0	3	30.0	6	60.0

**Table 2 : Complete response to saline nasal therapy (No. (%))**

	Day 4		Day 5		Day 6		Day 7		Total	
	No.	%								
Nasal congestion (n=39)	5	12.8	3	7.7	17	43.6	6	15.4	31	79.5
Nasal pain (n=33)	13	39.4	10	30.3	6	18.2	1	3.0	30	90.9
Nasal bleeding (n=13)	5	38.5	5	38.5	3	23.1	0	0.0	13	100.0
Rhinorrhoea (n=35)	5	14.3	11	31.4	13	37.1	2	5.7	31	88.6
Loss of smell (n=10)	0	0.0	0	0.0	2	20.0	4	40.0	6	60.0

therapy was as seen in Table 2. At the end of the treatment 79.5% had complete response for nasal congestion, 90.9% for nasal pain, 100% for nasal bleeding, 88.6% for Rhinorrhoea and 60% for loss of smell.

#### **Global Efficacy Evaluation**

For global efficacy evaluation the doctors rated the therapy as excellent for 35% of patients, good for 62.55% and satisfactory for 2.55%. For global efficacy evaluation the 10% patient rated the therapy as excellent, 77.5% rated as good and 12.5% rated as satisfactory. Nor the doctors neither the patients rated the therapy as poor.

#### **Global Tolerability Evaluation**

For global tolerability evaluation the doctors rated the therapy as excellent for 35% of patients, good for 57.5% and satisfactory for 7.5%. For global tolerability evaluation the 25% patient rated the therapy as excellent, 60% rated as good and 15% rated

as satisfactory. Nor the doctors neither the patients rated the therapy as poor.

#### **Discussion**

The results of the present study indicate Saline Nasal spray when used during the post operative nasal surgery period is well tolerated and provides significant reduction in symptoms like Nasal Congestion, Nasal Pain, Nasal Bleeding, Rhinorrhoea and Loss of sense of smell.

A study was conducted to review clinical evidence on the efficacy of saline nasal irrigation for treatment of sinonasal conditions and to explore its potential benefits. It was concluded from the study that Nasal irrigation is a simple, inexpensive treatment that relieves the symptoms of a variety of sinus and nasal conditions, reduces use of medical resources, and could help minimize antibiotic resistance.<sup>3</sup>

Another study was carried out to compare two application forms for isotonic

sodiumchloride solution in postoperative sinus-surgery wound care. It was found that only significantly reduced grade of obstruction was found in the ethmoidal system in the group using nasal spray. The results in the other locations showed no difference comparing both irrigation methods. The acceptance rate was higher in the group of nasal spray users. Thus, Nasal spray seems to be superior to manual irrigation in regard to postoperative wound conditioning, handling, and hygienic aspects.<sup>4</sup>

### Conclusion

In Indian patients during the post operative period, therapy with Saline Nasal spray is well tolerated and provides significant reduction in symptoms like Nasal Congestion, Nasal Pain, Nasal Bleeding, Rhinorrhoea and Loss of sense of smell. The incidence of side effects is very low thus

improving the compliance and tolerability.

### Acknowledgement

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### References

1. Harvey R, Hannan SA, *et al.* Nasal saline irrigations for the symptoms of chronic rhinosinusitis. *Cochrane Database Syst Rev* 2007 Jul 18; (3) : CD006394.
2. Marple B, Roland P, *et al.* Safety review of benzalkonium chloride used as a preservative in intranasal solutions: an overview of conflicting data and opinions. *Otolaryngol Head Neck Surg* 2003; 130 (1) : 131-Head Neck 41.
3. Papsin B, McTavish A. Saline nasal irrigation: Its role as an adjunct treatment. *Can Fam Physician* 2003; 49 : 168-73.
4. Scheithauer MO, Scheithauer I, *et al.* Comparison of two application forms for isotonic sodiumchloride solution in postoperative sinus-surgery wound care. *Laryngorhinootologie* 2006; 85 (1) : 14-9.

### RANOLAZINE FOR CHRONIC STABLE ANGINA?

Ranolazine is a new and unique antianginal drug that has been approved for the treatment of chronic stable angina pectoris. The drug is administered as a sustained-release formulation. Although the drug's mechanism of action has not been fully elucidated, current thinking is that ranolazine, a selective inhibitor of late sodium influx, attenuates the abnormalities of ventricular repolarisation and contractility associated with ischaemia. Three randomised trials have shown efficacy for ranolazine in increasing exercise testing or reducing anginal episodes or use of glyceryl trinitrate. Side-effects include dizziness, constipation, nausea, and the potential for prolongation of the QT interval. Ranolazine seems to be a safe addition to current traditional drugs for chronic stable angina, especially in aggressive multidrug regimens.

David T Nash, Stephen D Nash; *The Lancet*, 2008; 372 : 1335-41.