

Title: Saline irrigation spells relief □for sinusitis sufferers. *J Fam Pract.* 2009;58:29-32.

Potential PURL Review Form: Randomized controlled trials

SECTION 1: IDENTIFYING INFORMATION FOR NOMINATED POTENTIAL PURL

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| 1. Citation | Pynnonen MA, Mukerji SS, Kim HM, et al. Nasal saline for chronic sinonasal symptoms: a randomized controlled trial. <i>Arch Otolaryngol Head Neck Surg.</i> 2007;133:1115-1120. |
| 2. Hypertext link to PDF of full article | http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=AbstractPlus-def&uid=18025315&db=pubmed&url=http://archotol.ama-assn.org/cgi/pmidlookup?view=long&pmid=18025315 |
| 3. First date published study available to readers | November 2007 |
| 4. PubMed ID | 18025315 |
| 5. Nominated By | Jim Stevermer |
| 6. Institutional Affiliation of Nominator | University of Missouri |
| 7. Date Nominated | August 13, 2008 |
| 8. Identified Through | InfoPOEMs Editorial Board |
| 9. PURLS Editor Reviewing Nominated Potential PURL | Bernard Ewigman |
| 10. Nomination Decision Date | August 14, 2008 |
| 11. Potential PURL Review Form (PPRF) Type | RCT |
| 12. Other comments, materials or discussion | |

13. Assigned Potential PURL Reviewer	Kate Rowland
14. Reviewer Affiliation	University of Chicago
15. Date Review Due	August 21, 2008
16. Abstract	<p>OBJECTIVE: To determine if isotonic sodium chloride (hereinafter "saline") nasal irrigations performed with large volume and delivered with low positive pressure are more effective than saline sprays at improving quality of life and decreasing medication use. DESIGN: A prospective, randomized controlled trial. SETTING: Community. PARTICIPANTS: A total of 127 adults with chronic nasal and sinus symptoms. INTERVENTIONS: Patients were randomly assigned to irrigation performed with large volume and delivered with low positive pressure (n=64) or spray (n=63) for 8 weeks. MAIN OUTCOME MEASURES: Change in symptom severity measured by mean 20-item sino-nasal outcome test (SNOT-20) score; change in symptom frequency measured with a global question; and change in medication use. RESULTS: A total of 121 patients were evaluable. The irrigation group achieved lower SNOT-20 scores than the spray group at all 3 time points: 4.4 points lower at 2 weeks ($P=.02$); 8.2 points lower at 4 weeks ($P<.001$); and 6.4 points lower at 8 weeks ($P=.002$). When symptom frequency was analyzed, 40% of subjects in the irrigation group reported symptoms "often or always" at 8 weeks compared with 61% in the spray group (absolute risk reduction, 0.2; 95% confidence interval [CI], 0.02-0.38 ($P=.01$)). No significant differences in sinus medication use were seen between groups. CONCLUSION: Nasal irrigations performed with large volume and delivered with low positive pressure are more effective than saline sprays for treatment of chronic nasal and sinus symptoms in a community-based population.</p>

SECTION 2: CRITICAL APPRAISAL OF VALIDITY

1. Number of patients starting each arm of the study?	63 spray, 64 irrigation.
2. Main characteristics of study patients (inclusions, exclusions, demographics, settings,	<p>Inclusion: 18+ years, nasal stuffiness, dryness, congestion, thick nasal discharge for at least 4 days a week and 15 of the last 30 days.</p> <p>Exclusion: recent upper respiratory infection or bacterial infection; use of nasal saline within past month.</p>

etc.)?

- 3. Intervention(s) being investigated?** Large-volume, low-pressure nasal saline irrigation.
- 4. Comparison treatment(s), placebo, or nothing?** Saline nasal spray.
- 5. Length of follow up? Note specified end points, eg, death, cure, etc.** 2, 4, and 8 weeks.
- 6. What outcome measures are used? List all that assess effectiveness.** 20-item sino-nasal outcome test (SNOT-20), symptom frequency, medication diary.
- 7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, *P*-values, etc.** At 8 weeks, the irrigation group had an average SNOT-20 score of 8.5 (15.2) vs 15.0 (17.6) for the spray group ($P=.04$). Also significant reductions at 4 weeks, but not at 2 weeks (Table 2 page 1118).
- 8. Study addresses an appropriate and clearly focused question - *select one***
- Well covered
 - Adequately addressed
 - Poorly addressed
 - Not applicable
- 9. Random allocation to comparison groups** Well covered
- 10. Concealed allocation to comparison groups** Well covered
- 11. Subjects and investigators kept “blind” to comparison group allocation** Adequately addressed
Comments: Cannot blind participants to intervention (spray vs irrigation).

12. Comparison groups are similar at the start of the trial	Well covered
13. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.	Well covered
14. Were all relevant outcomes measured in a standardized, valid, and reliable way?	Well covered
15. Are patient-oriented outcomes included? If yes, what are they?	Yes, nasal symptoms as detailed above.
16. What percent dropped out, and were lost to follow up? Could this bias the results? How?	2 in the spray group and 4 in the irrigation group (3% vs 6%). Seems unlikely to bias the results.
17. Was there an intention-to-treat analysis? If not, could this bias the results? How?	Yes, ITT analysis was done.
18. If a multisite study, are results comparable for all sites?	N/A

- 19.** Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?
Sponsorship from NeilMed, a company that makes NetiPots and nasal saline solution, but authors include a disclaimer that the sponsor did not have access to or influence the data or results.
- 20.** To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.
Patients with chronic nasal congestion.
- 21.** In what care settings might the findings apply, or not apply?
Primary care; ear, nose, and throat (ENT).
- 22.** To which clinicians or policy makers might the findings be relevant?
Primary care, ENT.

SECTION 3: REVIEW OF SECONDARY LITERATURE

- 1.** DynaMed excerpts
Saline irrigation and saline nasal spray improve chronic rhinosinusitis symptoms, based on a Cochrane collaboration meta-analysis.
- 2.** DynaMed citation/access date
Chronic sinusitis. DynaMed. Accessed August 16, 2008.
- 3.** UpToDate excerpts
Nasal lavage improves symptoms of nonallergic chronic rhinitis and chronic sinusitis.
- 4.** UpToDate citation/access date
Chronic nonallergic rhinitis. UpToDate. Accessed August 16, 2008.
- 5.** PEPID PCP excerpts
Nasal irrigation:
 - Daily irrigation with 2% saline shown to improve symptoms, reduce medication use.

6. PEPID citation/access data Chronic sinusitis. PEPID PCP. Accessed August 16, 2008.

SECTION 4: CONCLUSIONS

1. Validity: How well does the study minimize sources of internal bias and maximize internal validity? 1

Give one number on a scale of 1 to 7

(1=extremely well; 4=neutral; 7=extremely poorly)

2. If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

3. Relevance: Are the results of this study generalizable to and relevant to the health care needs of patients cared for by “full scope” family physicians? 2

Give one number on a scale of 1 to 7

(1=extremely well; 4=neutral; 7=extremely

poorly)

4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

5. Practice-changing potential: 3

If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice?

Give one number on a scale of 1 to 7

(1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)

6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

Recommend large-volume saline irrigation for patients with nasal symptoms such as stuffiness and congestion in the absence of other diagnoses.

7. Applicability to a Family Medical Care Setting: 1

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention?

Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)

8. If you coded 4.7 as a 4, 5, 6 or 7, please explain.

9. Immediacy of Implementation: Are there major barriers to immediate

1

implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)

10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

11. Clinically meaningful outcomes or patient-oriented outcomes:

Are the outcomes measured in the study clinically meaningful or patient oriented?

Give one number on a scale of 1 to 7

(1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient

2

oriented)

12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

13. In your opinion, is this a Pending PURL? 3

Criteria for a Pending PURL:

- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine.
- Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
- Applicability in medical setting:
- Immediacy of implementation:

Give one number on a scale of 1 to 7 (1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)

14. Comments on your response in 4.13 Not sure if this practice is widely acceptable to patients. Duration of symptom relief is unclear, and significance of results vs nasal spray is unclear.

SECTION 5: EDITORIAL DECISIONS

1. FPIN PURLs editorial decision Pending PURL

2. Follow-up issues for Pending PURL Reviewer

3. FPIN PURLS Editor making decision Bernard Ewigman

4. Date of decision September 11, 2008

5. Brief summary of decision Well-done RCT that supports prior findings that lavage is superior to standard saline irrigation for chronic nasal symptoms. Patient acceptance may be an issue.