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Elective tracheostomy is an alternative treatment in patients with severe obstructive sleep apnoea syndrome and CPAP failure

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Abstract

Conclusions. Elective tracheostomy with custom-made tubes was tolerated in a majority of patients with severe obstructive sleep apnoea syndrome (OSAS), as it reduced daytime symptoms and served as a link to other treatments. Objectives. To evaluate the tolerability of elective tracheostomy and changes in excessive daytime sleepiness and nocturnal oxygen desaturations (ODI) in patients with severe OSAS and obesity. Patients and methods. The medical records of 10 patients, median age 53.5 years (range 31–77), BMI 36 kg/m² (31–50), ODI 81 (55–126) during a 5-year period were reviewed. Inclusion criteria were failure of continuous positive airway pressure (CPAP), acceptance of tracheostomy, excessive daytime sleepiness and ODI >50. All patients received a custom-made tube. Sleep apnoea recordings and questionnaires with Epworth sleepiness scale (ESS) were performed before and after tracheostomy. Results. Eight of 10 patients tolerated the tube for more than 6 months. The ESS score was reduced from median 18 (range 8–23) to 5 (0–7) and the ODI values from 81 (55–126) to 13 (1–87). Two patients insisted on decannulation because they had nocturnal breathing problems, two underwent palatal surgery and were decannulated, and five still have their tubes. Severe cough, sputum infections and stoma granuloma were seen in all patients.

Keywords: OSAS, custom-made cannula, long-term tracheostomy, obstructive sleep apnoea syndrome, CPAP, continuous positive airway pressure, ODI, oxygen desaturation index

Introduction

Obstructive sleep apnoea syndrome (OSAS) is a relatively common disease; 4% of men and 2% of women suffer from this syndrome [1]. The syndrome is defined by repetitive upper airway obstruction during sleep, which closes off the airflow during breathing despite continued inspiratory effort, as the oropharyngeal airway is occluded. The apnoeas result in oxygen desaturations, fragmented sleep and frequent awakenings. The quality of life is affected with increased risk of poor sleep quality, excessive daytime sleepiness [2] and prolonged reaction time, which can cause increased risk for traffic accidents [3]. It also leads to an augmented risk of developing cardiovascular diseases [4], stroke and death [5,6]. Obesity has been found to be a strong contributing factor, adding to the risk for developing OSAS [1].

Patients with OSAS can be treated in several alternative ways. The first option for treatment is continuous positive airway pressure (CPAP). However, approximately 50% of the patients are CPAP failures due to poor mask fit, machine noise or nasal irritation [7]. Other options are a mandibular retaining device (MRD) or uvulopalatopharyngoplasty (UPPP). MRD is recommended mainly to patients with mild to moderate OSAS and has side effects as well as a rather low long-term compliance of 56% [8]. Other OSAS surgery, i.e. UPPP or tongue-base reduction, can be too risky to perform in obese patients with severe OSAS. They may postoperatively develop profuse bleeding and pharyngeal oedema with respiratory compromise [9]. An alternative treatment is tracheostomy, in which the patients receive an artificial airway, bypassing their
narrow upper airways. Tracheostomy as an elective treatment is a situation for which we can carefully prepare the patient, in contrast to an emergency situation due to sudden airway obstruction. However, when tracheostomy is used as a treatment, it is important to offer the patient support and regular follow-ups.

The patients in this study were receiving treatment at the Department of Otorhinolaryngology at the Karolinska University Hospital and the National Respiratory Centre (NRC) at Danderyd Hospital, both in Sweden. These clinics collaborate in work with patients who are considered for elective tracheostomy because of severe OSAS. The NRC started in 1982 and is classified by the National Board of Health and Welfare as a national referral clinic for patients with chronic respiratory disorders. The clinic has a unique team of doctors, who are specialized in both otorhinolaryngology and anaesthesiology, nurses and technicians. NRC makes custom-made tubes and provides careful preoperative information as well as postoperative support for each patient [10].

The aims of this retrospective study were to evaluate the tolerability of elective tracheostomy with custom-made tubes, as well as to measure the effects on daytime sleepiness and nocturnal respiration in obese patients with severe OSAS, who had failed or had not accepted CPAP.

Patients and methods

Data were collected from medical records for all tracheostomized patients with OSAS who attended the Department of Otorhinolaryngology, Karolinska University Hospital Huddinge from 2002 to 2007. Ten men from this group met the inclusion criteria for this study: acceptance of elective tracheostomy, failure of or not accepting treatment with CPAP or Bi level pressure devices (BiPAP), a score larger than 10 on the Epworth Sleepiness Scale (ESS) or severe morning drowsiness and a high score for the oxygen desaturation index (ODI), indicating a severe degree of OSAS. Seven of these male patients had hypertension, five patients had suffered from stroke or myocardial infarction and four had diabetes mellitus. The only patient with ESS <10 complained about a marked morning drowsiness, in combination with insulin-resistant diabetes mellitus. Table I shows the baseline characteristics for the patients included in the study.

Outcomes

The primary outcome was tolerability of the custom-made tube for more than 6 months. Other outcomes were changes in excessive daytime sleepiness and ODI.

Epworth Sleepiness Scale (ESS)

The Epworth Sleepiness Scale (ESS) measures excessive daytime sleepiness (EDS) and is a self-administered eight-item questionnaire about the propensity to fall asleep in different situations in daily life. It is the most commonly used subjective sleepiness assessment test [11]. The items are presented in scales of 0–24. The interpretation of the scale results varies among studies, but in general an ESS score of 8–10 is defined as mild sleepiness, 11–15 moderate sleepiness, 16–20 severe sleepiness, and 21–24 excessive sleepiness [12]. The ESS questionnaire was distributed during medical consultations at the clinic and in connection with the sleep recordings.

Sleep apnoea recordings

Ambulant recordings were made with the use of Embletta (Medcare Flaga, Reykjavik, Iceland) and MicroDigitrapper (Synectics Medical, Stockholm, Sweden) included monitoring of respiratory movements, oro-nasal flow, snoring, pulse oximetry and body position. The ODI, measuring the number of oxygen desaturations of 4% or more per sleeping hour, was determined. The apnoea-hypopnoea index measured by the thermistor was not considered to be a consistently reliable measure of the airflow at this time, and was therefore excluded. All recordings were interpreted by specialists in neurophysiology.

Custom-made tracheostomy tubes

The tubes were designed at NRC for each patient exclusively with regard to material (e.g. silicon, silver or polyurethane), thickness, length, curvature, position of the window, quality of stoma, the need for an inner tube, ability of speech and the patient’s requests [13]. All patients with a tube underwent monthly follow-ups of their stoma at the NRC.

Results

Eight of the 10 patients tolerated the tube for more than 6 months. Table I shows anthropometric data as well as results of preoperative and postoperative scores for ESS and ODI and clinical outcome. A flow diagram showing the treatment pathways for the 10 patients is provided in Figure 1.

Two patients (nos 1 and 2) insisted on decannulation at 3 and 5 months, respectively, after tracheostomy due to respiratory problems during sleep, severe cough and infections. Thereafter they were treated...
with CPAP again. Two additional patients were decannulated; the two youngest (nos 3 and 4) underwent UPPP 1 year after tracheostomy, and 3 months after UPPP they were successfully decannulated with normalized ODI values. One of these two had dramatically reduced weight and required no additional treatment. The other had high ODI values after 1 year and his symptoms had returned. He was treated with CPAP again.

One patient (no. 5) with persistent high ODI values despite the tube was offered invasive CPAP (CPAP connected to the tube). At the time of completion of this study, he had no more symptoms of sleepiness and was not motivated to use invasive CPAP. One patient (no. 6) with severe diabetes mellitus resistant to insulin injections had normalized glucose levels with insulin injections shortly after surgery. He had to use a ventilator during the first months after tracheostomy because of hypercapnoea. His daytime sleepiness and ODI did not normalize, therefore he was offered an invasive CPAP. However, he experienced great benefit from the tubes, with less severe morning drowsiness and is not motivated to use an invasive CPAP. One of the patients (no. 7) died of cancer while retaining his tube and therefore it was not possible to perform the evaluation with postoperative sleep recordings and questionnaires. Three patients (nos 8, 9 and 10) were complete responders, and are still using their tubes with no additional treatment, with normalized values for daytime sleepiness score and ODI.

None of the patients had serious postoperative bleeding or any other serious complication. There was no mortality associated with the tracheostomy.

**Discussion**

Our main finding was that 8 of the 10 patients accepted and tolerated tracheostomy as a treatment after 6 months. Furthermore, all patients with complete follow-up data reduced their daytime symptoms. Five of nine patients did not normalize their ODIs with the tubes. Tracheostomy served as a link to other treatments.

Tracheostomy may be considered as a very aggressive treatment option. However, the patients in the present study received a custom-made tube, which was distally or proximally extended and always provided with an individually created window to facilitate speech. A majority of the patients seemed to tolerate the treatment with a tracheostomy, even the long-term aspects. The custom-made tube in combination with correct information and follow-up seem to have been success factors. On the other hand, a high tolerability has also been shown in other
studies, in which custom-made tubes were not used [14–16].

Tracheostomy as an elective treatment is a situation for which the patient can be carefully prepared, in contrast to an emergency situation caused by sudden airway obstruction. However, when tracheostomy is used as a treatment, it is crucial to offer the patient support and regular follow-ups to help in avoiding social problems and depressive reactions [16]. Thus, it is also essential to consider the patient’s current social situation before the tracheostomy is performed. Expected adverse effects, such as granulation of the tracheostoma, severe cough and airway infections, were seen in all patients. At the NRC the patients received individual care that allowed for personal and regular management of potential complications [17], which could be treated with regular oral antibiotics. In addition, the careful provision of preoperative information is likely to help the patient to be well prepared for life with a tube.

In this study the patients reduced their daytime symptoms, i.e. excessive sleepiness or morning drowsiness, a finding which is in agreement with results of a study by Guilleminault et al. [16]. Despite persistent high ODI values in several patients, they perceived decreased daytime symptoms. This could be explained by fewer deep desaturations and shorter time of oxygen tension lower than 90% after tracheostomy, even though the ODI was still elevated. This could be seen in several patients (nos 1, 5 and 6). The divergent results between objective and subjective outcomes is a common finding in clinical studies, and has been described previously [18]. Poor nocturnal sleep and increased daytime sleepiness are associated with decreased quality of life [19]. Tracheostomy has the possibility to reduce sleepiness and thereby it has the potential to increase quality of life in this patient group, which must be seen as an advantage. In addition, other studies have shown that a tracheostomy does not lead to a reduced quality of life or decreased life expectancy [10,20].

The general opinion is that tracheostomy gives a normalized nocturnal respiration for most patients. However, in the follow-up to the present study, five of nine patients did not normalize their ODI values with the tubes. Two of these patients suffered from morbid obesity and had the highest BMIs in the group. Even though the tube bypasses the nocturnal upper airway obstruction, obviously the tube does not eliminate all oxygen desaturations. It is therefore important to perform postoperative sleep recordings after tracheostomy, especially in patients with excessive obesity. Such patients may have an additional restrictive cause of their respiratory problems, which is also accentuated during sleep. CPAP is frequently used in patients who are weaned from a tracheostomy tube. Recently, home mechanical ventilation with CPAP mode has been developed. This invasive CPAP treatment is known to open up the upper airways with high air pressure connected to the tube. The reason that our patients were difficult to motivate for this treatment could be have been that their daytime symptoms were reduced by the tracheostomy.

An additional finding in the present study was that tracheostomy served as a link to other treatments.
Two of the patients could undergo UPPP in a safe way, three were willing to use CPAP treatment again after decannulation, and one was able to lose weight. In obese patients neither CPAP treatment nor tracheostomy are known to decrease weight [14–16]. UPPP surgery was successful for the only patient who had reduced weight. In obese patients tracheostomy maintains a safe airway and thereby reduces the postoperative risks with airway obstruction and even mortality, which have been reported after OSAS surgery [9].

Most patients with severe OSAS who are offered a tracheostomy have failed other non-surgical treatment. A tracheostomy may improve the patients’ knowledge of OSAS. An untreated patient with severe OSAS often suffers from cognitive impairment and may not realize that his excessive daytime sleepiness and poor quality of life are effects of the disease, with chronic inflammation, sleep fragmentation, oxygen desaturations and/or hypercapnoea. After treatment with tracheostomy these symptoms usually diminish. Despite that, some patients prefer to be decannulated, as tracheostomy involves a substantial cosmetic and medical discomfort. Those patients may be better motivated for another attempt with non-surgical treatments. Some suitable patients may be offered other OSAS surgery, which should be performed while they still have their tubes.

This study has several weaknesses. First, it was retrospective with a small number of subjects, which made statistical analyses inadequate. Second, ambulant sleep apnoea recordings were used instead of polysomnography, which is the gold standard. However, in the Nordic countries and Great Britain ambulant sleep apnoea recordings are widely used and have been validated against polysomnography. Besides the fact that the nasal thermistor was unreliable at the start of the study, we did not consider it to be a reliable parameter when measuring the nasal airflow in these tracheostomized patients who were mainly breathing through their tubes during sleep. Therefore, changes in ODI, instead of the apnoea-hypopnoea index, were chosen as the primary outcome factor. As the same recordings were used pre- and postoperatively, and the interpretations were performed by a specialist, we consider the results of changes in ODI to be valid. Third, data were missing for one patient, as he died of cancer before the follow-up. Fourth, it is possible that the custom-made tubes may have improved the tolerability, compared with regular tubes. We are aware that most clinics do not have a special license to manufacture custom-made tubes and that it is unusual to be able to offer patients this treatment. A randomized study is needed to demonstrate differences in results between custom-made and regular tubes.

We consider that there are also several strengths of this study; it reflects the difficult clinical situation with severely ill patients who have failed CPAP treatment and for whom it is considered too risky to perform other OSAS surgery. As a majority tolerated the tube, we do not consider tracheostomy to be such an aggressive option any longer, especially when the alternative is no treatment at all. An additional strength is that the study emphasizes the need for postoperative recordings, as the tube may not be enough to keep the airways open in these obese patients.

A larger number of patients is desirable for future studies of the effect of tracheostomy in patients with severe OSAS. In addition, such studies should include measures of the changes in metabolic parameters, quality of life, the occurrence of hypercapnoea and the need for additional ventilator treatment.

**Conclusions**

Elective tracheostomy was a tolerable and effective treatment in terms of daytime symptoms in patients with severe OSAS. Tracheostomy also served as a link to other treatments.

Not all the patients improved their nocturnal respiration and therefore we recommend postoperative sleep recordings. Obese patients with severe OSAS, who have failed CPAP and are considered too risky to undergo other OSAS surgery, should be offered tracheostomy as an alternative.

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**References**


