NASAL IRRIGATION WITH LAVONASE® AS ANCILLARY TREATMENT OF ACUTE RHINOSINUSITIS: A PILOT STUDY

M. GELARDI, A. MEZZOLI, M.L. FIORELLA, M. CARBONARA[2], M. DI GIOACCHINO[3] and G. CIPRANDI[4]

Department of Otolaryngology, University of Bari, Bari; [1]Puglia Regional Statistics Bureau; [2]Division of Otolaryngology, Villalba Hospital Bologna; [3]Allergy-Related Disease Unit, G. d'Annunzio University Foundation, Chieti; [4]Department of Internal Medicine, Azienda Ospedaliera Universitaria San Martino, Genoa, Italy

Received September 24, 2008 – Accepted January 16, 2009

A wide variety of nasal irrigation systems are currently available for improving nasal symptoms, but few studies have compared their effectiveness with respect to patient age and type of nasal disease. This pilot study aims to compare the efficacy of two irrigation systems in 20 patients (12 males and 8 females; age range, 19-54 years; mean age, 36) with acute rhinosinusitis and treated only with antibiotic (levofloxacin 500 mg/day for 10 days) and topical nasal decongestant (naphazoline 2 puffs in each nostril twice daily for 7 days). Patients were randomly assigned to the treatments, using either a nasal syringe (10 mL saline solution, 3 times daily for 14 days) (Group 1) or the recently available Lavonase® system (250 mL saline solution sac, twice daily for 14 days) (Group 2). Work-up included history, evaluation of signs and symptoms (nasal obstruction, rhinorrhea), nasal endoscopy, and anterior rhinomanometry. Nasal irrigation with the Lavonase® system was found to be more effective in reducing symptoms, as all significantly diminished ($p<0.05$). In addition, the Lavonase® system significantly decreased nasal resistances ($p<0.05$). This preliminary study shows that the ancillary treatment of acute rhinosinusitis with Lavonase® may be useful.

As the prevalence of allergic rhinitis and upper airway infections is still increasing, numerous studies on topical treatments have been performed to reduce the side effects of systemic therapy and to improve nasal symptoms (1-4). For treating rhinosinusitis, the latest guidelines of the European Academy of Allergology and Clinical Immunology (EAACI) (5) and of the International Rhinologic Society (6-7) indicate the use of saline nasal irrigation among the various therapeutic options (including antibiotics, topical corticosteroids, topical decongestants, etc.). Saline nasal irrigation is widely employed to reduce nasal congestion and mucopurulent secretion and as a useful aid to stimulate cleansing of the paranasal sinuses and restoration of mucociliary clearance.

A huge variety of systems are currently available to cleanse the paranasal sinuses (such as drops, sprays, aerosols, nasal douche, and irrigation) (7-9) as well as the types of solution used in treatment (isotonic and hypertonic saline solutions, with the addition of copper, magnesium, sulfur, etc). Numerous studies have evaluated the therapeutic

Key words: acute rhinosinusitis, nasal irrigation, rhinosinusitis treatment, nasal symptoms, rhinomanometry

Mailing address: Dr Gelardi Matteo,
Department of Otolaryngology,
University of Bari,
P.zza G. Cesare,
70120, Bari, Italy
Fax: ++39 0805593315
gelardim@inwind.it

0393-974X (2009)

effect of these systems on children and adults; however, very few have compared their efficacy with respect to patient age and type of nasal disorder (10-22).

The aim of this study is to compare the therapeutic efficacy of two nasal irrigation methods, the widely used syringe and the recently introduced Lavonase® system, on 20 patients with acute rhinosinusitis undergoing treatment with only antibiotic and topical nasal decongestants.

MATERIALS AND METHODS

The study cohort comprised 20 patients (12 males [60%] and 8 females [40%]; age range, 19-54 years; mean age 36) with acute rhinosinusitis.

Acute rhinosinusitis was diagnosed according to EAACI and EPOS criteria (5-6). Clinical work-up (Table I) included thorough history taking to reveal nasal obstruction and the presence and characteristics of rhinorrhea (serous, catarrhal, mucopurulent, purulent-bleeding secretion, anterior and/or posterior, such as post nasal drip). Exclusion criteria were acute allergic rhinitis, obstructive nasal polyposis, systemic diseases, and confirmed or suspected quinolone allergy.

Patients then underwent a complete otolaryngological examination, including endoscopic study using a flexible nasopharyngolaryngoscope (Vision Sciences ENT-2000) and anterior rhinomanometry. Endoscopic criteria were: 1) absence of secretions; 2) catarrh in the nasal fossae; 3) purulent secretions on the floor of the nasal cavities (mono- and/or bilateral); 4) purulent secretions from the meatus or the sphenoethmoidal recesses.

The following parameters were considered: nasal obstruction, rhinorrhea, post nasal drip, and nasal resistances. To measure the degree of nasal obstruction, rhinorrhea (purulent and catarrhal) and post nasal drip patients were asked to rate their discomfort on a 10-point visual analogue scale from 0 (no symptom) to 10 (very troublesome symptom) (23).

Active anterior rhinomanometry was performed using an ATMOS Rhinomanometer 300. The standard parameters were those of the International Committee for Rhinomanometry Standardization (24).

The patients were randomly assigned to one of two treatment groups (Table I). Group 1 performed nasal irrigation with warm (36°) saline solution 3 times daily using a sterile disposable 10 mL syringe for 14 days; plus medication with a nasal decongestant spray (naphazoline 2 puffs daily for 7 days) and levofloxacin 500 mg (1 tablet/day for 10 days).

Group 2 performed nasal irrigation with warm (36°) Lavonase® (250 mL sacs of premixed solution) twice daily for 14 days; plus medication with a nasal decongestant spray (naphazoline 2 puffs daily for 7 days) and levofloxacin 500 mg (1 tablet/day for 10 days).

The Lavonase® system consists of a sac (250 mL) of premixed sterile saline solution and a delivery system with a 60-cm tube to which an irrigator is attached. The irrigator tip is placed at the nostril to dilate the valve and the solution is directed into all portions of the nasal cavity.

Visits were carried out at enrolment in the study (V0), at 7 (V1), 14 (V2) and 21 days (V3) during the study (Table I).

Statistical analysis was performed as follows: the non-parametric Mann-Whiney test was applied to determine differences in the variable nasal obstruction and rhinomanometry between the two treatment groups at 7, 14, 21 and 21 days. The chi square test was applied to all other variables. P values <0.05 were taken as indicating statistical significance. Statistical analysis was carried out using the SPSS software package.

RESULTS

Symptoms

Nasal obstruction Group 1: the mean self-evaluated nasal obstruction score was 7.8 (range, 6-10) at V0, 7.1 at V1, 6.8 at V2 and 6.0 at V3. Group 2: the mean self-evaluated nasal obstruction score was 8.3 (range, 7-10) at V0, 7.0 at V1, 5.7 at V2 and 4.0 at V3. Intragroup analysis showed that there was no statistical difference in Group 1, whereas there was in Group 2 for all visits (for all $p<0.05$) (Fig. 1). Intergroup analysis showed no difference.

Rhinorrhea Group 1. Purulent rhinorrhea was present in all patients at V0, continued in 8 (80%) and changed to catarrhal in 2 (20%) at V1; purulent rhinorrhea continued in 2 (20%) and changed to catarrhal in 8 (80%) at V2; catarrhal rhinorrhea persisted in 6 (60%) and resolved in 4 (40%) at V3.

Group 2. Purulent rhinorrhea was present in all patients at V0, changed to catarrhal in 8 (80%) and resolved in 2 (20%) at V1; catarrhal rhinorrhea continued in 3 (30%) at V2; catarrhal rhinorrhea persisted in 1 (10%) and resolved in 9 (90%) at V3 (Fig. 2). Intragroup analysis showed a significant difference at V1, V2, and V3 (for all $p<0.05$) in favor of Group 2.

Postnasal drip Group 1. Post nasal drip was present in 9 (90%) patients and absent in 1 (10%)

Table I. *Clinical work-up.*

Time	History taking	Endoscopy	Rhinomanometry	Therapy
V0 (baseline)	X	X	X	X
V1 (7 days)	X	X	X	X
V2 (14 days)	X	X	X	
V3 (21 days)	X	X	X	

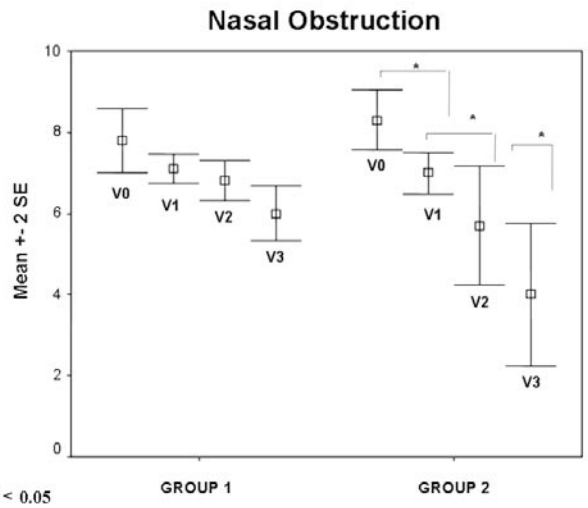

Fig. 1. *Nasal obstruction evaluated in Group 1 and Group 2 at V0, V1, V2, and V3, data are expressed as mean ±SD; P<0.05. Group 2 showed a significant diminution compared with Group 1 at V1, V2 and V3.*

at V0; post nasal drip persisted in 8 (80%) at V1, in 7 (70%) at V2 and in 3 (30%) at V3. Group 2. Post nasal drip was present in 9 (90%) patients and absent in 1 (10%) at V0; post nasal drip persisted in 3 (30%) at V1, and resolved at V2 (Fig. 3). Intragroup analysis showed a significant difference at V1 and V2 (for both $p<0.05$) in favor of Group 2.

Diagnostic measurements

Active anterior rhinomanometry Group 1. Mean nasal resistance 1.50 Pa at V0, 0.99 Pa at V1, 0.88 Pa at V2, 0.77 Pa at V3. Group 2. Mean nasal resistance 0.95 Pa at V0, 0.76 Pa at V1, 0.56 Pa at V2, 0.31 Pa at V3 (Fig. 4). Intragroup analysis showed that there was no statistical difference in Group 1, whereas there was in Group 2 for all visits (for all $p<0.05$) (Fig. 1). Intergroup analysis showed no difference.

DISCUSSION

Cleansing of the nasal cavities represents a main step in the treatment of nasal diseases and infections of the sinonasal cavities (rhinoadenoiditis, rhinosinusitis, nasal polyposis with bacterial or mycotic over-infection, etc.). Nasal irrigation is indicated as adjuvant treatment by the 2005 EAACI Position Paper on Rhinosinusitis. Abnormal accumulation of catarrhal or mucopurulent secretion, sometimes presenting as crust, is a known predisposing factor to the development of local (such as otitis, rhinosinusitis) and distant inflammation (such as rhinobronchial syndrome, bronchitis, pneumonia, asthma). Removal of secretions allows reactivation of the nasal cavity's defense systems and restoration of mucociliary clearance by which endonasal bacterial load is eliminated or reduced.

An analysis of our results shows that the two methods of treatment led to different clinical courses. Nasal irrigation with the Lavonase® system was found to be more effective in relieving nasal symptoms as well as in improving nasal patency.

A simple explanation for the basic clinico-diagnostic differences between the two groups is that the Group 2 patients using the Lavonase® system (250 ml sac) had to irrigate the nasal cavities longer than Group 1 patients who used a syringe system (10 ml). This difference in irrigation time should not be neglected since brief irrigations do not sufficiently cleanse the mucosal surfaces, leaving a purulent secretion with a high bacterial load behind.

Another consideration in favor of the Lavonase® system is the pressure at which irrigation is delivered and the distribution of the spray inside the nasal cavity. The delivery system, which consists of a

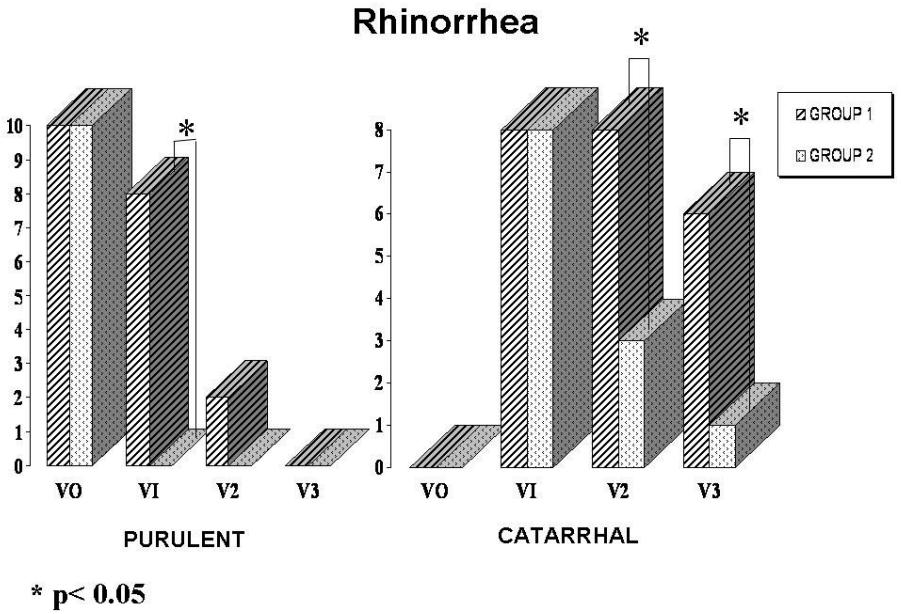

Fig. 2. *Rhinorrhea. (Purulent and Catarrhal) in Group 1 and Group 2 at V0, V1, V2, and V3, data are expressed as mean ±SD; P<0.05. Group 2 showed a significant diminution compared with Group 1 at V1 for the purulent form , at V2, V3 , for the catarrhal form.*

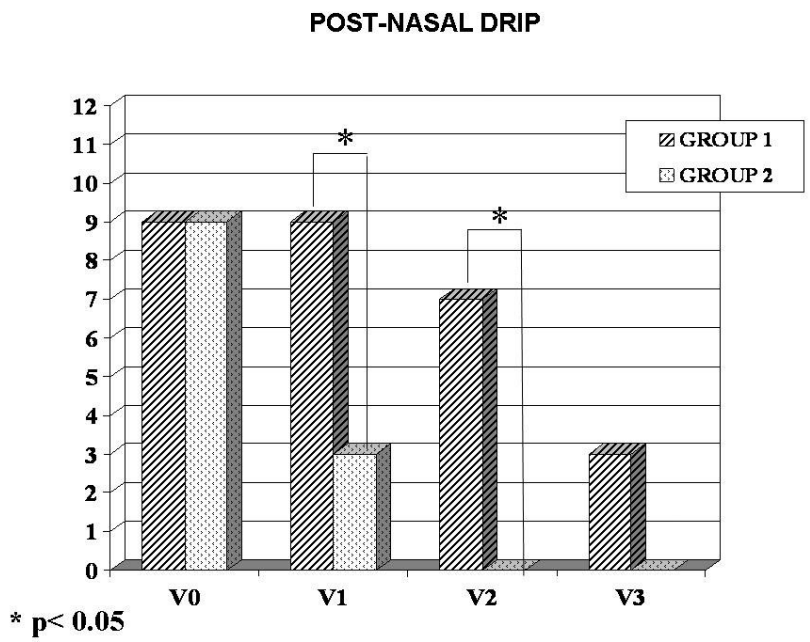

Fig. 3. *Postnasal drip in Group 1 and Group 2 at V0, V1, V2, and V3, data are expressed as mean ±SD; P<0.05. Group 2 showed a significant diminution compared with Group 1 at V1 and V2.*

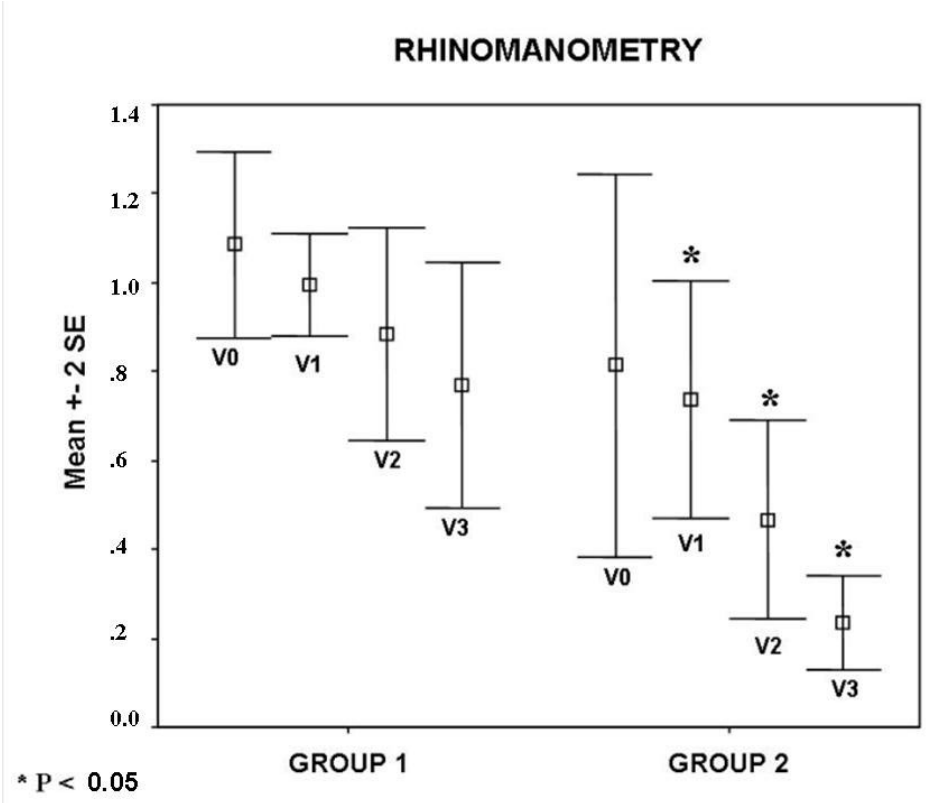

Fig. 4. *Rhinomanometry in Group 1 and Group 2 at V0, V1, V2, and V3, data are expressed as mean ±SD; P<0.05. Group 2 showed a significant diminution compared with Group 1 at V1, V2 and V2.*

60-cm tube, generates a standard irrigation pressure of 0.058 Pa that is still too low to possibly damage the nasal mucosa or the middle ear through the Eustachian tube. The irrigator tip fits snugly and adapts to the nasal vestibule, permitting a fan-shaped spray of the solution inside the nasal cavity. The spray is directed into the three passages of the meatus by three small grooves in the irrigator tip. By keeping the head bent forward during irrigation, the solution first flows through the nasal cavity closed off by the irrigator, and after reaching the rhinopharynx, crosses postero-anterior to the contralateral cavity, thus washing out with the saline solution not only pathogenic secretions but dust, allergens and contaminants as well.

These design features are unique to the Lavonase® system, making it a useful adjuvant medical treatment to others, such as antibiotics, anti-inflammatory drugs, and decongestants, in patients with acute rhinosinusitis, and part of postoperative therapy for subjects with sinonasal diseases (atrophic rhinitis, nasal polyposis, rhinosinusitis, allergic rhinitis).

In conclusion, this pilot study provides the preliminary evidence that the ancillary treatment of acute rhinosinusitis with Lavonase® may be useful. However, further controlled studies should be performed to validate these findings.

REFERENCES

1. Lacronique J. Primum non nocere...inhaled glucocorticosteroids in 2003. Rev Pneumol Clin 2003; 59:129-37.
2. Mortimer KJ, Tattersfield AE. Benefit versus risk for oral, inhaled, and nasal glucocorticosteroids. Immunol Allergy Clin North Am 2005; 25:523-39.

3. Kaszuba SM, Baroody FM, de Tineo M, Haney L, Blair C, Naclerio RM. Superiority of an intranasal corticosteroid compared with an oral antihistamine in the as-needed treatment of seasonal allergic rhinitis. Arch Intern Med 2001; 161:2581-7.
4. Johnson DW, Jacobson S, Edney PC. A comparison of nebulized budesonide, intramuscolar dexametasone and placebo for moderately sever croup. N Engl J Med 1998; 339:498-503.
5. European Academy of Allergology and Clinical Immunology (EAACI) Position Paper on Rhinosinusitis. Rhinol Suppl 2005; 18:1-136.
6 Fokkens W, Lund V, Mullol J EPOS 2007: European position paper on rhinosinusitis and nasal polyps 2007. A summary for otorhinolaryngologists. Rhinology 2007; 45:97-101.
7. Dautzelnberg B, Nikander K. Choice of a device for each disease and medicine. Eur Respir Rev 2000; 10: 545-8.
8. Dolovich M. Clinical aspects of aerosol physics. Resp Care 1991; 36:931-938.
9. Dolovich MB, Fink JB. Aerosols and devices. Respir Care Clin N Am 2001; 7:131-73.
10. Brown CL, Graham SM. Nasal irrigations: good or bad? Curr Opin Otolaryngol Head Neck Surg 2004; 12:9-13.
11. Papsin B, McTavish A. Saline nasal irrigation: Its role as an adjunct treatment. Can Fam Physician 2003; 49:168-73.
12. Adam P, Stiffman M, Blake RL Jr. A clinical trial of hypertonic saline nasal spray in subjects with the common cold or rhinosinusitis. Arch Fam Med 1998; 7:39-43.
13. Keojampa BK, Nguyen MH, Ryan MW. Effects of buffered saline solution on nasal mucociliary clearance and nasal airway patency. Otolaryngol Head Neck Surg 2004; 131:679-82.
14. Bachmann G, Hommel G, Michel O. Effect of irrigation of the nose with isotonic salt solution on adult patients with chronic paranasal sinus disease. Eur Arch Otorhinolaryngol 2000; 257:537-41.
15. Keerl R, Weber R, Draf W, Dshambazov K. Tolerance, subjective complaints and mucociliary clearance in rhinitis sicca before and after nasal irrigation with Rhinomer Force 1. Laryngorhinootologie 1998; 77: 196-200.
16. Raza T, Elsherif HS, Zulianello L, Plouin-Gaudon I, Landis BN, Lacroix JS. Nasal lavage with sodium hypochlorite solution in *Staphylococcus aureus* persistent rhinosinusitis. Rhinology 2008; 46(1):15-22.
17. Tomooka LT, Murphy C, Davidson TM. Clinical study and literature review of nasal irrigation. Laryngoscope 2000; 110:1189-93.
18. Shaikh WA. Ephedrine-saline nasal wash in allergic rhinitis. J Allergy Clin Immunol 1995; 96:597-600.
19. Bachmann G, Hommel G, Michel O. Effect of irrigation of the nose with isotonic salt solution on adult patients with chronic paranasal sinus disease. Eur Arch Otorhinolaryngol 2000; 257:537-41.
20. Taccariello M, Parikh A, Darby Y, Scadding G. Nasal douching as a valuable adjunct in the management of chronic rhinosinusitis. Rhinology 1999; 37:29-32.
21 Rabago D, Zgierska A, Mundt M, Barrett B, Bobula J, Maberry R. Efficacy of daily hypertonic saline nasal irrigation among patients with sinusitis: a randomized controlled trial. J Fam Pract 2002; 51: 1049-55.
22. Shoseyov D, Bibi H, Shai P, Shoseyov N, Shazberg G, Hurvitz H. Treatment with hypertonic saline versus normal saline nasal wash of pediatric chronic sinusitis. J Allergy Clin Immunol 1998; 101:602-5.
23. Fahmy FF, McCombe A, McKiernan DC. Sino nasal assessment questionnaire, a patient focused, rhinosinusitis specific outcome measure. Rhinology 2002; 40:195-7.
24. Clement PAR. Committee report on standardization of rhinomanometry. Rhinology 1984; 22:151-155.