OBJECTIVES:
Hypertonic saline aerosol delivered intranasally is currently being studied to enhance mucociliary clearance. There is evidence of patients’ reluctance to use concentrations above 3% due to potential discomfort. Our study was performed to determine the short term tolerance of 3.5% and 7% hypertonic saline versus normal saline (0.9%) delivered intranasally via a nebulizer/ compressor system (PARI SinuStar®, PARI Respiratory Equipment, Midlothian, VA, USA).

METHODS:
The SinuStar™ nasal aerosol delivery system uses a Pari LC® Star reusable nebulizer with nasal adapter and 1.2 bar air compressor. The nasal adapter directs aerosol upward into the nares when held below the nose. (Figure 1) We administered 3 concentrations of saline solution (0.9%, 3.5%, 7%) to 18 healthy, adult volunteers for 5 minutes each concentration. A washout period of 5 minutes between treatments allowed volunteers to wipe their nose and cleanse their mouth with water if they desired. A 6 question self-administered questionnaire between treatments allowed volunteers to wipe their nose and cleanse their mouth with water if they desired. A 6 question self-administered questionnaire was completed following each treatment using a 9 point scale (1=high; 9=low). Comfort, burning, cold sensation, cough, throat irritation and rhinorrhea were measured at 15 seconds, 1 minute, 2 minutes and 5 minutes after the treatment started. Overall comfort scores were recorded after 5 minutes only. The order of treatments was randomized and volunteers were blinded to the concentration. The study was approved by Pari North American internal review committee. Data was compared across time and concentrations for each variable using ANOVA with post hoc Fisher’s LSD comparison. The alpha value was considered to be <0.05. Scores are reported as mean ± standard deviation.

RESULTS:
No variable averaged more than 3.8 for any concentration at any time. There were no differences in scores for any concentration when measuring burning and cough with average scores 1.8 or below.

Although throat irritation trended upward over the three concentrations the only statistically significant difference (<0.01) was found between 0.9% (1.3 + 0.6) and 7% (2.1 + 1.2) at two minutes but this difference did not persist to 5 minutes. (Figure 2)

The sensation of cold was significantly different (<0.05) only when using 0.9% saline concentration between 13 seconds (1.8 + 0.9) and both 2 and 5 minutes (2.6 + 1.0 and 2.7 + 1.2, respectively). (Figure 3) Runny nose scores were higher than other times for each concentration at the 2 minute (p<0.05) and 5 minute (p<0.01) times. (Figure 4) Overall comfort scores trended down (less comfort) as saline concentration increased however the differences were not statistically significant. (Figure 5)

CONCLUSIONS:
Our study indicates that during the time of treatment nasal aerosol delivery of hypertonic saline of 3.5% and 7% is well tolerated in healthy adults. Although we did not measure attitudes toward the use of hypertonic saline before the study in our volunteers, there was apprehension expressed that higher saline concentrations would not only be uncomfortable but the discomfort, especially burning, would be concomitantly greater. This was not supported in our results although comfort level scores trended toward slightly less comfort at 3.5% and 7% but not significantly. There were no dropouts which would have indicated intolerability to any of the measures; even after taking 3 treatments within 30 minutes which would represent a much higher exposure to hypertonic saline over a short time than normal prescription practices. As expected, rhinorrhea scores increased over time even with normal saline and although scores trended higher with greater saline concentration these differences were not statistically significant. In summary, there appears to be no issue of discomfort associated with hypertonic saline that would prevent nasal aerosol treatment compliance.

SUMMARY:
> Use of intranasal hypertonic saline aerosol at 3.5% and 7% is well tolerated.