Effect of New Oral Neuromuscular Training Method on Sleep Apnoea and Snoring. Pilot Study Results and Discussion.

Overall Summary of Pilot Study

Title:
Effect of New Oral Neuromuscular Training Method on Sleep Apnoea and Snoring. Pilot Study Results and Discussion

Background:
Snoring and Obstructive Sleep Apnoea (OSA) have debilitating primary effects on sufferers, and secondary complications include cardiovascular disease, stroke, heart attack and diabetes. The conditions are caused by muscular weakness in parts of the oropharyngeal regions and there are no current treatments targeted at improving this. IQoro Neuromuscular Training (IQNT) has been shown in earlier studies to improve this muscle function, and individuals report success with self-treatment, there is a need to study the effect in a more controlled environment.

Aims/Objectives:
To investigate whether IQNT can improve OSA symptoms in a cohort of long-term sufferers.

Material and Methods:
Ten patients with diagnosed OSA who have used Continuous Positive Airway Pressure (CPAP) devices for more than twelve months were tested at baseline and after 3 months' IQNT at eight different sleep speciality clinics in Sweden. All patients continued using their CPAP during the intervention.

Results:
All ten patients improved considerably and nine moved down one or more categories in severity. One improved greatly but remained in 'Severe' at end of IQNT.

Conclusions and Significance:
This is a pilot study of the effects of IQNT on OSA sufferers and showed promising results for a condition which is widely prevalent, costly to the individual and the healthcare services, and that has no other recommended treatments apart from surgery in extreme cases.

Introduction

An analysis of seven earlier independent studies shows a prevalence of snoring and sleep apnoea of 22% of men and 17% of women[1]. Snoring occurs when the slack musculature in the soft palate and pharynx vibrate on inhalation when asleep; in the cases where the airway collapses in on itself completely, an Obstructive Sleep Apnoea (OSA) occurs. Over time, this can affect both the motor and sensory function of the tissue in the upper airway. The deterioration process is not fully understood, but previously published data shows a correlation between the level of snoring/OSA and altered sensory and motor function[2,3]. This is probably due to the negative effects of the vibration and stretching of the nerves and muscles in the airway during snoring and apnoeas.

OSA is recognised by international health authorities to have serious effects on health and wellbeing; both primary and secondary.

The primary symptoms include: snoring, abnormal daytime tiredness, dryness of the mouth, pain in the pharynx in the mornings, disturbed sleep, urinating several times per night, mood swings, reduced sexual drive, waking during the night with the sensation of suffocation, a feeling of never being rested, prone to fall asleep in various everyday situations, becoming easily tired when driving or as a passenger in a car, high blood pressure, headache in the morning, acidic indigestion, coughing at night, giddiness.

The secondary effects include an increased susceptibility to the complications of[4]: developing high blood pressure (hypertension), having a stroke or heart attack, developing an irregular heartbeat – such as atrial fibrillation, developing type 2 diabetes – although it's unclear if this last complication is the result of an underlying cause, such as obesity. Research has shown someone who has been deprived of sleep because of OSA may be up to twelve times more likely to be involved in a car accident.

There are no recognised treatments for the underlying cause – muscle weakness – of the condition of OSA except surgery in a few cases, and this has been discontinued by some countries' health authorities as a recommended treatment. Advice to patients centres on lifestyle changes: lose weight, drink less alcohol, sleep on your side, etc. Many patients instead receive help with workaround devices which function by keeping the patient's airways open at night and thus prevent the incidence of snoring and OSA. They are therefore an aid to avoiding the effects, rather than being targeted at the underlying physiological cause: the weakened, collapsed muscle and tissue. The first intervention device is a Mandibular Advancement Device (MAD) which alters the position of the lower jaw when sleeping to minimise the risk of the air pathway becoming blocked. The second is a Continuous Positive Airway Pressure (CPAP) which is a powered, bedside unit with a mask that fits over the patient's face and delivers a slightly elevated air pressure to keep the airways open. Some find the CPAP intrusive, and studies in the US have shown non-compliance rates as high as 85%.

According to the Swedish Sleep Apnoea Registry (NKR14-173), the total healthcare cost of OSA in Sweden is estimated to be approximately SEK 1 billion p.a. The high costs of OSA to society are internationally recognised: in the UK the estimated annual savings to the NHS would be £28 million and 20 000 extra Quality Added Life Years (QALY)[5], if all people with moderate to severe OSA were to be diagnosed and treated, compared with the current estimated level of treatment of 330 000 adults[5]. That is the marginal extra saving of treating all, instead of the proportion that actually are treated. These figures build on issuing CPAP devices which have both high initial costs and ongoing maintenance costs.

A study conducted in 2015[6], has relevance for treatment of snoring and OSA in stroke survivors and helped to provoke this current study. IQNT was performed for a 13 week period. Outcome measures included measuring the improvement in muscular activity in the tongue, the soft palate, pharynx, jaw muscles and other facial muscles including the lips (Tables 1 ,2). Poor function in these muscles has a high correlation to snoring and OSA.

Table 1.

Improved *orofacial muscle function in an early intervention group at end of IQNT and at late follow-up.

Early Intervention Group	Median Values			*p*-value	
	Before IQNT	End of IQNT	Follow-up 1 year after End of IQNT	End of IQNT	Follow-up 1 year after End of IQNT
Tongue muscles	1.6	0.5	0.6	<.008	<.250
Soft palate	1.5	1.0	0.5	<.004	<.094
*All orofacial muscles	1.3	0.6	0.4	<.004	<.039

Scale: 0 = Normal function; 4 = No muscular activity at all.
*All orofacial muscles, means all facial muscles, jaw muscles, lips, tongue and soft palate.
Wilcoxon's signed rank test was used to evaluate possible changes within a group between different test occasions.
The Mann-Whitney test was used to compare data between the early and late intervention groups.
A value of p <0.05 was considered significant.

Table 2.

Improved *orofacial muscle function in a late intervention group at end of IQNT and at late follow-up.

Late Intervention Group	Median Values			*p*-value	
	Before IQNT	End of IQNT	Follow-up 1 year after End of IQNT	End of IQNT	Follow-up 1 year after End of IQNT
Tongue muscles	1.4	0.6	0.6	<.001	<.307
Soft palate	2.5	1.0	1.0	<.001	<.219
*All orofacial muscles	1.4	0.5	0.4	<.001	<.035

Scale: 0 = Normal function; 4 = No muscular activity at all.
*All orofacial muscles, means all facial muscles, jaw muscles, lips, tongue and soft palate.
Wilcoxon's signed rank test was used to evaluate possible changes within a group between different test occasions.
The Mann-Whitney test was used to compare data between the early and late intervention groups.
A value of p <0.05 was considered significant.

Swallowing capacity was also measured before and after intervention, and the significant improvement in this reflect the improved muscle function and coordination. The improvements in the long-term and short-term intervention groups from baseline to long-term follow up, both displayed three-star statistical significance.

In the same study, five patients presented at baseline with PEG feeds; by end-of-training four PEGs had been removed and the fifth patient could eat orally and drink water: his PEG was removed a week after end-of-training. This is further evidence of the positive effect on the constrictor muscles in the pharynx: a key component in OSA dysfunction.

Velum Closure Ability (VCA) was similarly measured and showed improvement. The improvements in the long-term and short-term intervention groups displayed three and one-star significance respectively. No positive or negative changes were seen after cessation of IQNT to long-term follow up. VCA too, has a high correlation to snoring and OSA dysfunction.

Muscle activity was rated on a four-point scale from 0 (no impairment), to 4 (no muscle activity at all). Improvement was significant in all cases, and still present at one year follow up. The improvements after IQNT did not differ significantly between the early-, and late intervention groups.

The present study aimed to determine whether the same training regime would also affect these organs and muscles to the extent that they would have a positive effect on snoring and OSA. It was determined that a pilot study was needed to provide data on the effectiveness of this method on a cohort of OSA sufferers.

IQoro is used by thousands of individuals to treat the conditions of snoring and OSA, and customer surveys (PSEUD 2018) report a high rate of success. This study aims to prove efficacy in a more controlled environment.

Method

Study design
This study is a pilot clinical intervention on 10 patients with severe or moderate Apnoea-Hypopnoea Index (AHI) values for sleep apnoea. The effect of IQNT was assessed, blinded, at sleep speciality clinics ranged across 8 different Swedish cities, using sleep registration equipment before and after 3 months' IQNT. All patients continued using their CPAP during the intervention.

Study population
The population comprised 10 patients with sleep apnoea, five women and five men, mean age 64 years (range 55 - 73 years). Body Mass Index (BMI) had a mean value of 28.1 (range 22 – 30), only one patient being in the ideal BMI range. Seven patients were measured to have "severe" sleep apnoea. The other three beeing "moderate". Inclusion criteria were that they were diagnosed OSA sufferers and had used CPAP equipment for at least 12 months. All gave their written permission to participate in the pilot study.

IQoro Neuromuscular Training (IQNT)
IQNT exercises the muscles in the orofacial region, and the oropharyngeal and swallowing processes from the face, lips, mouth, throat, upper airways and esophagus down to the diaphragm and stomach[9, 10]. IQNT causes the muscles to strengthen as IQoro triggers the nerve pathways and the swallowing sensory motor reflex arcs that control them. By closing the lips tightly against the handle and pulling the device forward, a low-pressure is created in the mouth making the tongue retract and seal against the anterior palatal arch and the soft palate. IQoro flexes and trains the muscles and components along the swallowing chain and they strengthen, both through the neurological effect of the sensory motor reflex arc activity, and the direct physical effect on them.

IQNT consists of three daily sessions, each of 30 seconds' duration, and is self-administered by the patient.

Sleep registration
It is presumed that the eight independent sleep clinics used adequate sleep registration equipment and that the methods used were consistent at baseline and at end of IQNT after 3 months. An apnoea is defined as a drop in the peak thermal sensor excursion of ≥ 90% of the baseline lasting at least 10 seconds, while a hypopnea is defined as a 30% reduction in airflow compared with baseline, in combination with an oxygen desaturation of ≥ 3%. OSA is defined as a mean of five or more obstructive apnoeas and hypopneas per hour of sleep. Mild sleep apnoea is considered when the Apnoea Hypopnea Index (AHI) is > 5 to ≤ 15, moderate sleep apnoea when the AHI is > 15 to ≤ 30 and severe sleep apnea when the AHI is > 30 (Table 3). Duration of sleep is usually an estimate from the recordings.

Statistical Analysis

The patient population in this pilot study is too small to allow a full statistical analysis.

Ethical Considerations

The ten patients in this study were under treatment at various sleep clinics for OSA. They were examined and treated according to normal practice and therefore no ethical considerations arose. The study was performed according to the declaration of Helsinki 1975.

Results

The mean AHI score for the whole group improved from 'Severe' (36.6), to 'Moderate' (17.7) as shown after three months' IQNT (Table 4). All except one patient improved and moved to lower severity bands: either 'Mild' category (five patients), or 'Moderate' category (four patients). The most severely-affected patient improved dramatically (from 59.3 to 35.4), but without changing his severity category (Table 4).

It is interesting that the mean BMI value for the group, was not significantly changed from baseline to end of IQNT (28.1 reduced to 27.8), hence reduced bodyweight was not a factor in the improvements. The following table shows these results.

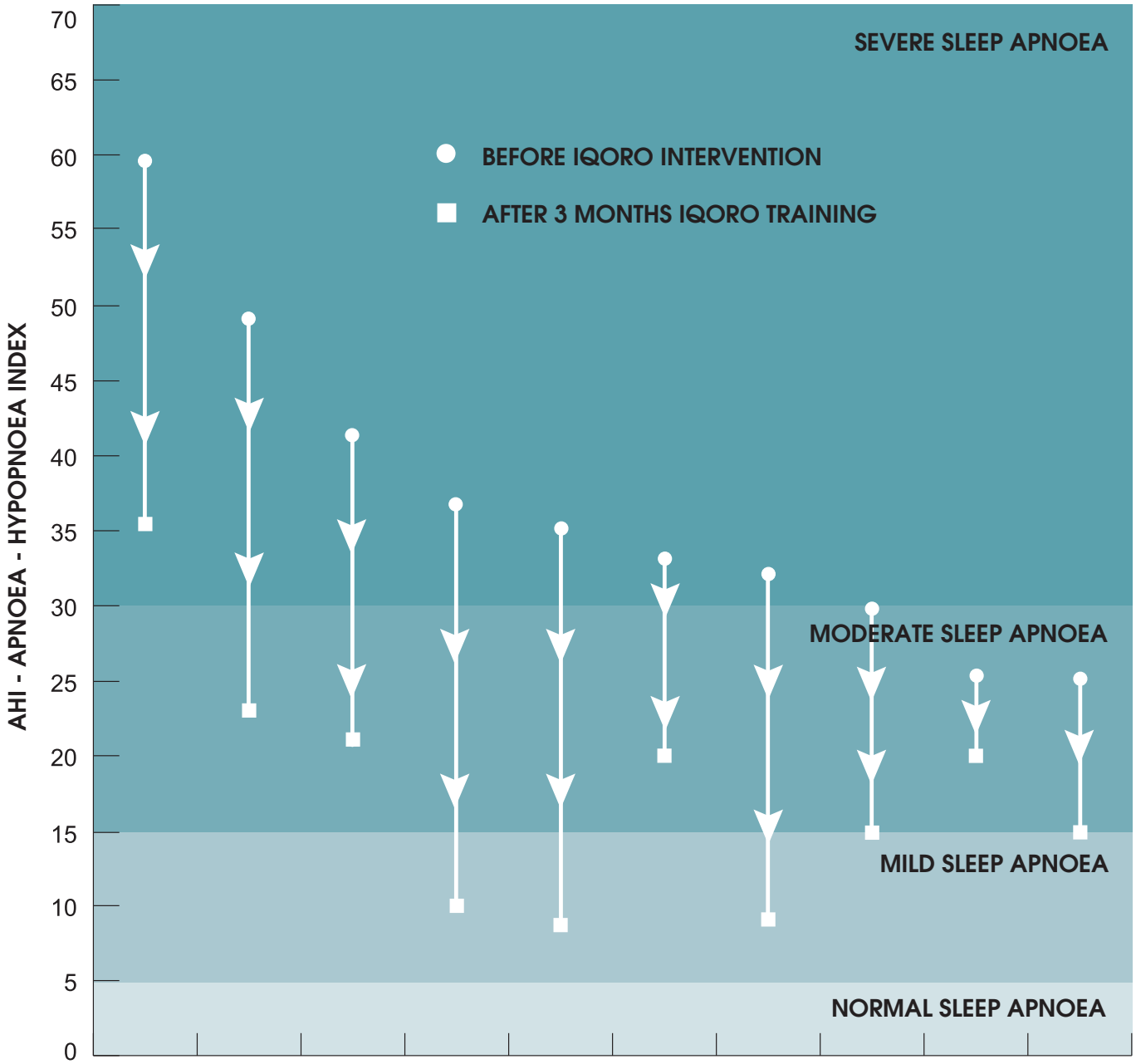
Table 3.
Explanation of AHI values and severity bands

Apnoea-Hypnoapnoea Index (AHI)		
Severity	**Value range**	
Severe sleep apnoea	> 30	
Moderate sleep apnoea	> 15	≤ 30
Mild sleep apnoea	> 5	≤ 15
Normal	0	≤ 5

Table 4.
Population description and improved condition after IQNT

Pat	Sex	Age	City	IQNT period	Value	Severity	Value	Severity	Improvement
6	M	65	Karlshamn	3 months	59.3	Severe	35.4	Severe	23.9
4	M	65	Örebro	3 months	49.0	Severe	23.0	Moderate	26.0
2	F	57	Sundsvall	3 months	41.0	Severe	21.0	Moderate	20.0
8	F	57	Härnösand	3 months	37.0	Severe	10.0	Mild	27.0
3	F	69	Sundsvall	3 months	35.0	Severe	8.7	Mild	26.3
7	M	55	Hudiksvall	3 months	33.0	Severe	20.0	Moderate	13.0
10	M	69	Hudiksvall	3 months	32.0	Severe	9.0	Mild	23.0
9	M	60	Allingsås	3 months	30.0	Moderate	15.0	Mild	15.0
1	F	73	Stockholm	3 months	25.0	Moderate	20.0	Moderate	5.0
5	F	70	Stockholm	3 months	25.0	Moderate	15.0	Mild	10.0
Mean		**64**			**36.6**	**Severe**	**17.7**	**Moderate**	**18.9**

Fig 1.
Population description and improved condition after IQNT



Discussion

The results of the pilot study are extremely encouraging, with ten out of ten patients improved, and with only one still in 'Severe' category at end of IQNT. All were long-term sufferers and had had CPAP assistance for at least 12 months. The earlier study[6], as illustrated (Tables 1, 2), showed with a high degree of certainty that muscle mass and strength could be improved in the orofacial and pharyngeal region – including in the tongue, soft palate and constrictor muscles where slack musculature is the underlying cause of snoring and OSA. The current pilot study indicates that these improvements have a positive effect on OSA as measured on the AHI – the aim of the study.

The result is especially significant given: the widespread prevalence of the condition, the huge healthcare costs associated with it, and the lack of any other treatment aimed at restoring the muscle weakness that underlies the condition.

On a wider point, the earlier study[6] showed improvement in Impaired Postural Control (IPC) despite the fact that IQNT has no direct effect on the muscles of the trunk or legs (some patients recovered from paralysis of the leg during IQNT), which further supports the contention that the IQNT treatment is effective because it stimulates and regenerates the neurological functions that drive muscle action.

IQoro is already shown in several studies[8,9,10,11,12,13,14,15,17,18,19] to treat swallowing difficulties (dysphagia), especially after stroke or neurological incident, and in others[16,17] to treat the symptoms of Hiatal hernia: reflux, GERD (GORD), LPR, sensation of stuck food, etc. Taken together, there is a compelling argument that IQNT is able to trigger improvements in many seemingly diverse conditions that are controlled from the same neurological processes.

Further research is obviously required to validate the positive results of this pilot study. In a separate ongoing study[7] it is hypothesized that "The deterioration process (in the upper air pathways) is not known, but previously published data shows a correlation between the level of snoring/obstructive sleep apnoea and altered sensory and motor function." This study will include 90 patients, 50% of either sex, randomized into an IQNT intervention group and a control group, and aims to replicate and build on the results of the pilot study reported here.

Conclusion

The results of this pilot and previous studies should trigger interest in researchers, healthcare professionals and others, in the possibility of a breakthrough treatment for OSA. It is truly a disruptive technology, that breaks with previous attempts to make CPAP technology more and more effective. It addresses the underlying cause of the problem, rather than alleviating the symptoms.

We should consider also the personal effects of snoring and OSA. Snoring is a uniquely unpleasant condition in that it can affect the sufferer's nearest and dearest more than it disturbs the patient his or herself. And because of that, can affect the relationships of the snorer in a most personal way: choosing to sleep in separate bedrooms being a dramatic step down that path. OSA is a similar problem, in that the sufferer is often not the first to notice the night-time breathing suspensions that this disease causes. More often, the patient notices the symptoms first, and the temporary breathing cessations are confirmed by a partner or measured by specially-designed sleep registration monitoring equipment.

IQNT therapy holds out the hope of improvements in care and costs for health authorities, and for health and quality of life in sufferers.

Author
Dr. Mary Hägg, Doctor of Medicine, Post-doctoral researcher at Uppsala University specialising in orofacial medicine, Head of Department at the Speech and Swallowing Centre: Ear, Nose and Throat Clinic at Hudiksvall Hospital, Sweden. Registered Dentist.

Proofreader
Terry W. Morris

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