NICE Health Technology Assessment of CPAP for treatment of the obstructive sleep apnoea syndrome

Personal statement - Clinical Specialist: Professor G J Gibson

Personal experience

My views are based on 20 years experience of treatment of patients with the obstructive sleep apnoea syndrome (OSAS). Currently, I am responsible for the care of 2500 patients on long term treatment with CPAP. I have also been involved in several research studies in the field of OSAS and its treatment.

Value of CPAP

CPAP is universally acknowledged among professionals dealing with sleep apnoea as the treatment of choice for controlling the disabling symptoms, most commonly excessive daytime sleepiness. CPAP treatment is highly effective and is virtually guaranteed to work in OSAS provided that the symptoms are due to the sleep apnoea syndrome and provided that the patient is able to continue use on a regular basis. In most individuals, the treatment should be regarded as potentially lifelong, although a minority are able to discontinue it if another intervention (eg bariatric surgery or tonsillectomy where appropriate) has been performed. In my view, CPAP for the treatment of OSAS represents the single most important therapeutic advance in respiratory medicine in the last 25 years. Of treatments commonly used in our specialty, no others have such dramatic benefit eg transforming a patient's life or saving jobs or marriages.

Disadvantages of CPAP

CPAP treatment, together with the associated masks, tubing etc is inconvenient, cumbersome and noisy, although much less so in recent years as technology has improved. It is a testament to its effectiveness that many thousands of patients are prepared to continue using CPAP every night despite these disadvantages.

Of the common adverse effects, drying of the mouth and throat and nasal congestion can usually be relieved by changing the interface and / or the addition of a humidifier; local pressure problems on the skin are manageable by varying the type of interface.

<u>Initial provision of CPAP</u>

The supply of a CPAP system is nearly always preceded by overnight investigation of a patient with symptoms suggestive of OSAS. The most common disabling symptom is daytime sleepiness which can seriously interfere with work performance, social functioning and the ability to drive safely. In some individuals investigation is prompted by other features such as concern by a partner who has witnessed apnoeas or by nocturnal choking episodes or morning headaches. Nowadays, in most centres, the investigation and initiation of CPAP treatment are performed at home with the patient coming to hospital to collect the recording device or CPAP machine and receiving detailed instructions from a health professional. In many centres, the first night on CPAP is spent with an auto-adjusting machine ("CPAP titration"), from which is derived the lowest pressure required to overcome 95% of the apnoeas and hypopnoeas. This pressure is then applied by a fixed pressure CPAP device. However, such precision may not be essential and some centres use a standard pressure setting or sometimes estimate the likely pressure required from a predictive

equation based on factors such as the patient's body mass index. The pressure can be adjusted emoirically at subsequent visits if symptoms are not completely suppressed or if evidence of partial airway narrowing remains (eg persistence or recurrence of snoring during treatment).

Monitoring treatment

Effective treatment with CPAP does not finish with the provision of a machine. Most patients require considerable time for education, encouragement and troubleshooting and time invested in the early stages of treatment is well worthwhile. After initial supply, it is good practice to make contact with the patient, either in person or by telephone, within 2-4 weeks, at which point many potential problems can be identified and resolved. In most patients who benefit from CPAP treatment this is obvious within days of starting treatment. Once effective treatment is established many departments operate a policy of annual review when the machine is checked for safety and efficacy, replacement consumables supplied and any further complications One significant advantage which CPAP has over pharmaceutical therapies, is the facility objectively to monitor compliance by calculating the average hours of nocturnal use. Discrepancies between measured hours of use and the patient's perception of use may be identified; an apparent lack of effectiveness is often due simply to insufficient use. It should, however, be noted that the minimum number of hours per night required to control symptoms is not known and it is likely that this varies considerably between individuals.

In my opinion, a good CPAP service involves much more than occasional out patient review, as replacements are often required when masks break, tubes develop holes or machines fail. Our Lung Function Department offers open access for unscheduled phone calls or visits during normal working hours. Because we serve a large geographical area, it is also frequently necessary to mail spares to patients after contact by phone. The precise designation of the health professionals operating a CPAP service (eg whether nursing, technical etc) is much less important than their level of practical experience with the considerable range of equipment and associated consumables now available.

The role of auto-setting as opposed to fixed pressure CPAP machines for long term use is somewhat uncertain. In my experience, the great majority of patients manage perfectly well with a fixed pressure device. An auto-setting device may have advantages in a few patients, particularly those in whom higher pressures are required, but, equally, there are some who find that the variation in pressure itself disturbs their sleep.

Literature on CPAP

A key publication which has influenced commissioners' attitudes to CPAP treatment was that by Wright et al (BMJ 1997). This review appropriately highlighted the lack of randomised controlled trials up to that point. However it also cast serious doubt on the value of CPAP and, indeed, on the reality of OSAS as a clinical problem. The lack of RCTs has been amply corrected subsequently, with several studies showing very clear benefits. Unfortunately, the views expressed in the paper by Wright et al have continued to colour the policies of some health commissioners on OSAS and CPAP treatment. In my view this has performed a major disservice to many thousands of patients with disabling symptoms.

While it is now established that there is an independent association between OSAS and hypertension and there is also clear evidence that effective treatment with CPAP

reduces blood pressure, the indication for treatment of OSAS remains the control of symptoms. It is unrealistic to expect this form of treatment to be accepted unless there is clear perception of symptomatic benefit.

Current availability of CPAP

In my opinion, CPAP should be available via the NHS to all patients with symptomatic OSAS in whom it can be demonstrated to produce benefit. In the region where I work the provision of CPAP has not been a major issue and all the patients I have treated have been provided with CPAP and related equipment, spares, replacements etc via the NHS, although at times this has involved tedious negotiations and needless delays. I am however, aware from surveys conducted by the British Thoracic Society and others that the pattern of CPAP provision by the NHS is very variable across the country with some commissioners still refusing to fund any CPAP treatment and others restricting the number of units supplied per annum or declining to pay for consumables.

Translation of published evidence to the individual patient

Published studies clearly show the dramatic benefits of CPAP in terms of improved daytime functioning and quality of life. In clinical practice, however, the decision whether or not to treat an individual on a long term basis is always a mutual one between the patient and clinician and usually is decided after a short trial period Although a relatively crude method of assessing daytime sleepiness, the Epworth Sleepiness Score (ESS) is very useful in practice. There are however, a minority of patients in whom the ESS does not adequately reflect the main symptoms. For example some patients may have serious disruption of nocturnal sleep and feel very sleepy without actually falling asleep (therefore scoring low on the ESS), others may complain more of fatigue than sleepiness and the almost universal symptom in OSAS of feeling unrefreshed after sleep is not reflected in the ESS. On the other hand, there are also individuals with documented sleep disordered breathing and the daytime symptoms which would be expected with OSAS, in whom these symptoms are due partly or completely to other factors, eg shift working, depression or treatment with strong analgesics or psychotropic agents. It is, therefore, essential to review the symptoms after a short period of treatment in order to make a clinical judgement on whether the consequences of OSAS are truly being treated. In published studies the ESS is used, very reasonably in selection of subjects and in grading the severity of sleepiness; not surprisingly, subjects scoring lower usually show less improvement. Nevertheless, in practice, there is a significant minority of individuals with a "normal" ESS in whom CPAP improves wellbeing. Not infrequently, patients only appreciate after starting CPAP how symptomatic they had been before treatment. In my view, the ESS, while very useful, is not a sufficiently robust measurement for an arbitrary cut off level to be used as the sole criterion when determining whether or not a trial of CPAP should be offered to an individual with documented sleep disordered breathing. One advantage of adopting a short term trial of treatment before deciding on long term use is, of course, that if unsuccessful, the machine can be reclaimed and issued to another patient.