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A new administration form of the nasal decongestant oxymetazoline: A study on the change of ostial patency in healthy individuals*†

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SUMMARY

A new administration form of the nasal decongestant oxymetazoline and the effect on patency of the maxillary ostium was investigated in five healthy volunteers. Registration and comparison of the equivalent diameter after administration of placebo spray and oxymetazoline spray, placebo solution and oxymetazoline solution were performed. It is our impression that administration of solution with the new spring-bellows container compared to spray oxymetazoline, is a more effective way of increasing the equivalent diameter of the maxillary ostium.

Key words: nasal decongestion, oxymetazoline, ostial patency

INTRODUCTION

Obstruction of the maxillary ostium caused by mucosal swelling is supposed to be the main reason for sinusitis (Drettner and Aust, 1977). Administration of decongestant nose drops will rapidly relieve congestion in parts of the mucous membrane in the nasal cavity. Distribution studies, however, indicate that nose drops administered in a traditional way hardly reach the maxillary ostium lateral to the middle turbinates (Hardy et al., 1985).

A technique has been developed with which one nasal cavity at a time can be filled with decongestant solution. The solution is administered from a spring-bellows container and kept in motion by container-compression and decompression (Figures 1 and 2).

The aim of this study was to measure the equivalent diameter of the maxillary sinus ostium after administration of placebo and oxymetazoline. Placebo and oxymetazoline were either supplied as spray with a metered pump or diluted as solution with the spring-bellows container.

PATIENTS AND METHODS

The study was designed as a cross-over open study with single-dose administration. Five healthy volunteers, three women and two men, underwent two treatments. Treatment 2 was performed two to five days later, allowing a sufficient clearance of decongestant from the nasal mucosa.

ENT-status had to be normal, maxillary ostium within normal limits (1-4, 5 mm; Jannert et al., 1984). Diseases and on-going therapy with drugs known to affect the nasal mucuosa were other criteria for exclusion. The same maxillary sinus was used in both treatment 1 and 2.

Treatment 1 consisted of placebo spray (0.1 ml), after 45 min followed by oxymetazoline spray (0.5 mg/ml; 0.1 ml). Treatment 2 consisted of placebo solution (10-18 ml), after 45 min followed by oxymetazoline solution (0.1 mg/ml; 10-18 ml), both administered with the spring-bellows container during 30 s.

A pressure-flow technique developed by Aust and Drettner (1974), and modified by Ivarsson et al. (1983), was used to measure the equivalent ostial diameter in sitting and recumbent position. Placebo was administered at 6 min, oxymetazoline at 51 min after the initial measurement at $t = 0$ (Figures 3 and 4). The measurements were repeated at 15, 30, 45, 65, 80, and 95 min in a sitting position. The measurements in recumbent position were performed 5 min later, respectively.

The spring-bellows container was filled with 25 ml oxymetazoline (0.1 mg/ml) solution.

The solution was slowly pumped to and fro during 30 s, complete filling of the nasal cavity is obtained when solution is seen dripping from the contralateral nasal vestibulum. The solution will not enter the oropharynx provided the head is flexed forward approximately 60°.

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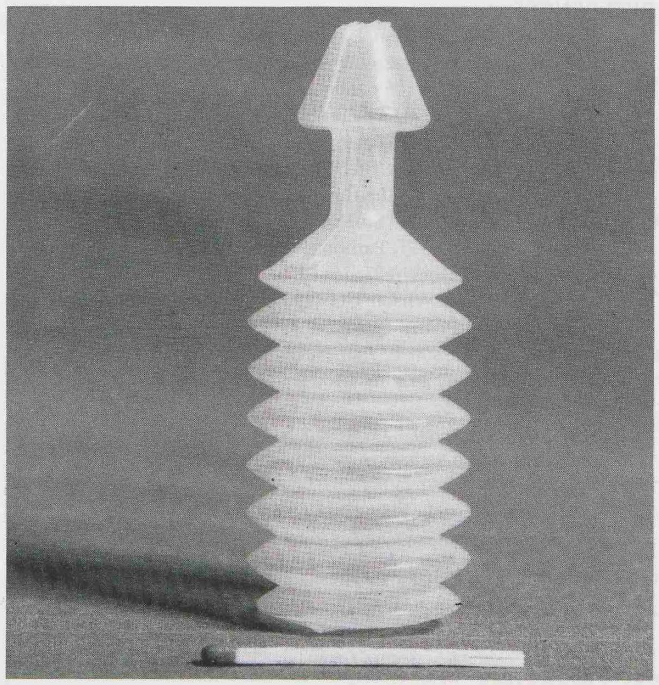

Figure 1. The spring-bellows container for administration of nasal decongestants.

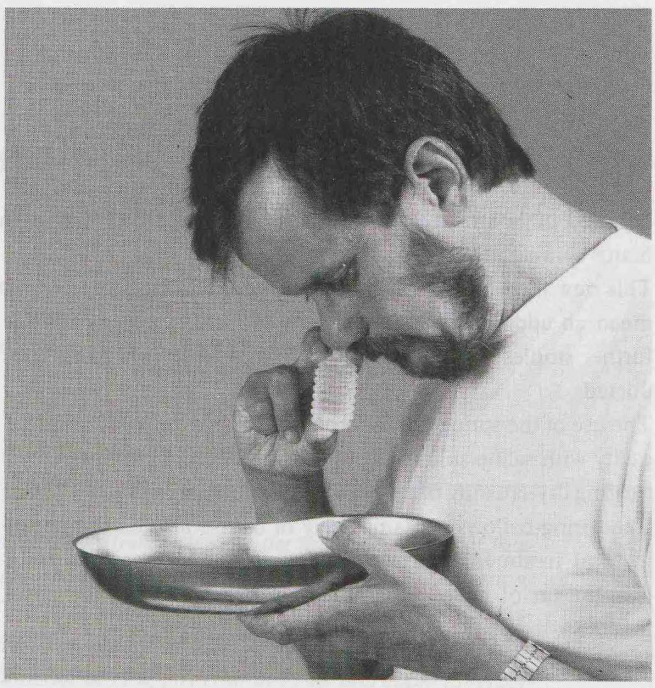

Figure 2. The spring-bellows container in use.

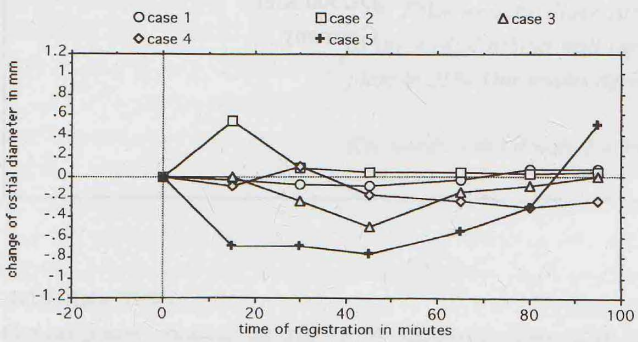

Figure 3. Change of equivalent ostial diameter after administration of placebo spray at 6 min, and oxymetazoline spray at 51 min, in five individuals in sitting position.

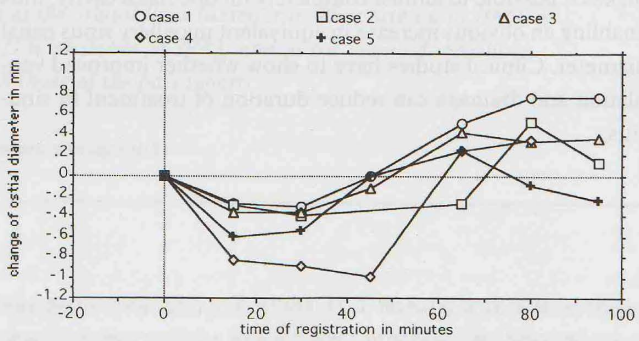

Figure 4. Change of equivalent ostial diameter after administration of placebo solution at 6 min, and oxymetazoline solution at 51 min, in five individuals in sitting position.

RESULTS

A comparison between placebo spray and oxymetazoline spray in cases Nos. 1-4 does not show any increase in equivalent ostial diameter. Case No. 5 shows a rather late increase in equivalent ostial diameter compared to changes recorded after administration of oxymetazoline solution.

Administration of oxymetazoline solution with the bellows container showed a pronounced increase in equivalent ostial diameter in four out of five cases. Unfortunately, in case No. 2 registration at 30 min, and in case No. 4 registration at 95 min, was not possible for technical reasons.

The registrations shown in Figures 3 and 4 were performed in sitting position. The changes of ostial diameter in recumbent position are similar to the ones shown in sitting position and not shown here for clarity's sake.

A direct comparison between the two different forms of administration of nasal decongestants is not possible since a "zero-value", i.e. placebo, is needed for comparison. No side effects were seen during this experimental study.

DISCUSSION

It is generally accepted that obstruction of the maxillary sinus ostia is important for developing a maxillary sinus infection (Drettner and Aust, 1977). However, only few reports have been published regarding pharmacological effects on the maxillary ostium.

Melen et al. (1986) performed a study on phenylpropanolamine compared with placebo and reported a significant increase in equivalent ostial diameter. This study shows an obvious increase in equivalent ostial diameter after administration of oxymetazoline solution for 30 s, compared to placebo solution, the time of observation being 45 min.

Placebo spray and oxymetazoline sprays (0.5 mg/ml) showed no such obvious effect, although some studies (Åkerlund et al., 1989) have shown the latter to be an adequate dose for reducing nasal obstruction in patients with common cold.

Late increase in equivalent ostial diameter, as seen in case No. 5, may, according to our experience, depend on slowly intensifying pain caused by the inserted cannula rather than being a pharmacological effect.

It is our impression that administration of oxymetazoline solution with the spring-bellows container is superior to oxymetazoline spray in increasing the equivalent diameter of the maxillary ostium. This difference can probably be explained by the complicated anatomical structure of the lateral nasal wall, where the middle turbinate, the uncinate process and the ethmoid bulla are an obstacle for spray intended to reach the hiatus semilunaris.

This new form of administration of nasal decongestants could mean an addition to the treatment of maxillary sinusitis, but further studies on volunteers with rhinitis will have to be conducted.

The use of the spring-bellows container in irrigation of the nasal cavity with saline solution could, furthermore, be of interest in treating dry-crusting nasal mucuosa, a problem in dry, hot areas. The spring-bellows container may of course also be of interest in local treatment following endonasal surgery as well as in distribution of drugs other than oxymetazoline to the nasal mucuosa.

CONCLUSION

This new technique of administration of a nasal decongestant makes it possible to almost completely fill one nasal cavity, thus enabling an obvious increase in equivalent maxillary sinus ostial diameter. Clinical studies have to show whether improved ventilation and drainage can reduce duration of treatment in sinusitis.

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