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Preservative-Free Nasal Spray Appears Safe, Remains Sterile

In a small, short-term study, a preservative-free, acidified nasal spray appears safe and well tolerated and maintained its sterility in an applicator used multiple times, according to a report in the November issue of Archives of Otolaryngology-Head & Neck Surgery, one of the JAMA/Archives journals.

"The health of a topical nasal spray user relies on the prevention of contamination of the solution," the authors write as background information in the article. "Pharmaceutical manufacturers add various preservatives to destroy or inhibit the growth of micro-organisms that may be introduced into the solution after the opening of its container." However, some of these preservatives have been associated with injury to the mucus membrane of the nose and sinuses, changes to the cells in the nasal lining, immobility of nasal hairs or cilia, damage to DNA and other adverse effects.

Making saline nasal spray more acidic is an alternative way of maintaining sterility without chemical preservatives. William R. Ryan, M.D., now of the University of California, San Francisco, and Peter H. Hwang, M.D., of Stanford University School of Medicine, Stanford, Calif., evaluated a saline solution formula acidified by hydrochloric acid. Twenty volunteers used the preservative-free nasal spray and a saline spray containing preservatives for one week each in random order, separated by a one-week washout period. At the beginning of the study and after the week of using each solution, participants reported their symptoms and underwent examination of their nasal passages with an endoscope. A sample from each nasal spray bottle was cultured for microorganism growth.

No differences were observed in symptoms or in endoscopy findings after using the preservative-free vs. Preservative-

containing spray. In addition, microorganism growth was not detected in any samples from either solution.

"Of those analyzed, we believe that the most important symptoms for determining the safety and tolerance of the preservative-free acidified solution nasal spray are nasal burning, smell disturbance, taste disturbance, nasal bleeding, purulent rhinorrhea [runny nose with pus], sore throat, need to blow nose, sneezing, runny nose, postnasal discharge, thick nasal discharge, ear fullness, ear pain and facial pain or pressure," the authors write. "There were no discernible differences in these symptoms between the two nasal sprays used." There were also no differences in discharge, swelling, redness and the growth of polyps in the nasal passages.

"In conclusion, the preservative-free acidified solution nasal spray used in this study seems to be safe, well tolerated and effective at maintaining a sterile solution in a multidose applicator among a small sample of users over a short period," the authors write. "A larger series with longer follow-up is planned. Further studies are also necessary to explore use of a preservative-free acidified solution as a medium for drug delivery."

Source: William R. Ryan; Peter H. Hwang. Safety of a Preservative-Free Acidified Saline Nasal Spray: A Randomized, Double-blind, Placebo-Controlled, Crossover Clinical Trial. *Archives of Otolaryngology-Head & Neck Surgery*, 2010;136(11):1099-1103. DOI: 10.1001/archoto.2010.179