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## [Intervention Review]

## Saline irrigation for allergic rhinitis

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#### ABSTRACT

#### Background

Allergic rhinitis is a common condition affecting both adults and children. Patients experience symptoms of nasal obstruction, rhinorrhoea, sneezing and nasal itching, which may affect their quality of life.

Nasal irrigation with saline (salty water), also known as nasal douching, washing or lavage, is a procedure that rinses the nasal cavity with isotonic or hypertonic saline solutions. It can be performed with low positive pressure from a spray, pump or squirt bottle, with a nebuliser or with gravity-based pressure in which the person instils saline into one nostril and allows it to drain out of the other. Saline solutions are available over the counter and can be used alone or as an adjunct to other therapies.

### Objectives

To evaluate the effects of nasal saline irrigation in people with allergic rhinitis.

### Search methods

The Cochrane ENT Information Specialist searched the ENT Trials Register; CENTRAL; Ovid MEDLINE; Ovid Embase; CINAHL; Web of Science; ClinicalTrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was 23 November 2017.

## Selection criteria

Randomised controlled trials (RCTs) comparing nasal saline irrigation, delivered by any means and with any volume, tonicity and alkalinity, with (a) no nasal saline irrigation or (b) other pharmacological treatments in adults and children with allergic rhinitis. We included studies comparing nasal saline versus no saline, where all participants also received pharmacological treatment (intranasal corticosteroids or oral antihistamines).

## Data collection and analysis

We used the standard methodological procedures expected by Cochrane. Primary outcomes were patient-reported disease severity and a common adverse effect - epistaxis. Secondary outcomes were disease-specific health-related quality of life (HRQL), individual symptom scores, general HRQL, the adverse effects of local irritation or discomfort, ear symptoms (pain or pressure) and nasal endoscopy scores. We used GRADE to assess the quality of the evidence for each outcome; this is indicated in *italics*.



#### Main results

We included 14 studies (747 participants). The studies included children (seven studies, 499 participants) and adults (seven studies, 248 participants). No studies reported outcomes beyond three months follow-up. Saline volumes ranged from 'very low' to 'high' volume. Where stated, studies used either hypertonic or isotonic saline solution.

## Nasal saline versus no saline treatment

All seven studies (112 adults; 332 children) evaluating this comparison used different scoring systems for **patient-reported disease severity**, so we pooled the data using the standardised mean difference (SMD). Saline irrigation may improve patient-reported disease severity compared with no saline at up to four weeks (SMD -1.32, 95% confidence interval (CI) -1.84 to -0.81; 407 participants; 6 studies; *low quality*) and between four weeks and three months (SMD -1.44, 95% CI -2.39 to -0.48; 167 participants; 5 studies; *low quality*). Although the evidence was *low quality* the SMD values at both time points are considered large effect sizes. Subgroup analysis showed the improvement in both adults and children. Subgroup analyses for volume and tonicity were inconclusive due to heterogeneity.

Two studies reported methods for recording adverse effects and five studies mentioned them. Two studies (240 children) reported no adverse effects (epistaxis or local discomfort) in either group and three only reported no adverse effects in the saline group.

One study (48 children) reported **disease-specific HRQL** using a modified RCQ-36 scale. It was uncertain whether there was a difference between the groups at any of the specified time points (*very low quality*). No other secondary outcomes were reported.

## Nasal saline versus no saline with adjuvant use of intranasal steroids or oral antihistamines

Three studies (40 adults; 79 children) compared saline with intranasal steroids versus intranasal steroids alone; one study (14 adults) compared saline with oral antihistamines versus oral antihistamines alone. It is uncertain if there is a difference in **patient-reported disease severity** at up to four weeks (SMD -0.60, 95% CI -1.34 to 0.15; 32 participants; 2 studies; *very low quality*) or from four weeks to three months (SMD -0.32, 95% CI -0.85 to 0.21; 58 participants; 2 studies; *very low quality*). Although none of the studies reported methods for recording **adverse effects**, three mentioned them: one study (40 adults; adjuvant intranasal steroids) reported no **adverse effects** (epistaxis or local discomfort) in either group; the other two only reported no adverse effects in the saline group.

It is uncertain if saline irrigation in addition to pharmacological treatment improved **disease-specific HRQL** at four weeks to three months, compared with pharmacological treatment alone (SMD -1.26, 95% CI -2.47 to -0.05; 54 participants; 2 studies; *very low quality*). No other secondary outcomes were reported.

## Nasal saline versus intranasal steroids

It is uncertain if there was a difference in **patient-reported disease severity** between nasal saline and intranasal steroids at up to four weeks (MD 1.06, 95% CI -1.65 to 3.77; 14 participants; 1 study), or between four weeks and three months (SMD 1.26, 95% CI -0.92 to 3.43; 97 participants; 3 studies), or in**disease-specific HRQL** between four weeks and three months (SMD 0.01, 95% CI -0.73 to 0.75; 83 participants; 2 studies). Only one study reported methods for recording **adverse effects** although three studies mentioned them. One (21 participants) reported two withdrawals due to adverse effects but did not describe these or state which group. Three studies reported no **adverse effects** (epistaxis or local discomfort) with saline, although one study reported that 27% of participants experienced local discomfort with steroid use. No other secondary outcomes were reported.

## Authors' conclusions

Saline irrigation may reduce patient-reported disease severity compared with no saline irrigation at up to three months in both adults and children with allergic rhinitis, with no reported adverse effects. No data were available for any outcomes beyond three months. The overall quality of evidence was *low* or *very low*. The included studies were generally small and used a range of different outcome measures to report disease severity scores, with unclear validation. This review did not include direct comparisons of saline types (e.g. different volume, tonicity).

Since saline irrigation could provide a cheap, safe and acceptable alternative to intranasal steroids and antihistamines further high-quality, adequately powered research in this area is warranted.

## PLAIN LANGUAGE SUMMARY

## Nasal saline for allergic rhinitis

## Background

Allergic rhinitis is inflammation (swelling and/or irritation) of the inside of the nose caused by allergies. It is common in both children and adults. Allergic rhinitis can be intermittent (fewer than four days per week, or four weeks per year) or persistent (more than four days per week, or four weeks per year). The allergy can be caused by many different things but common allergens (things causing allergy) are: grass or tree pollen, mould, dust mites or animal dander (tiny flakes of skin). People with allergic rhinitis experience symptoms (nasal obstruction, runny nose, nasal itching and sneezing) that may affect their quality of life.

Nasal saline irrigation (also known as nasal douche, wash or lavage) is a procedure that rinses the nasal cavity with saline (salt water) solutions. How saline works is not fully understood but it is probably through making the mucus (snot) thinner, making it easier to remove and also removing some of the allergens from the nose that cause irritation. Nasal saline irrigation can be performed with sprays, pumps or squirt bottles. Saline solutions can be isotonic (the same concentration of salt that is found in the body - 0.9% NaCl) or hypertonic (more salty than found in the body - more than 0.9% NaCl). Although saline irrigation is thought to be safe there have been reports of epistaxis (nosebleeds) and irritation or discomfort in the nose and ears. This therapy is available without prescription and can be used alone or as an add-on to other pharmacological treatment for allergic rhinitis, such as intranasal (in the nose) steroids and oral antihistamines).

## Search date

The evidence is up to date to November 2017.

## Study characteristics

We found 14 studies with a total of 747 participants (260 adults; 487 children). The volume of saline used in the studies varied: five studies used 'very low' volumes (nasal sprays providing less than 5 mL saline per nostril per application), two studies used low-volume (between 5 and 59 mL saline per nostril per application introduced with a syringe) and four studies used high-volume solutions (more than 60 mL per nostril per application). Eight studies used hypertonic saline, five used isotonic saline and three studies did not provide this information. Two studies used two different types of saline solutions.

## Study funding sources

Seven studies did not say how they were funded. The other seven were funded either by the investigators' department or research grants from regional or national government. No studies were funded by pharmaceutical companies.

## **Key results**

Nasal saline irrigation compared with no saline irrigation

Nasal saline irrigation may have benefits in both adults and children in relieving the symptoms of allergic rhinitis compared to no saline irrigation and it is unlikely to be associated with adverse effects. It is not possible to tell from this review whether there is a difference between the different volumes and concentrations of saline solution.

Adding nasal saline irrigation onto 'pharmacological' allergic rhinitis treatment

It is uncertain whether adding nasal saline irrigation to pharmacological treatment (intranasal steroids or oral antihistamines) helps to improve the symptoms of allergic rhinitis compared to using pharmacological treatments alone. The use of nasal saline irrigation is unlikely to be associated with adverse effects.

Nasal saline irrigation compared to 'pharmacological' allergic rhinitis treatment

There is not enough evidence to know whether nasal saline irrigation is better, worse or the same as using intranasal steroids. No studies reporting the outcomes we were interested in compared nasal saline irrigation with oral antihistamines.

## Quality of evidence

The overall quality of evidence for nasal saline irrigation compared with no saline treatment was either *low quality* (our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect) or *very low quality* (we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect). This was because the studies were mostly very small and used different methods to measure the same outcome. Since saline irrigation could provide a cheap, safe and acceptable alternative to intranasal steroids and antihistamines further high-quality studies are needed.