Patient-reported outcome measures following maxillomandibular advancement surgery in patients with obstructive sleep apnoea syndrome

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Abstract

Maxillomandibular advancement (MMA) is an effective treatment for obstructive sleep apnoea syndrome (OSAS) that is refractory to conventional treatment. However, it is a highly invasive procedure with several recognised side effects, and we know of few data on its effect on important patient-reported outcome measures (PROMS). Here we describe a case series of patients selected for MMA through our joint respiratory/maxillofacial surgery clinic, detailing the effect of MMA on objective physiological measurements and important PROMS. Patients with confirmed moderate/severe symptomatic OSAS who could not tolerate continuous positive airway pressure (CPAP) or mandibular advancement devices (MAD) were assessed in the clinic for consideration of MMA. Preoperative and postoperative airway measurements, apnoea/hypopnoea index (AHI), Epworth sleepiness scale (ESS) score, and quality of life (10-point Likert scale), were recorded. A customised questionnaire was administered postoperatively to assess selected psychosocial and functional domains (sleep quality, energy levels, appearance, ability to perform daily activities, and mood) and patient satisfaction using five-point Likert scales. Over an 18 month period, 39 patients were referred for consideration of MMA. Ten patients (7 men and 3 women, mean age 49.9, mean BMI 27.5) underwent surgery, which resulted in significant improvements in ESS, quality of life, AHI, and airway diameters. All patients reported improvements in all psychosocial/functional domains except appearance, in which five reported no change or worsened appearance. All subjects felt that MMA provided better symptom control than CPAP. The most commonly reported side effects were facial/lip numbness (9/10) and affected bite (6/10). MMA resulted in significant improvements in ESS, quality of life, and a range of PROMS, with a high level of patient satisfaction.

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Keywords: Obstructive sleep apnoea syndrome; Maxillomandibular advancement; Patient-reported outcome measures

Introduction

Obstructive sleep apnoea syndrome (OSAS) is an increasingly common condition, with the most recent US data estimating a prevalence of ~14% in men and 5% in women. It is associated with sleepiness, fatigue, impaired concentration and memory, as well as significant psychological and marital problems. This in turn can have an impact on work and, if left untreated, is associated with an increased risk of road traffic accidents and workplace accidents.

Whilst patients with mild to moderate OSAS may be treated with a mandibular advancement device (MAD) the mainstay of treatment in moderate to severe cases is continuous positive airway pressure (CPAP) therapy. Although CPAP is effective in treating OSAS, tolerance is frequently suboptimal with reported rates of adherence between 30% and 60%. In addition, CPAP is associated with multiple problems including claustrophobia, sleep fragmentation, social embarrassment, and interference with intimacy.

There is a lack of other treatment options for this patient group, who often find weight loss extremely difficult or

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impossible, so surgical intervention must sometimes be considered. Patients with certain anatomical features such as retroglossia may find it particularly beneficial.\textsuperscript{11}

Multiple surgical approaches have previously been described in patients with OSAS.\textsuperscript{12} More recently, hypoglossal nerve stimulation has also been tried but this may be of limited efficacy in moderate to severe cases, particularly in the presence of morbid obesity.\textsuperscript{13} The most efficacious approach is widely considered to be maxillomandibular advancement (MMA).\textsuperscript{14} MMA, which was first described as a surgical procedure to treat OSAS by Riley et al in 1986, aims to widen the nasopharyngeal, retropalatal, and hypopharyngeal airways by approximately 10 mm by osteotomy and forward advancement of the maxilla and mandible.\textsuperscript{15} It has since been recognised as a treatment option for OSAS that is refractory to conventional treatment, in those who cannot tolerate CPAP, and in those with surgically correctable anatomical abnormalities that predispose to OSAS. A meta-analysis of MMA for OSAS has revealed significant improvements in the apnoea-hypopnoea index (AHI) and Epworth sleepiness scale scores, as well as high rates of surgical success and surgical cure.\textsuperscript{16} There is also a great deal of evidence that MMA significantly increases the calibre of the pharyngeal airway.\textsuperscript{17} However, despite the observed improvements in these physiological measurements, we know of few data on the effect of MMA on metrics that are likely to be of prime importance to patients, such as quality of life.\textsuperscript{18} We know of only a few relatively small studies that have assessed quality of life measures (such as the Functional Outcomes of Sleep Questionnaire (FOSQ)\textsuperscript{19} and the Ottawa Sleep Apnea Questionnaire (OSA-Q)) before and after surgery.\textsuperscript{18}

MMA is a highly invasive surgical procedure with a number of recognised side effects, and it is currently unclear if its advantages outweigh the potential risks. Given the increasing prevalence of OSAS, the number of patients considered for MMA is likely to increase. We therefore feel that it is essential to develop rational and robust screening criteria to assess suitability for surgery. We routinely record patient-reported outcome measures (PROMS) following MMA to ensure that our service meets patients’ expectations, and to establish a greater understanding of levels of patient satisfaction regarding the procedure. To this end we have instituted a joint respiratory maxillofacial surgery clinic approach to identify and assess suitable patients for MMA. Here we outline our joint clinic pathway for appropriate case selection. We describe a case series of patients selected for MMA through this clinic and detail the effect of MMA on objective physiological measurements and selected important PROMS.

\textbf{Methods}

Patients referred to our services for the assessment of potential sleep apnoea were managed as per the pathway in Figure 1. Those with confirmed moderate/severe OSAS who were intolerant of CPAP and remained symptomatic were assessed in the joint respiratory/maxillofacial surgery clinic for further evaluation and consideration of MMA with genioplasty.

\textbf{Data collection}

A customised questionnaire was designed (Appendix A) and administered two months postoperatively for the purposes of service evaluation, hence no formal ethics permission was required for the study. The questionnaire was designed to assess a number of psychosocial and functional domains (sleep quality, energy levels, appearance, ability to perform daily activities, and mood) and patient satisfaction using five-point Likert scales (see Figure/online supplement).

Patients who underwent MMA had preoperative measurements (respiratory polygraphy, Epworth sleepiness score (ESS), quality of life score (using a 10-point Likert scale), and lateral cephalograms) to assess their nasopharyngeal (NPH), oropharyngeal (OPH) and hypopharyngeal (HPH) airway dimensions.

All patients in the study had MMA along with advancement genioplasty. The surgical procedure involved a standard Le Fort I osteotomy with 1 cm advancement of the maxilla achieved using bone spreaders to mobilise the maxilla. Bilateral sagittal split advancement osteotomy of the mandible was done and, as per standard practice, a 1 cm advancement genioplasty was undertaken at the same time as the mandible was advanced by 1 cm. Patients went back to the high dependency unit (HDU) for one night and were discharged on the first postoperative day. They were followed up at weeks one and four.

Two months after the procedure, respiratory polygraphy, quality of life score, and lateral cephalograms were undertaken. The ESS score, a measurement of a subject’s level of daytime sleepiness, was assessed using the standard ESS questionnaire.\textsuperscript{20} Preoperative and postoperative quality of life were also assessed using a 10-point visual analogue scale (VAS). Duration of CPAP use, reasons for CPAP intolerance, preferred treatment option (CPAP vs surgery), and the effects of surgery on the symptoms of snoring and sleepiness at different time points postoperatively, were also recorded.

\textbf{Statistical methods}

Demographics and baseline clinical measures were determined using Stata Statistical Software release 11.0 (StataCorp). For continuous variables, normality was assessed through the visual inspection of histograms. For all normally distributed parameters, the paired \textit{t} test was used to compare mean values before and after treatment. The AHI was not normally distributed and could not be transformed to normality, so median values before and after treatment were calculated and compared using the Wilcoxon signed-rank test.

The proportion of patients with a complete surgical cure and objectively successful surgery was calculated. Complete surgical cure was defined as a postoperative AHI of less than five events/hour and objectively successful surgery was
defined as an an AHI of less than five events/hour or a reduction in the AHI of more than 50%.

Results
Over an 18-month period ~2000 patients were referred to the OSAS service and of them, 39 (~2%) were referred on to the joint clinic for assessment for MMA. Of them, 10 patients (7 men) with a mean age of 49.9 years and mean BMI of 27.5 underwent the surgery (Table 1). The reasons for unsuitability for surgery, including other identified causes of symptoms, are listed in Figure 2. The median duration of CPAP use prior to surgery was three months, with subjects reporting that CPAP led to a worsening of their sleep (8/10) or
did not control their symptoms of sleepiness effectively (5/10). Other commonly reported problems were mask leaks (5/10) and excessive noise from the device (7/10) (Table 1).

The median (range) preoperative AHI was 24 (9–110) events/hour. Following surgery five patients had a complete cure with an AHI of less than five events/hour, and eight had successful surgery (AHI <5 or >50% reduction) (Table 2). The median (range) postoperative AHI was significantly reduced at 5.4 (2.7–26) events/hour ($p = 0.003$), and mean NPH, OPH, and HPH airway diameters increased significantly (Table 2).

In two patients, despite an adequate increase in airway volume, the procedure was unsuccessful (postoperative AHI 26 and 21). Both had critical points of more than 1 cm in their airways. The mean ESS score improved from 15.1 preoperatively to 4.3 postoperatively ($p = 0.0005$).

All patients reported improvements in all the psychosocial and functional domains measured except appearance, in which 5/10 reported improvements and 5/10 reported no change or worsened appearance (Table 3). There was an improvement in average quality of life score (on a 10-point VAS scale) from 2.8 preoperatively to 8.1 postoperatively ($p = 0.0005$).

All patients reported side effects two months after surgery, most commonly facial/lip numbness ($n = 9/10$) and affected bite ($n = 6/10$) (Table 4). The mean (range) length of stay following the procedure was 2.3 (1–4) days ($n = 10$) with a mean (range) of 8 (3–16) weeks off work for those in employment ($n = 6$).

**Discussion**

*MMA is a highly effective treatment in selected patients with OSAS who cannot tolerate CPAP.*

In terms of optimising patient selection for the procedure, our experience supports a joint approach between respiratory/sleep physicians and maxillofacial surgeons. Our approach (Fig. 2) is based on a two-stage process. First, the referral of patients with confirmed moderate to severe OSAS (other important causes of sleepiness ruled out or treated) from the respiratory/maxillofacial clinic to the joint clinic if they cannot tolerate CPAP (with or without a MAD) and are still
symptomatic, and secondly, workup in the joint clinic for potential surgery including optimal support with CPAP/MAD, respiratory polygraphy, ESS, the FOSQ, and cone beam computed tomography (CBCT) of the airway.

By using this approach and emphasising robust screening for alternative pathologies prior to referral to the joint clinic, 2% (n = 39) of approximately 2000 patients who were referred to our service with OSAS (over an 18-month period) were subsequently assessed in the joint clinic, and 10 (0.5%) proceeded to surgery. Improvements in the AHI (8/10) and/or improvements in the ESS (9/10) were achieved in all patients. The two with a high postoperative AHI (26 and 21) had adequate increases in airway volume following surgery, and both had had critical points of more than 1 cm in their airways preoperatively. One was still symptomatic following surgery (partly likely due to vitamin D deficiency) whilst the other had significant symptomatic benefit. It is possible that preoperative measurement of critical airway dimensions may be a useful tool in patient selection for MMA.

We have recorded some previously undocumented benefits of MMA in a range of important PROMS and measures of patient satisfaction. These include improvements in energy levels, mood, and ability to perform daily activities, in addition to enhanced sleep quality and reduced daytime sleepiness. Most importantly, patients indicated significant improvements in their quality of life.

Our study supports previous observations of the common reasons for poor tolerance of CPAP therapy, which lead to poor compliance. Compared with CPAP, the effects of surgery on the airway are immediate and sustained, and these were supported by the majority of our patients who reported sustained improvements in snoring and sleepiness from one week to six months postoperatively. The high levels of satisfaction compared with CPAP support the idea that MMA is a potentially valuable treatment in CPAP-intolerant subjects, despite its side effects. Side effects occurred relatively commonly in our patients, and included facial/lip numbness and affected bite, which are well described complications.

Table 2
Preoperative and postoperative objective measures (n = 9). Data are mean (SD) unless otherwise stated. Significance testing with Wilcoxon signed-rank.

<table>
<thead>
<tr>
<th></th>
<th>Preoperatively</th>
<th>Postoperatively</th>
<th>Difference</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epworth sleepiness scale</td>
<td>15.1 (6.3)</td>
<td>4.3 (3.7)</td>
<td>-10.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Median (IQR) apnoea/hypopnoea index (events/hour)</td>
<td>24 (41)</td>
<td>5.4 (52)</td>
<td>-18.6</td>
<td>0.003</td>
</tr>
<tr>
<td>Nasopharyngeal (cm)</td>
<td>0.73 (0.34)</td>
<td>1.23 (0.54)</td>
<td>+0.5</td>
<td>0.003</td>
</tr>
<tr>
<td>Oropharyngeal (cm)</td>
<td>0.58 (0.19)</td>
<td>1.22 (0.35)</td>
<td>+0.64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypopharyngeal (cm)</td>
<td>1.06 (0.40)</td>
<td>1.51 (0.61)</td>
<td>+0.45</td>
<td>0.04</td>
</tr>
<tr>
<td>Quality of life (10-point VAS)</td>
<td>2.8</td>
<td>8.1</td>
<td>+5.3</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Table 3
Results of patient-reported outcome measures (PROMS) questionnaire (frequency of responders on 5-point Likert scale).

<table>
<thead>
<tr>
<th>Change since surgery</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep quality</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Daytime sleepiness</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Energy levels</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Appearance</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Daily activities*</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Mood</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Symptom control CPAP vs surgery</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Satisfaction with surgery (1 highly dissatisfied → 5 highly satisfied)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>9</td>
</tr>
</tbody>
</table>

CPAP: continuous positive airway pressure.

Table 4
Length of stay, recovery time, and side effects of surgery. Data are number unless otherwise stated.

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Mean (range) length of stay (days)</td>
<td>2.3 (1–4)</td>
<td></td>
</tr>
<tr>
<td>Mean (range) time off work (weeks)</td>
<td>8 (3–16)†</td>
<td></td>
</tr>
<tr>
<td>Affected bite</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Facial/lip paraesthesia</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Postoperative infection</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

† Only 6/10 patients in work.
preoperatively), none of the others wanted further intervention for their altered bite.

Our study was subject to several limitations. Our main aims were to establish and evaluate a functioning service for the selection of patients for MMA, and to evaluate the outcomes. Hence our a priori endpoints were broadly defined and included standard physiological measurements taken before and after surgery with the customised (and unvali
dated) PROMS questionnaire, which was designed and administered postoperatively for service evaluation. These PROMS were measured using five-point Likert scales, and whilst they could have been subjected to formal statistical testing, their lack of validation would have limited the interpretation of any results. As the questionnaire was administered only postoperatively, responses were subject to recall bias. Our conclusions are also limited by the small sample size. Further studies in this area should ideally include structured qualitative interviews as well as other validated instruments such as preoperative and postoperative FOSQ scores.

Now that our service has been established and has demonstrated efficacy in the treatment of an often problematic patient cohort, more focused clinical questions regarding optimal patient selection and outcomes may be assessed in the future.

Conclusions

MMA, when used judiciously, is an effective tool for the treatment of patients with OSAS who cannot tolerate CPAP. Close links between physicians and surgeons help to optimise patient selection. As well as recognised improvements in objective physiological measurements, MMA also leads to improvements in important psychosocial measures and quality of life, with high levels of patient satisfaction.

Ethics statement/confirmation of patients' permission

This work was conducted for the purpose of service evaluation, hence no formal ethics permission was required for the study. All participants were aware that completion of the PROMS questionnaire and collection and analysis of their fully anonymised clinical data were entirely optional and would be submitted for publication.

Conflict of interest

Matthew Martin and Milind Sovani report personal fees outside the submitted work. The other authors declare they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bjoms.2022.03.006.

References