THE EFFECT OF NORMAL SALINE AND 3.5% HYPERTONIC SALINE ON MUCOCILIARY CLEARANCE IN SINUSITIS
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ABSTRACT: Introduction: Sinusitis is usually treated with antibiotics, decongestants, mucolytics and steroids. Long term use of these drugs has many side effects. This has led to the use of other modalities of treatment such as saline nasal irrigation. Saline nasal irrigation helps in clearance of secretions, debris and crusts, thus improving the mucociliary clearance. OBJECTIVE: This randomized comparative study was undertaken to assess the ciliary function by performing saccharine test and to evaluate the effect of 3.5% hypertonic saline nasal drops against normal saline nasal drops on mucociliary transit time of saccharine. MATERIALS AND METHODS: Fifty patients diagnosed as chronic sinusitis in the age group of 18 to 45 years were randomized into two groups; Group A treated with 0.9% normal saline and Group B with 3.5% hypertonic saline for a period of 4 weeks. Mucociliary transit time was recorded by performing saccharine test before and after treatment. RESULTS: Significant improvement was seen in both the groups but when compared to normal saline, hypertonic saline significantly improved the mucociliary clearance. The mean mucociliary transit time of saccharine in Group A patients before treatment was 19.860 minutes and after treatment was 17.634 minutes (t=14.012, p=0.0001). The mean mucociliary transit time of saccharine in Group B patients before treatment was 21.881 minutes and after treatment was 16.689 minutes (t=14.662, p=0.0001). All the patients reported relief of symptoms, but relief was much earlier in Group B when compared to Group A. Mild burning sensation in the nose and throat was reported by 4% of patients in Group A and 8% in Group B. CONCLUSION: Both 0.9% normal saline and 3.5% hypertonic saline significantly improved the mucociliary clearance. Hypertonic saline is more efficacious than normal saline in the treatment of chronic sinusitis. KEYWORDS: Chronic sinusitis; saline nasal irrigation; saccharine test; mucociliary clearance.

INTRODUCTION: Para nasal sinus disease is one of the commonest diseases prevalent all over the world. Chronic sinusitis is defined as chronic inflammatory process affecting the mucosa of the sinuses. The inflamed mucosa of the sinuses may swell considerably and rapidly. Bacterial or viral infection may follow, not only are the mucosal glands get affected but the entire mucosal surface may be partially destroyed or paralyzed thus unable to provide its mucociliary clearance function.

Mucociliary clearance is an important defense mechanism of the upper and lower respiratory tracts.

Any disturbance in this mechanism leads to stagnation of secretions and secondary infection. The commonest factor affecting ciliary function in vivo is an upper respiratory tract infection which may damage the respiratory epithelium and cause irreversible damage. A permanently defected mucociliary mechanism predisposes to chronic sinusitis and disease of the lower respiratory tract. Sinusitis is usually treated with antibiotics, decongestants, mucolytics and steroids.
Long term use of these drugs has many side effects. This has led to the use of other modalities of treatment such as saline nasal irrigation.

Saline nasal irrigation is an inexpensive technique that can be used alone or with other interventions. This helps in clearance of secretions, debris and intranasal crusts, thus improving the mucociliary clearance. Several methods have been used to evaluate the mucociliary clearance. Early studies were based on direct observation of dyes or particles deposited on nasal mucosa. The purpose of this study is to know the effect of normal saline and hypertonic saline nasal drops on mucociliary clearance in sinusitis by performing saccharine test.

MATERIALS AND METHODS: The present prospective randomized comparative study was conducted in the Department of Otorhinolaryngology. Fr. Muller Medical College Hospital, Mangalore during August 2012 to June 2014. During this period, fifty patients diagnosed to have chronic sinusitis in the age group of 18 to 45 years were selected. They were randomized into two groups.

Group A included twenty five patients treated with 0.9% normal saline (Solution A) ten drops three times a day into both nostrils for a period of 4 weeks and the remaining twenty five patients in Group B were treated with 3.5% hypertonic saline (Solution B) ten drops three times a day into both nostrils. Patients with acute sinusitis and who had undergone sinus surgery were excluded from the study.

Detailed history was taken and clinical examination was carried out in the selected cases. The diagnosis of chronic sinusitis was made with two major criteria – nasal discharge, post nasal drip and one minor criterion – headache the diagnosis was confirmed by X-ray PNS (Water's view). The mucociliary transit time was recorded by performing saccharine test. Preliminary saccharine test was done prior to the beginning of the study.

SACCHARINE TEST: The nasal mucociliary clearance time is measured by saccharine clearance test method. Subjects sat with their heads upright, and a small piece of saccharine measuring about 0.5mm was placed approximately 1 cm behind the anterior border of the inferior turbinate using jobson horne ear probe. The subjects were asked to avoid sniffing, coughing and sneezing.

The mucociliary clearance time is then noted as the time elapsed at the subject's first perception of a sweet taste. The patients were randomly selected preliminary saccharine clearance test was done. Either 0.9% normal saline (Solution A) which is commercially available or hypertonic saline, 3.5% sodium chloride solution (Solution B) which was prepared by dissolving 3.5gm of sodium chloride in 100ml of double distilled water was given as nasal drops and were advised to instill ten drops intra nasally three times a day.

The patients were asked to report every week for a period of 1 month. Saccharine clearance test was performed at the end of fourth week and the mucociliary transit time was recorded. The mucociliary transit time before and after treatment were compared. The data was analyzed from findings recorded in the pre-designed proforma. To test the effectiveness of the treatment, paired‘t’ test and unpaired‘t’ test was used. To find the association, chi-square test and Fischer's exact test was used.

RESULTS: The present study was conducted in patients with chronic sinusitis attending Otorhinolaryngology outpatient department at Fr. Muller Medical College Hospital, during the period
of August 2012 to June 2014. The mean age in Group A was 29.36 years and that in Group B was 32.64 years. Females constituted 52% and males 48% in Group A, whereas males constituted 68% and females 32% in Group B. Overall male preponderance was noted but statistically not significant. (t=1.548, p=0.128 > 0.05). The mean duration of symptoms in Group A was 2.4 years and that of Group B was 2.8 years. The combined mean being 2.6 years.

The mean mucociliary transit time of saccharine in Group A patients before treatment was 19.860 minutes and mucociliary transit time after treatment was 17.634 minutes (t=14.012, p=0.0001 vhs). The mean mucociliary transit time of saccharine in Group B patients before treatment was 21.881 min and after treatment was 16.689 minutes (t=14.662, p=0.0001 vhs) statistically both are very highly significant.

|        | Mean of Difference | Std. Deviation | ‘t’ test  |
|--------|-------------------|----------------|----------|
| Group A| 2.23              | 0.79           | p=0.0001vhs |
| Group B| 5.19              | 1.77           |          |

Table 1: Comparison of effectiveness of treatment

The mean difference of before and after treatment in Group A is 2.23 (Std. deviation 0.79) whereas in Group B is 5.17 (Std. deviation 1.77) p=0.0001 statistically very highly significant.

**DISCUSSION:** Otorhinolaryngologists commonly recommended topical saline solutions in the treatment of rhinitis and sinusitis. The beneficial effects of this treatment may be related to the
improved mucociliary clearance. The present prospective randomized comparative study was conducted in patients attending the outpatient department of Otorhinolaryngology at Fr. Muller Medical College and Hospital, Mangalore. Fifty adult patients with chronic sinusitis in the age group of 18 to 45 years were divided into two groups randomly.

Group A included twenty five patients treated with 0.9% normal saline drops (Solution A) and the remaining of the twenty five cases in Group B were treated with 3.5% hypertonic saline nasal drops (Solution B) for a period of four weeks. All the fifty patients in the study groups reported relief of symptoms but the relief was much earlier in Group B when compared to Group A. Shoseyov\textsuperscript{1} reported improvement but no significant difference between the groups treated with 3.5% hypertonic and 0.9% normal saline nasal drops.

Saline nasal irrigation was earlier identified as an adjunctive care for sinusitis.\textsuperscript{1,2,3} Our study shows both normal saline and hypertonic saline to reduce the symptoms of chronic sinusitis but hypertonic saline was more prudent in reducing the symptoms earlier when compared to normal saline. In various studies different concentration of hypertonic saline solutions were used, we used 3.5% hypertonic saline solution because it was about the same concentration of sea water and was considered harmless and better tolerated by the patients, including even children.\textsuperscript{1} The mechanism of action is unclear.

It has been hypothesized that it improves mucociliary function,\textsuperscript{4,5,6} decreases mucosal oedema and inflammatory mediators\textsuperscript{7} and mechanically clears inspissated mucus.\textsuperscript{8} In addition, hypertonic saline is said to have a mild vasoconstrictive effect\textsuperscript{8} and antibacterial property. The saccharine clearance test has been shown to be a reliable method of assessing mucociliary clearance time and is closely correlated to the clearance rates with tagged insoluble particles, which have been considered the most accurate technique.

In our study the mean mucociliary transit time of saccharine in Group A patients before treatment was 19.860 minutes and mucociliary transit time after treatment was 17.634 minutes (t=14.012, p=0.0001 vhs). The mean mucociliary transit time of saccharine in Group B patients before treatment was 21.881 minutes and after treatment was 16.689 minutes (t=14.662, p=0.0001 vhs). Statistically, both were very highly significant.

But when comparison of effectiveness of treatment between the groups was done, it showed the mean difference of improvement of Group B (5.19 minutes) was more than twice that of Group A (2.23 minutes). In a similar study, Grossan\textsuperscript{5} used saccharine clearance test to determine mucociliary clearance after daily saline irrigation at 20 pulses / sec. which showed increased mucociliary clearance rate at least by two folds in 13 patients with chronic sinusitis, 11 of who had complete disappearance of pus.

Talbot et al\textsuperscript{9} study showed buffered hypertonic saline irrigation to improve mucociliary transit time of saccharine, while buffered normal saline had no such effect. (3.1 minute improvement compared to 0.14 minutes, p=0.02 and 17% improvement compared to 2% p=0.013 respectively). But in our study both hypertonic saline and normal saline showed improvement in mucociliary clearance, 5.19 minutes (p=0.0001) and 2.23 minutes (p=0.0001). When compared to normal saline, hypertonic saline improved the mucociliary transit time more.

Similarly Bachmann\textsuperscript{10} compared effectiveness of endonasal irrigation with hypertonic solution to that with sodium chloride solution in treatment of 40 patients with chronic paranasal sinus disease, which showed significant improvement in both the groups.
In comparison, no significant differences were observed among the two groups. Mucociliary clearance may be modified by the changes in ciliary beat frequency and rheologic changes in the mucous blanket such as viscosity and shearing forces.

Other factors, including cilial loss, outflow obstruction and mucosal apposition, may also play a role, especially in chronic sinusitis. Rheologic alterations in this study may be the most important factor, saline improves mucociliary clearance, this may be a result of the saline increasing the depth and thinning of the sol layer of mucus. Sodium chloride also decreases the viscosity of mucus in vitro. From the above discussion, it is evident that both normal saline and hypertonic saline improve the mucociliary clearance time but hypertonic saline gives better results.

**CONCLUSION:** The study showed that both 0.9% normal saline solution and 3.5% hypertonic saline significantly improved the mucociliary clearance. Hypertonic saline affected saccharine clearance times to a greater degree than normal saline. Hypertonic saline can be used in chronic sinusitis. Those patients with other causes of rhinitis, including acute sinusitis may also benefit from regular nasal irrigation with this solution.

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