Efficacy of Distribution of Nebulized Nasal Therapies: A Preliminary Report

Principal Investigators
Peter H. Hwang, MD
Karen J. Fong, MD

Oregon Sinus Center
Department of Otolaryngology - Head & Neck Surgery
Oregon Health & Science University, Portland, Oregon *

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Introduction
Nasal drug delivery is now gaining attention for administration of pharmaceuticals since the highly-vascularized nasal mucosa provides quick entry into the bloodstream. Nasal nebulization has been already been shown effective in treating chronic sinusitis\(^1\) and trials are underway to evaluate nasal drug delivery as a means of treating a wide range of medical conditions\(^2\) \(^3\). A five subject, preliminary clinical trial was conducted to compare transnasal deposition of a saline solution via the Kurve Technology, Inc.’s ViaNase device with that of a standardized metered dose nasal spray bottle.

Method
The ViaNase\(^\text{TM}\) nasal nebulizer system and spray bottle were evaluated for nasal distribution of nebulized particles using nuclear scintigraphy. Five normal subjects transnasally received 0.4cc of saline labeled with technetium-99 using the Vianase device. Coronal and sagittal scintigrams of the nasal cavity and head were taken within 5 minutes after completion of the dose administration. After a minimum washout period of 72 hours to allow for radiodecay of particles, subjects repeated the dose administration using a standardized metered dose nasal spray calibrated to deliver 0.1cc per spray. Two sprays of Tc-99 labeled saline were delivered to each nostril, providing a total equivalent dose of 0.4cc of radiolabeled saline. Coronal and sagittal scintigrams of the nasal cavity and head were again taken.

Results
In all five patients the area of intranasal distribution was as much as 65% greater for the ViaNase nebulizer device compared to the nasal spray device (Figure 1-5). In particular, the ViaNase device demonstrated a greater propensity for delivery of particles to the superior aspect of the nasal cavity in all cases. In one case, there was definitive penetration of the right frontal sinus (Figure 1), and in a second case, there was probable penetration of both frontal sinuses and the sphenoid sinus (Figure 2). Given the limitations of two-dimensional scintigraphy, penetration of the ethmoid sinus could not be adequately assessed. The maxillary sinus and sphenoid sinus did not appear to be penetrated in any of the subjects. Notably, the nasal spray device consistently deposited a greater number of particles in the nasopharynx and oropharynx in all patients.
Figure 1. Scintigrams Comparing ViaNase™ vs. Spray Bottle for Delivery of Tc-99 in 0.4cc saline in patient AC
Figure 2. Scintigrams Comparing ViaNase™ vs. Spray Bottle for Delivery of Tc-99 in 0.4cc saline in patient ZB
Figure 3. Scintigrams Comparing ViaNase™ vs. Spray Bottle for Delivery of Tc-99 in 0.4cc saline in patient AA
Figure 4. Scintigrams Comparing ViaNase™ vs. Spray Bottle for Delivery of Tc-99 in 0.4cc saline in patient MA
Figure 5. Scintigrams Comparing ViaNase™ vs. Spray Bottle for Delivery of Tc-99 in 0.4cc saline in patient PG

Summary

The ViaNase™ nebulizer device appears to provide a consistently larger volume of intranasal distribution in normal subjects when compared to standard metered dose nasal spray bottles. The ViaNase™ nebulizer shows a propensity for enhanced delivery of particles to the superior nasal cavity. The particles delivered by nebulizer may penetrate the frontal sinuses in selected patients. The ViaNase™ nebulizer shows diminished extranasal distribution of particles as demonstrated by consistently lower rates of nasopharyngeal and oropharyngeal penetration. Clinical testing is ongoing at the Sinus Center, Oregon Health & Sciences University.
References

