Obstructive sleep apnoea: patients' experiences of oral appliance treatment

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SUMMARY Over the past few decades, there has been a pronounced increase in the number of patients being treated by general dental practitioners for obstructive sleep apnoea (OSA). The purpose of this study was to survey the care and patient experiences and the self-reported effectiveness of OSA treatment with an oral appliance (OA) incorporating mandibular advancement. The design was a retrospective, cross-sectional study, with follow-up between 6 months to 1 year after commencement of treatment. A survey form was posted to 1150 subjects, identified in the regional register over a 1year period as having been treated with an OA for OSA. The questionnaire comprised 70 questions and assertions in various domains, such as general health/lifestyle, changes in symptoms/quality of life and sleep-related experiences, daytime sleepiness, changes in life situation, evaluation of treatment and the value of treatment. The overall response rate was 64% (n=738). Treatment with OA gave relief of symptoms in 83% of the respondents. Quality of life, somatic and cognitive symptoms improved significantly in patients who used the appliance frequently (P < 0.001). Daytime sleepiness decreased significantly (P < 0.001). Treatment satisfaction and willingness to recommend the similar treatment to a friend were high (>85%). OA treatment of OSA by general dental practitioners is a safe procedure. Most of the survey respondents experienced relief of symptoms. Those who used their appliance frequently reported improvement in quality of life, somatic and cognitive symptoms. Excessive daytime sleepiness was reduced in the majority of the patients under treatment.

KEYWORDS: dentistry, effectiveness, follow-up, PROM, questionnaire, treatment

Accepted for publication 8 January 2016

Introduction

Obstructive sleep apnoea (OSA) is a public health issue. When daytime sleepiness is included, the condition affects 2% of women and 4% of men (1). OSA is characterized by disordered breathing and intermittent hypoxaemia (2). There are correlations with hypertension, cardiovascular disease, stroke and premature death (3–6). Patients with OSA report diminished quality of life (QoL), cognitive dysfunction and impaired general health because of respiratory disorders (3, 7–11).

The goal of treatment is to reduce the negative daytime symptoms and improve respiration. The aim of all treatment modalities was to widen the respiratory space, either by removing the excess tissues or by stimulating the airway opening.

The three most common treatments for the condition are as follows: continuous positive airway pressure (CPAP) (12), surgical removal of the soft tissue in the throat and intra-oral appliances combined with mandibular advancement (OA). Treatment with OA is undertaken by dentists: the appliance holds the mandible in a protruded position. Studies have shown that OA successfully reduces respiratory disturbances in 57–81% of mild and moderate OSA, and in 14–61% of more severe cases (13, 14). For more severe conditions, CPAP is the preferred therapy option

(3). However, compliance with CPAP is reported to vary between 51 and 76%, depending on the follow-up time (3, 15), indicating a need for alternative therapy options. Improved QoL is reported for the three most widely used treatment modalities (16–18) and improvement in neurocognitive skills (12, 19).

Over the past few decades, the number of patients being treated with OA by their general dental practitioners has increased and has become much more frequent in Sweden than in the other Nordic countries (3). Questions have been raised about patient compliance and the quality of treatment, and not least about patients' experiences of this long-term treatment. These issues are seldom addressed in the literature.

The purpose of this study was to evaluate the care and patients' reported experiences of OA treatment of OSA performed in general dental practice.

Materials and methods

Materials

The study was based in southern Sweden, in the region of Scania, with a population of about 1 200 000. During a 1-year period, from 2009 to 2010, the regional register showed that 1150 patients had undergone OA treatment for a medically verified diagnosis of OSA: the treatment had been provided by 66 dentists in the Public Dental Service and 77 private practitioners.

Method

The design was a retrospective cross-sectional study, with follow-up approximately >6 months to 1 year after commencement of treatment. The follow-up comprised a survey in the form of a questionnaire, posted to all patients identified in the regional register. The participants received written information about the purpose of the study and were advised that participation was voluntary and could be withdrawn by not responding to the survey. The participants were requested to return the completed questionnaire within 2 weeks. Those who did not respond to the first mailing were sent a reminder. The participants' identities were protected in the survey through the use of a serial number only.

The survey covered a total of 70 questions in 12 key areas, covering frequency and degree of discom-

fort/change (in Likert scales, 3 to 7 grades). These key areas were as follows: personal data, general health, lifestyle, treatment experiences, treatment effects, treatment compliance, drowsiness/sleepiness, satisfaction, health treatment, assessment of treatment importance/value and quality of life. The questionnaire also included the Epworth Sleepiness Scale (ESS), which is a validated index for detecting excessive daytime sleepiness (20, 21). Most of the questions have been used in a previous study (22).

In open fields of the survey, the respondents had the option of describing experiences not adequately covered by the survey questions. The questionnaire was pre-tested for content and language comprehension in a group of 10 volunteers, 5 of non-dental background and 5 in the dental profession. The questionnaire was revised to take into account the comments received from the volunteers.

The study design was tested and approved by the local ethics committee at the Faculty of Odontology, Malmö University, Sweden.

Statistics

The descriptive analysis included the mean, standard deviation and percentage distribution. Intergroup differences at baseline and during treatment with respect to the perceived factors and somatic and cognitive symptoms were tested with the McNemar test. Spearman's correlation (two-tailed) test was used to investigate any significant differences between satisfaction with treatment with respect to the quality of life and with respect to the frequency of appliance use. In all tests, a *P*-value <0.05 was regarded as statistically significant. The data were analysed using IBM SPSS Statistics, version 20*.

Results

The overall response rate was 64%: 70% in males and 30% in females. The mean age was 58 years: 57 (± 32) in males and 61 (± 37) in females. Self-reported general medical and pain conditions are shown in Table 1. At follow-up, 85% of the respondents had been under treatment for >1 year and the remaining 15% for >6 months. In 55% of cases, the respondents

*SPSS Inc., Chicago, IL, USA.

Table 1. Self-reported general medical and pain conditions (n = 738)

Body mass index (kg/m ²)	
Male	27.8 ± 3.5
Female	27.6 ± 4.9
Obese (BMI > 30), %	
Male	23
Female	28
Self-report of systemic disease, %	64
Diabetes	10
Cardiovascular disease	15
Hypertension	36
Prostatic complaints	5
Frequent headache after treatment	19
(>once a week), %	
No sleep disturbance due to pain, %	68

were treated in private general practice, 43% were treated by dentists in the Public Dental Service and 2% were treated at the Dental School in Malmö.

The experienced waiting time for professional care by dentists and physicians varied somewhat throughout the region: 19–25% experienced the wait as long or very long, while 34–45% felt that the time was short or very short.

The type of OA used was a monobloc design in 90% (n = 568), moving the mandible into protrusion. In 10% (n = 63), bibloc OA was used, comprising two parts which can be moved towards each other, but also with the mandible in a protruded position. In 92% (n = 532), the OA was made of hard acrylic and in 8% (n = 48) of a soft elastomer material.

Regular use of the appliance, every night for the past month, was reported by 61% of respondents: 73% used it \geq 5 nights/week, while 17% had not used their OA at all. Of those using their OA, 71% wore it throughout sleep, and 11% wore it for 75% of sleeping time. The remains wore it less than the above mentioned.

Excessive daytime sleepiness (ESS), measured as >11 points, was reported by 23% of the respondents, with a mean value of 7.5. Before treatment, only 26% felt refreshed after a night's sleep: there was a significant increase in frequency after treatment, 77% (P < 0.001).

Compared with those who did not drink any type of fluid 1 h before bedtime, no association was disclosed, either before or during treatment with OA, between beverage intake 1 h before bedtime and the need to urinate nocturnally. The majority of the

Table 2. Respondents' experience of using the oral appliance during the past month and the level of treatment satisfaction

Q: How satisfied are you with the use of the	ne oral appliance?	(n = 672)
Answer	n	%
Very well	274	41
Well	209	31
Neither well nor bad	84	13
Bad	39	6
Very bad	66	10
Q: How satisfied are you with the received	treatment? (n = 64)	46)
Answer		
Very satisfied	212	31
Satisfied	286	42
Neither satisfied nor dissatisfied	119	17
Dissatisfied	29	4
Very dissatisfied	40	6

respondents felt that the ease of use of their OA had been 'very good' or 'good'. A greater proportion of patients were 'very satisfied' or 'satisfied' with the treatment, (Table 2). Of the patients who were satisfied with the treatment (very satisfied or satisfied), 81% had favourable experiences of medical care and 83% of dental care. The level of satisfaction with the prescribed type of OA was 'very satisfied' or 'satisfied' for the monobloc type in 76%, for the bibloc type in 66% and with the OA of hard acrylic in 74% and of soft elastomer in 68%, respectively.

Men and women were equally satisfied with the treatment. The respondents presented for follow-up at their dentists in 44% (n = 322) of cases and at their physicians in 25% (n = 184) of cases. Of those who had undergone follow-up at the dentists, 78% were very satisfied or satisfied with the treatment and 8% were completely dissatisfied or dissatisfied. Of those who attended follow-up by their physician, 80% were 'very satisfied' or 'satisfied' and 8% were 'completely dissatisfied' or 'dissatisfied'. Of the respondents who had not attended a follow-up appointment with the dentist, 68% were 'very satisfied' or 'satisfied', while 10% were 'completely dissatisfied' or 'dissatisfied'. The corresponding levels of satisfaction among those who did not attend a follow-up appointment with their physician were as follows: 73% 'very satisfied' or 'satisfied' and 14% 'completely dissatisfied' or 'dissatisfied'.

There was a correlation between the frequency of use (number of nights/week during the past month) and improved quality of life at follow-up (r = 0.34,

P < 0.01) and treatment satisfaction (r = 0.58, P < 0.01).

After the start of treatment, 30% of respondents had undergone an objective assessment of the current respiratory status and a follow-up sleep recording, with the OA inserted. Of those who had undergone sleep recording, 46% had not been informed of the outcome.

In a self-assessment of their general QoL during treatment, 77% of the women and 72% of the men reported positive improvement (very much/very/quite good). Deterioration was reported by 2% of the women and 1% of the men, while 21% of the women and 26% of the men reported no change.

Self-recorded experiences before and during treatment are shown in Table 3. Table 4 presents the respondents' somatic and cognitive symptoms before treatment and at follow-up, showing statistically significant differences (P < 0.001).

Table 5 shows the respondents' self-reported assessment of their physical strength, mental energy, concentration ability, well-being/joyfulness, social intercourse and general QoL before treatment and at follow-up. For the different domains, there was a positive change (very much better/much better) in 22 to 39%. General QoL was rated as greatly improved by 39% of the respondents. In <1%, a sharp deterioration in the different domains was reported.

Table 3. Self-reported experiences of daytime and night-time complaints before treatment and at follow-up (%)

Self-reported experiences	Before treatment	At follow-up	Difference, <i>P</i> -value
Refreshed after a night's sleep (very often, often)	27	83	<0.001
Daytime tiredness (very tired, tired)	70	26	<0.001
Mean number of disturbances (≥2 times during sleep)	65	41	<0.001
Waking up with need to urinate (≥1 time/night)	70	67	Ns
Complaint about noisy snoring sounds often, sometimes)	88	48	<0.001
Use of hypnotics for sleep (often, sometimes)	13	12	Ns

Mc Nemar test.

Table 4. Self-reported somatic and cognitive symptoms, daytime and night-time, before treatment and at follow-up (%)

Self-reported experiences	Before treatment	At follow-up	Difference, P-value
During sleep (often)			
Dry mouth	48	31	< 0.001
Wake up and need to urinate	36	21	<0.001
Sweating	29	14	< 0.001
Respiratory arrests	77	12	< 0.001
Snoring sounds	93	22	< 0.001
Daytime (often)			
Daytime sleepiness	66	21	< 0.001
Reduced concentration	34	11	< 0.001
Increased mental irritability	28	9	<0.001
Decreased libido	26	16	< 0.001
Anguish, anxiety and panic symptoms	19	8	<0.001

Mc Nemar test.

Of those who used the OA regularly, 85% of respondents would recommend this type of treatment to a friend with the same problem ('Yes, absolutely').

Discussion

This study evaluated patients' reported experiences and outcomes after an intervention treating the verified OSA with an OA. Self-assessment data before and after at least 6 months of treatment showed that the patients perceived positive changes in QoL, somatic and cognitive symptoms. Satisfaction with the treatment was high. Furthermore, the patients reported that the OA was easy to use and functioned well.

With respect to the prevalence of general medical conditions among the study subjects, the results are consistent with those of other studies (23). Obesity has a negative effect on the progression of OSA and is thereby a negative prognostic factor. The prevalence of obesity was lower in this study than in other OSA studies, but higher than in the general population of Sweden (12%) (23).

No significant difference was reported in the need to urinate at night before or during treatment, even though a remarkably high percentage of the respondents reported drinking within an hour of bedtime. These habits were the same as before treatment, and this explains why nocturnal urinary need/frequency was unchanged.

	Physical strength	Mental energy	Concentration ability	Social intercourse	Well-being/ joyfulness	General quality of life
Very much better	3	4	3	4	5	6
Much better	21	23	19	20	20	33
Somewhat better	39	33	34	32	30	35
No difference	34	38	40	42	42	28
Somewhat worse	17	3	3	2	3	1
Much worse	1	0.2	0.5	0.5	0.5	0.2
Very much worse	1	0.2	0.2	0.2	0.2	0.2

Table 5. Self-reported life situation at follow-up, compared with before treatment start (%)

Frequent headache in association with OSA is described in several studies and reported to affect between 35 and 50% of patients (24). In the present study, no data were available on the pre-treatment frequency of headache. One-tenth of the respondents reported frequent headaches, and >50% had almost never experienced headache during actual treatment. It is probable that the frequency of headache decreased during treatment, as described in an earlier study by Tegelberg *et al.* (25).

It was equally common for patients to be treated in public dental clinics as in private practice, suggesting that this form of therapy is now accessible not only by referral to specialist clinics, but is widely available through general dental practitioners in this part of Sweden.

The monobloc appliance was the most frequent treatment modality at that time. It is the most reliable type of intra-oral device, the most thoroughly investigated and the earliest to be scientifically verified (13). Recently, several studies comparing monobloc and bibloc appliances have disclosed only minor differences in efficacy; hence, more treatment options are available for patients (14). Differences in the cost of production of the different types of appliance and own skills as dentist may be a factor contributing to the frequent use of the monobloc OA in Sweden. In later clinical studies, the results of bibloc appliances seem to have some superior effect due to better compliance compared to a monobloc design (26, 27). Whether or not adjustable oral appliances improve the effectiveness better than monobloc appliances remains uncertain, and rigorous prospective randomized clinical trials evaluation are required. The use of either a monobloc or bibloc appliance could not be analysed by the op-outs in the study, and thereby, we could not answer the question whether the bibloc appliances have any superior effect.

OA with mandibular advancement reduces nocturnal respiratory arrest/disturbances more efficiently than appliances which do not include advancement. This is more evident in severe OSA (28). Mandibular advancement in the structure of the OA is therefore considered to be critical for treatment effectiveness (14). The most common choice of material for OA was position and the occlusion. In most studies, the most common range of follow-up times is from 1 to 5 years, with few extending over longer periods (29). In one long-term follow-up study, the orthodontic side effects were more pronounced with appliances made of hard acrylic than soft elastomeric appliances (30). Patient satisfaction was comparable for the different types of OA and was not influenced by the choice of material or construction. The level of satisfaction may also be associated with the good therapeutic effect (14).

The proportion of patients who experience occlusal changes increases during the first 2 years of treatment and then remains relatively constant. Previous reports have shown that the dental/occlusal changes are usually minor and at times imperceptible to the patient (28, 30). The prerequisites for treatment to proceed are the absence of unacceptable or progressive symptoms and the presence of adequate posterior support (30). In the absence of knowledge about factors contributing to these occlusal changes, it may be important to continue follow-up even if it does not increase satisfaction with the treatment.

The study showed that those who used their OA very frequently perceived a greater improvement in their QoL after treatment than those who used their OA less frequently. This finding has not been presented in the previous studies. The OA only exerts an effect when in active use (14); hence, those patients who used their OA more frequently may have per-

ceived a greater benefit from the treatment. However, it is most likely that the patient's perception of well-being and quality of life improved because treatment relieved the symptoms (16).

Regular use of OA, *that is* 5 nights or more per week, was reported by 73%, which is in agreement with the other studies (25, 31, 32). When treatment compliance is inadequate, it is important to evaluate the OA therapy and to interact with the patient's physician to find the alternative treatment to relieve symptoms and improve the patient's quality of life.

All signs and symptoms asked about in the survey had declined significantly in comparison with the pretreatment values, especially for episodes of apnoea, snoring and daytime sleepiness. Similar results are reported in other studies with reference to daytime sleepiness, irritability, sweating and the need to urinate at night (33). The treatment effect was that 77% of respondents had an ESS value <11, which is considered to be non-morbid daytime sleepiness, and average value was 7.5 during treatment, which is similar to another study (19, 34).

We found no differences between those who attended follow-up at their dentist and/or physician and those who did not. Satisfaction with the treatment was the same. Studies of CPAP have shown that appointments to monitor treatment improve patient compliance (33). Similar effects might be achieved for all patients if those showing poor compliance with the OA treatment were encouraged by more frequent recall to continue treatment. It was a smaller proportion of patients who had been on the subsequent verification of their treatment were satisfied with the treatment compared to the percentage of all study materials that were satisfied with the treatment. This might be because they had treatment problems sought care for the post.

A small number of patients underwent follow-up sleep recording as a part of the medical evaluation of the condition. Almost 50% of the respondents did not know whether they had undergone follow-up sleep recording. From the perspective of quality of medical care, it is then difficult to draw conclusions about the respiratory effect of the treatment. Respiratory disturbances increase the risk of, *for example*, cardiovascular disease: hence, medical practitioners have a responsibility to treat obstructive sleep apnoea effectively.

For the majority of patients, both dental and medical care had been a good experience. When OSA is

treated as a multifactorial condition with several personal care contacts, one can imagine that the patient feels noticed and is therefore more likely to be satisfied with the treatment.

There was a wide range of waiting times in the study. There are no other studies related to waiting times in health care in the treatment of OSA, but the variation may be due either to personal traits such as impatience and disease activity or to pronounced regional variations in waiting times.

The majority of the respondents rated their quality of life as higher at follow-up, which is consistent with other studies. Treatment with OA, surgery or CPAP can all provide an increase in perceived QoL of patients (21–25, 28). Physical strength, mental energy, ability to concentrate and to feel joyfulness as well as social intercourse increased or remained unchanged in almost all patients during treatment, which is in accordance with other studies (33).

Most of the respondents were willing to recommend OA therapy to a friend, regardless of whether they had themselves perceived a positive treatment result or not.

The limitation of this kind of study is the ability to generalize from the results of a questionnaire depends on a sufficient number of responders. In this study, there was an overall response rate of 64%. A response rate of at least 60% is set as a minimum requirement for publication by some scientific journals (35). However, there is a steady decline in response rates in the published surveys of healthcare providers in the USA, and during 2005-2008, only about 35% met the 60% criteria and none in 2009 (36). This was also true for postal surveys of healthcare professionals covering 1996 to 2005 where the response rate (350 studies, average response rate 58%) was significantly lower than the previous 10-year period. It was even lower in studies with more than 1000 participants. The conclusion drawn in 2005 was that response rates to postal surveys of healthcare professionals were low and probably declining, which may lead to the unknown levels of bias (37). With this as background, we find the results as reliable as possible at that time and with this research design. However, the results should be interpreted with some caution as the nonresponders could be more frequent non-satisfied patients to the treatment.

It can be concluded that OA treatment of OSA by a general dental practitioner is safe and gives symptomatic relief in the majority of patients. Quality of life, somatic and cognitive symptoms changed favourably for the patients who used their appliances frequently. The majority reported that treatment reduced excessive daytime sleepiness.

Acknowledgments

Financial support was given from Region Skåne and the Faculty of Odontology, Malmö University, Sweden.

Ethical approval

The study design was tested and approved by the local ethics committee at the Faculty of Odontology, Malmö University, Sweden.

Declaration of interest

The authors report no conflict of interests. The authors alone are responsible for the content and writing of the paper.

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