

Summary Report

THE EFFECT OF NASAL APPLICATION OF ASONOR[®] and POLYGLYCOSIDE 80 ON SNORING AND SLEEP APNEA

A double blind controlled study and an acceptance study

(the full report can be requested by contacting TannerMedico A/S)



by

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INTRODUCTION

Epidemiological studies have shown that snoring is very prevalent in the adult population. Snoring is more common among men and increases with age, until the age of 60-70. Snoring has been found to imply social and family welfare (difficulties in maintaining work, family problems, e.g. because of separate bed rooms, hypersomnia, sexual dysfunction). Snoring has been found to be a risk factor for cardiovascular and cerebrovascular disorders and complications, including high blood pressure, angina pectoris, myocardial and cerebral infarction.

Surgical treatment (UvuloPalatoPharyngoPlastic (UPPP), Mandibular advancement e.g.) are effective in some patients but are associated with operative and postoperative complications and risk for side effects. Nasal CPAP (Continuous Positive Airway Pressure) is very effective in reducing sleep apnea in patients suffering from severe sleep apnea, but most people suffering from simple snoring do not accept this treatment. Non-surgical and non-CPAP interventions, e.g. position training, tongue or dental devices have been found to be able to reduce snoring in some patients but their use has been debated and disputed. Because most of the snorers does only have "simple snoring" any simple treatment of the snoring problem are of major interest.

SUBJECTS AND METHODS

Study population

The study population was selected from a large-scaled epidemiological study performed in 1986 in the Copenhagen area involving 3439 men, age 50-75. Of those 49.9% reported every night or nearly every night snoring according to the questionnaire. 550 were selected by the following criteria:

1. Age 50-65,
2. Every night snoring according to the questionnaire
3. Abnormal ENT-findings, acute nasal allergies, alcoholism,

abuse of sleeping tablets, major cardiovascular, cerebrovascular and psychiatric diseases were exclusion criteria.

Controlled and stable cardiovascular diseases were accepted. Former cerebrovascular disorders were excluded.

All persons were invited by postal invitation. Of the 550 invitations 278 accepted entry into the study and were found to fulfil the inclusion criteria. This population was divided in 224 persons to the acceptance study and 54 persons to the controlled study.

All were invited to the hospital. A standardized questionnaire was given. All participants underwent a general physical examination and a otolaryngological examination. Blood pressure was measured on the left arm after at least 10 minutes at rest in sitting position. Weight and height were determined and body mass index (BMI) was calculated using Quetelets index (weight / height²).

All participants received written and oral information about the study. Written informed consent was given by all participants. The study was accepted by the local ethical committee.

STUDY SUMMARY

Earlier small, open human and animal studies have indicated, that nasal application of Asonor[®] solution reduce snoring. In order to characterize the effect of Asonor[®] with and without polysorbate 80 (P-80), a long acting tissue-lubricating polyglycols, on snoring and sleep apnoea, two studies were performed:

- 1) a double blind controlled study with inclusion of 50 every-night snorers, and
- 2) an open acceptance study with inclusion of 218 every night snorers.

218 male, self-reported every-night snorers, age 50-65, participated in an open, acceptance study with a daily use of 1.2 mg Asonor[®]. All participants were instructed to use Asonor[®] freely. After 6 months 67.9% were still using Asonor[®]. A significant improvement in self or bed-partner reported snoring, and a significant improvement in sleep quality, daytime tiredness and sleepiness were observed compared to baseline values (72%).

In the double blind controlled study, 50 every-night male snorers, age 50-65 were included. All were using a nasal application of 1.2 mg Asonor[®] with P-80 every night or a control preparation with Asonor[®], but without P-80.

In the double blind controlled study, a significant improvement was found in self and bed partner reported snoring, tiredness, sleepiness and in sleep quality both in the control and in the test period compared to baseline values (72%). No significant differences were found between the two groups, neither in the use of medication, in self reported snoring, in bed-partner reported snoring, in sleep quality or in daytime symptoms: tiredness and sleepiness compared to the control solution.

The study shows, that nasal installation of a solution of Asonor[®] improves snoring and the effect of P-80 in the solution not have any side effect.

Side effects are minimal and no serious side effects were observed.

The drug was supplied from Boehringer Ingelheim, Germany.

The full report can be requested by contacting TannerMedico A/S at

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