

A prospective, single-blind, randomised, crossover study comparing three nasal hygiene systems and corresponding patient preference for such devices

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Abstract

Objective: To assess subjective preference using three nasal hygiene systems: Stérimar Original[®], Emcur[®] and Sinus Rinse[™].

Design: We used a prospective, single-blind, randomised, crossover study to compare three nasal hygiene systems: Stérimar Original, Emcur and Sinus Rinse.

Subjects: Eighteen adult volunteers were recruited and were asked to rate their experience over three days using three well-established nasal hygiene systems. A standard visual analogue scale was used to assess five criteria: (1) simplicity of instructions; (2) ease of use; (3) comfort; (4) perceived nasal clearance (effectiveness) and (5) single best overall system.

Results: Stérimar Original was found to have the easiest instructions to understand compared to the other two systems. There was no significant difference between Stérimar Original and Sinus Rinse with regards to ease of use but they were both significantly easier to use than Emcur ($p < 0.05$). There was no statistically significant difference between the three systems when comparing the last three criteria. There was no alteration in preference when the cost of each treatment was disclosed to the subjects, and no significant side effects were reported.

Conclusion: The instructions accompanying Stérimar Original appeared to be the easiest to understand, while Stérimar Original and Sinus Rinse were easier to use than Emcur.

Key words: Nasal Lavage; Saline Solution; Nasal Cavity; Postoperative Care; Rhinitis

Introduction

The benefits of using saline and mineral irrigation systems for a variety of sinonasal conditions, such as chronic rhinosinusitis, allergic rhinitis and as part of post-operative care after sinonasal surgery have been well established.^{1–3} Nasal hygiene systems are generally well tolerated and have been shown to improve nasal hygiene and reduce patient symptoms. A variety of hygiene systems are available – some of which have been compared with others to assess the effectiveness in cleaning the nose using objective measures, such as volume/distribution in the paranasal sinuses,⁴ mucociliary clearance⁵ and the use of outcome scores, such as the Sino-Nasal Outcome Test 20.⁶

Compliance is an important issue in the treatment process and has been shown to be up to 70 per cent in the treatment of chronic conditions. Naturally, comfort, ease of use, simplicity of instructions and

effectiveness of the treatment are vital to maintain high compliance. Cost is also a factor where treatments are not publically funded.^{7–11}

The aim of this study was to look at the subjective preference of three well-established nasal hygiene systems and the overall ease of use, which could influence compliance.

Methods

We used a prospective, single-blind, randomised, crossover study to compare three nasal hygiene systems: Stérimar Original (SOFIBEL – Laboratoires Santé Beauté and Laboratoires Fumouze, Levallois-Perret, France), Emcur (Emcur Gesundheitsmittel aus Bad Ems GmbH, Bad Ems, Germany) and Sinus Rinse (NeilMed Pharmaceuticals Ltd, Coulsdon, Surrey, UK). All three nasal hygiene systems were saline

based, with differences in mineral content and method of administration (Table I).

The study was conducted at a tertiary hospital setting. Eighteen healthy adult volunteers with no previous history or prior knowledge of using nasal hygiene systems were recruited. All subjects completed a general health questionnaire, were in good health, had no prior sinonasal conditions and had a basic nasal examination by the lead investigator prior to the study. Informed consent was obtained from all study participants.

Data collection

Subjects were prospectively assigned to use each of three different methods of nasal hygiene, Stérimar Original, Emcur and Sinus Rinse, in a randomised order. Each individual thus acted as their own control. Randomisation was conducted by a designated statistician using a random number generator program. The study was performed at the same time on three consecutive days allowing a 24-h wash-out period to prevent the results of each system from being influenced by usage of prior one/ones. The subjects were provided with the manufacturer's written instructions on how to use each system and were required to complete a short questionnaire about each one. No assistance or advice on how to use the systems was provided by the researcher supervising the study. A standard visual analogue scale (VAS) ranging from 1 (very difficult, very uncomfortable or least effective) to 10 (very easy, most comfortable or most effective) was completed after using each system to measure the simplicity of the instructions, ease of use, comfort and perceived nasal clearance (effectiveness).

Volunteers were also asked to specify the single best overall system as well as any adverse events and general comments.

Analysis of data

Analysis and reporting of the study findings was completed within approximately one month of data collection.

The numerical results, as scored by participants on the VAS, were analysed using linear regression. In addition to the overall difference in outcome between the three treatments, the specific difference between pairs of treatments was assessed. To allow for multiple comparisons, *p* values from these analyses were inflated upwards using a Bonferroni adjustment. Additionally, treatment preference was examined using the chi-square test to examine if the responses were significantly different to those that might be expected if all treatments were equally preferred.

Ethical considerations

The research protocol was approved by the Royal Free Hospital NHS Trust Research Ethics Committee. The study was registered with the Research and Development Department of the Royal Free Hospital NHS Trust.

Results

A 10-point VAS was used to assess the main outcomes and these are summarised in Table II. Linear regression showed no significant carry-over effect of one treatment into the next period and was used to assess any statistical difference between treatments.

Stérimar Original was found to have significantly simpler instructions, with an average of 2 and 1.8

TABLE I
COMPARISON OF CONTENT AND COST OF THREE NASAL HYGIENE DEVICES

Parameter	Emcur	Sinus Rinse	Stérimar Original
Description	Preservative-free, natural spring salts	Preservative-free, natural salts	31.82 ml preservative-free seawater per 100 ml in isotonic physiological concentration
Content	Sodium chloride, sodium bicarbonate and potassium sulphate	Sodium chloride and sodium bicarbonate	Sodium chloride, potassium chloride, magnesium chloride and sulphate, calcium chloride and sulphate, various naturally occurring trace elements (e.g. silver, copper, zinc and manganese)
Isotonicity	When diluted in a specific volume of water, it produces an isotonic physiological solution	When diluted in a specific volume of water, it produces an isotonic physiological solution	When diluted in a specific volume of water, it produces an isotonic physiological solution
Delivery	Gravity-dependent	Positive pressure	Aerosol spray
Cost*	Emcur nasal douche + four sachets of Emcur nasal irrigating salt = approximately £9.95 Emcur nasal irrigating salt, 30 sachets = approximately £8.95	Regular kit (1 bottle, 1 cap, 1 tube, 50 mixture packets) = approximately £13.75 100 packets of sodium chloride and sodium bicarbonate mixture = approximately £16.75	Stérimar Original nasal spray 100 ml (approximately 300 sprays) = approximately £5.98

*When purchased online.

TABLE II
SUMMARY OF MAIN OUTCOMES USING THE VISUAL ANALOGUE SCALE

Outcome on VAS (0–10)	Emcur Mean (SD)	Stérimar Original Mean (SD)	Sinus Rinse Mean (SD)
Simplicity of instructions	7.2 (2.0)	9.2 (1.1)	7.4 (2.0)
Ease of use	6.5 (2.4)	8.6 (2.2)	8.4 (1.5)
Comfort	7.2 (2.3)	7.6 (2.4)	7.3 (1.9)
Perceived nasal clearance (effectiveness)	7.6 (1.8)	7.3 (2.0)	8.2 (2.0)

VAS = visual analogue scale; SD = standard deviation

units on the VAS more than Emcur and Sinus Rinse respectively. Stérimar Original and Sinus Rinse were statistically significantly easier to use than Emcur, with an average of 2.1 and 1.9 units more on the VAS than Emcur respectively. However, there was no significant statistical difference shown between Stérimar Original and Sinus Rinse with regards to ease of use (Table III). No difference was demonstrated between any of the three systems with respect to comfort.

There was a trend towards better perceived nasal clearance using the Sinus Rinse and Emcur irrigation devices than using the Stérimar Original aerosol spray, though this was not shown to be statistically significant (Tables II and III).

The chi-square test failed to show a statistically significant difference between the three systems in terms of overall preference. Interestingly, none of the volunteers changed their minds with regards to their choice of device after being informed about the daily average cost (Table IV). There were no reported complications or side effects.

Discussion

Nasal hygiene systems for nasal lavage have been shown to be an effective part of treatment of many chronic sinonasal disorders. Several types of these

systems have been developed and there is much peer-reviewed published literature confirming their beneficial role. However, there is a paucity of literature regarding compliance and adherence to recommended treatments for chronic nasal conditions.

Medicines adherence is an increasingly important issue with potentially significant implications, such as increased morbidity, unnecessary medical or surgical treatments and raised cost both to patients and health-care systems. Non-adherence may be intentional or unintentional. Often, unintentional non-adherence is due to practical issues with the use of the medicines and treatments prescribed.^{7–11}

Our study looked at three widely used nasal hygiene devices and aimed to quantify the user-friendliest of the three with respect to ease of understanding the instructions provided, ease of use, comfort and perceived nasal clearance (effectiveness). As far as we are aware, this is the first study performing such a comparison.

All subjects in our study were healthy adult volunteers, competent in the English language and with no history of chronic sinonasal disease. They had no prior knowledge of, nor experience with, nasal hygiene systems. All subjects were provided with the manufacturer's instructions on usage. There was no prior demonstration or advice provided by the investigators. We felt that although this may not have been completely reflective of all prescribers' practice, it was the most uniform way to establish the user-friendliest system and make an accurate comparison between the three products.

Our study demonstrated that Stérimar Original nasal spray had the easiest instructions to follow compared to the others. Stérimar Original and Sinus Rinse were easier to use compared to Emcur. None of the three systems was deemed to be statistically more comfortable or effective in nasal clearance than the others. This may be because our subjects did not have any sinonasal disease, or it may be a type II error due to an insufficient number of participants.

TABLE III
PAIRED COMPARISON OF FOUR VARIABLES BETWEEN NASAL HYGIENE SYSTEMS

Variable	Treatment 1	Treatment 2	Difference – Mean (98.3% CI)	Pair-wise <i>p</i> value
Simplicity of instructions	Emcur	Stérimar Original	1.9 (0.4, 3.5)	0.009
	Emcur	Sinus Rinse	0.2 (–1.3, 1.7)	1.00
	Stérimar Original	Sinus Rinse	–1.8 (–3.3, –0.3)	0.02
Ease of use	Emcur	Stérimar Original	2.1 (0.2, 3.9)	0.02
	Emcur	Sinus Rinse	1.9 (0.1, 3.8)	0.04
	Stérimar Original	Sinus Rinse	–0.1 (–1.9, 1.7)	1.00
Comfort	Emcur	Stérimar Original	0.4 (–1.3, 2.2)	1.00
	Emcur	Sinus Rinse	0.2 (–1.5, 1.9)	1.00
	Stérimar Original	Sinus Rinse	–0.3 (–2.0, 1.4)	1.00
Perceived nasal clearance (effectiveness)	Emcur	Stérimar Original	–0.3 (–2.0, 1.3)	1.00
	Emcur	Sinus Rinse	0.6 (–1.1, 2.2)	1.00
	Stérimar Original	Sinus Rinse	0.9 (–0.8, 2.5)	0.55

CI = confidence interval

TABLE IV
PREFERENTIAL COMPARISON OF NASAL HYGIENE SYSTEMS WITH AND WITHOUT KNOWLEDGE OF PRICE

Variable	Treatment	Observed number (%)	Expected number (%)	<i>p</i> value
Best overall	Emcur	3 (17%)	6 (33%)	0.31
	Stérimar Original	7 (39%)	6 (33%)	
	Sinus Rinse	8 (44%)	6 (33%)	
Best with knowledge of price (twice-daily use)	Emcur 68 pence/day	3 (17%)	6 (33%)	0.31
	Stérimar Original 8 pence/day	7 (39%)	6 (33%)	
	Sinus Rinse 39 pence/day	8 (44%)	6 (33%)	

We were unable to demonstrate a statistically significant difference between the three systems in terms of overall preference. None of the subjects altered their choice of system when they were told about the daily cost of the respective treatments (Table IV). However, there is only one observation per subject for these outcomes, and therefore a low statistical power may have failed to detect any statistically significant differences between the three treatments. It is possible that cost may have had an impact on choice, if this was not a hypothetical question and the subjects had to purchase these nasal hygiene systems without subsidy from their respective dispensing authorities for a prolonged period of time.

It is important to acknowledge that this study sought a statistically significant difference of one unit on a VAS of 1–10, which does not necessarily correlate with a clinically significant difference.

- Nasal hygiene systems have been used widely in the treatment of a variety of sinonasal conditions
- Our study looked at three widely used nasal hygiene devices and aimed to quantify the user-friendliest of the three with respect to simplicity of instructions, ease of use, comfort and perceived nasal clearance (effectiveness)
- There were statistically significant differences in ease of understanding the instructions and ease of use between the three hygiene systems but none shown for comfort, perceived nasal clearance (effectiveness) and single best overall system

Participants generally had positive comments to make about all three systems. For example, Emcur was found to be comfortable to use and good at cleaning the nose. Stérimar Original was felt to be a convenient size to carry around and easy to use away from home, while positive comments on Sinus Rinse stated that it was simple to use, the pressure could be controlled and there was a step-by-step instruction card. Common negative remarks included the fact that the pictures provided in the Emcur instruction leaflet were difficult to comprehend and that the design of the device was too complex. Some subjects did not

find the operation of the Stérimar Original nozzle intuitive and felt that its use would be difficult for patients with poor manual dexterity, such as patients with rheumatoid arthritis. Stérimar Original was also found to continue spraying onto the face momentarily after releasing the nozzle while withdrawing it from the nose. Some felt that the Sinus Rinse instructions were too long and that too much information was provided for patients with no medical background.

Conclusion

This prospective study on three different nasal hygiene systems and their impact on patient preference provides a useful insight into the subjective nature of medicines compliance and adherence. It highlights the importance of acknowledging compliance issues when prescribing. All three nasal hygiene systems have a role in the management of nasal conditions.

To optimise compliance, clinicians should ideally explain the correct method of device use, inform patients of alternative devices and tailor the choice of device to the patient's medical and social circumstances. Educational and language barriers are also important issues to bear in mind. This undoubtedly impacts on an already overstretched service with financial and time constraints. Nevertheless, improved compliance may avoid unnecessary medical or surgical treatments thus reducing morbidity and cost. We acknowledge that incorporating patients into the study in the future will add to our understanding of patient behaviour and may possibly help to develop a more effective adjunct for the treatment of sinonasal disease.

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