Sleep, 16:S120–S123
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Feasibility of a Self-Setting CPAP Machine*

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This paper presents the results of a preliminary study testing a self-setting continuous positive airway pressure (CPAP) machine. The device adjusts CPAP pressure on a minute-by-minute basis according to the degree of upper airway obstruction. This has several advantages. First, it would aid compliance by allowing a minimal awake pressure, and reduce pressure-related side effects by presenting a lower mean pressure. Second, by sensing the degree of partial obstruction, it would adjust to changing upper airway resistance produced by changing sleep state, posture, degree of nasal congestion, blood alcohol level, hormone status and sleep deprivation. This would improve on, and possibly do away with, the one-size-fits-all pressure determination night. Finally, by constantly recording respiratory parameters to memory, it would document long-term compliance and efficacy, aiding long-term management.

ALGORITHM

The device measures mask pressure, respiratory airflow and snoring sounds. From these raw measurements, it detects a hierarchy of progressively more sensitive indices of upper airway obstruction: apnea, snoring and silent inspiratory flow limitation. The pressure is then increased or decreased breath by breath, as appropriate.

The newest measurement (Fig. 1) is the index of silent inspiratory flow limitation, based on the shape of the inspiratory flow-time curve. On the horizontal axis is time, as a fraction of inspiratory duration, and on the vertical axis is inspiratory flow rate, scaled to produce unit tidal volume.

The solid curve represents a normal breath (the mean of several hundred breaths on a normal subject, awake and supine) and the dotted curve represents the shape of a partially obstructed breath, showing flow limitation over the middle half. Some degree of flow limitation is present in normal subjects during sleep.

A heuristic index of the degree of flow limitation is then derived from the shape of the inspiratory flow-time curve. Figure 2 shows this index, breath by breath, in one subject with obstructive sleep apnea (OSA) in stable slow wave sleep, plotted against CPAP pressure. The flow limitation index decreases towards zero as the CPAP pressure is manually increased. In normal operation, the self-setting algorithm increases CPAP pressure until the flow limitation index is in the normal range.

CLINICAL TRIAL

Twenty patients were chosen on the basis of repetitive desaturations to at least 80% SaO_2 on their diagnostic study. Pickwickians and patients with predominantly central apneas were excluded.

The first 12 patients (Fig. 3) had been on long-term CPAP prior to the study, and the solid circles show their conventionally determined CPAP pressure. The remaining eight patients had never had CPAP before and were severely sleep fragmented.

In six patients, there was an intermittent valve-like expiratory leak through the lips of 0.3–1.5 l/second. This confused the auto-setting algorithm, resulting in over-prescription of CPAP. Pressing the lips together with a modified chin strap helped, but was unreliable, and the patient would have been over-treated if sent home on the device.

In the remaining 14 patients, the device prescribed varying pressures throughout the night. The boxes show the 90% range and the horizontal lines the mean pressures. In the nine of 12 patients on long-term conventional therapy without mouth leaks, the mean pressure was much lower than the conventional pressure.

Figure 4 shows the number of obstructive apneas and hypopneas per hour, on the diagnostic study, and on the auto-setting study, in nonrapid eye movement (NREM) and rapid eye movement (REM) sleep. (This figure includes data on patients with severe leaks, in whom it was possible to continue by occasionally reducing the pressure manually.) In all but one patient,

* Presented at the Satellite Meeting of the 3rd International Symposium on Sleep and Breathing, Cairns, 1992.

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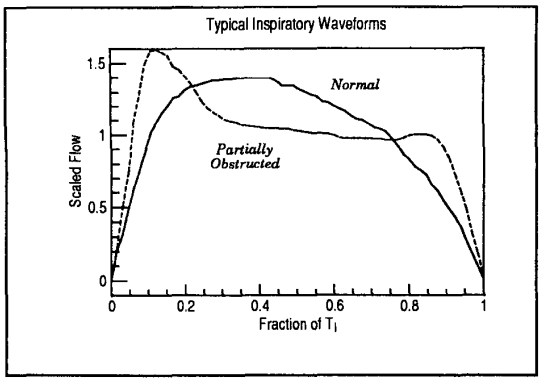

Fig. 1. Typical inspiratory waveforms. A partially obstructed breath shows flow limitation over the middle half.

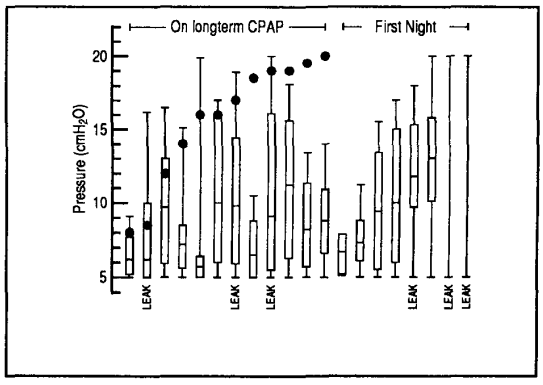

Fig. 3. Auto-setting pressures in first 20 patients. Range, 90% range and mean. Solid circles: prior conventional CPAP pressure. LEAK: severe mouth leaks interfered with auto-setting.

obstructive events were in the normal range of <5 per hour. The one exceptional subject was very fragmented pre-treatment.

SUMMARY

Auto-setting over-prescribed in six of 20 patients due to severe mouth leak. Mouth leak during CPAP has not previously been quantified, and these results, with leaks of 0.3–1.5 l/second, suggest a mechanism for the dry mouth and nasal symptoms commonly observed with CPAP.

Obstructive events were reduced to the normal range in 19 of 20 patients and acceptably reduced in the 20th patient.

In the nine nonleakers, mean CPAP pressure was reduced to 54% of the traditionally prescribed pressure.

These preliminary results suggest that a self-setting CPAP machine, based on subtle indices of partial obstruction, is practicable in patients without severe mouth leaks.

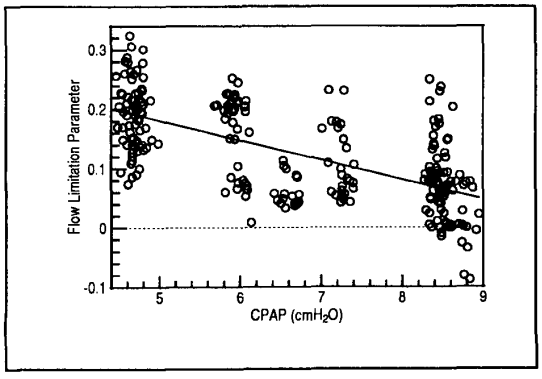

Fig. 2. Index of flow limitation decreases as CPAP pressure is manually increased. Each circle represents one breath.

DISCUSSION OF THE ARTICLE

C. Zwillich: Michael, can I ask you what you think is the most sensitive means of determining whether the system is working? I am a little concerned about using apneas or hypopneas because you may be measuring those using the device and there could be an error in the system. What about using arousals or something

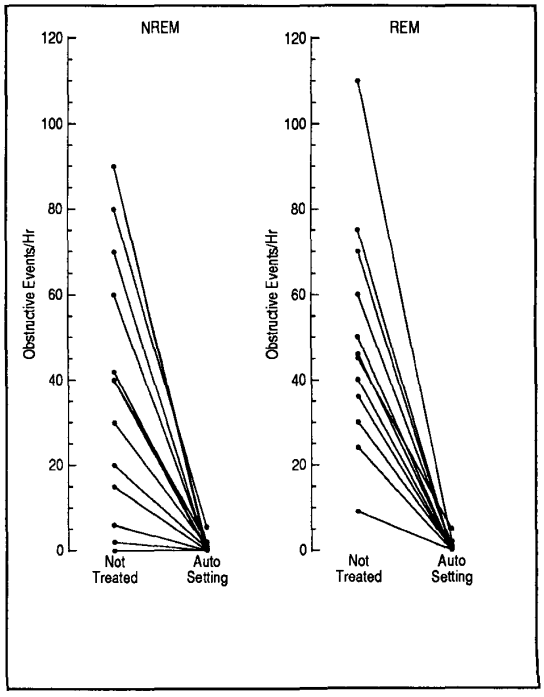

Fig. 4. Number of obstructive events (apneas and hypopneas) per hour was reduced to the normal range (5/hour) in all but one subject, in both nonrapid and rapid eye movement sleep.

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that is independent to the system to determine if the system is working well?

M. Berthon-Jones: The current plan—we have just barely commenced a double blind cross-over study in which the patients will be sent home for a couple of months with the device switched either to conventional mode or to self-setting mode. The patients will keep a diary of things like how sleepy they are, whether they are waking up refreshed. The device itself will record events and as well as that they will be brought back for a review study with all-night polysomnography in which we will measure arousals, desaturations. I agree that the device can't be used to test how well the device is working, so we will be reviewing them in the lab.

D. Rapoport: I had a question about the implications. First, I guess I should make a comment. I think that the day of this type of approach to CPAP is clearly around the corner and I have to compliment you (as we did 10 years ago Colin) for being involved in it yourself a few months ahead of the rest of us. I think there are a certain number of similar approaches that will bear fruit in the very near future. I did have a question about data you didn't present. You are still presenting the final pressure in terms of a single CPAP prescription, and clearly this device goes completely counter to that.

M. Berthon-Jones: If I gave that impression I apologize terribly. The whole point of that graph was that there is no magic number. It's different if you are on your back. It's different if you are on your side. It's different if your nose is blocked. It's different if you are in REM. It's different if you are in non-REM. It's probably different if you have had alcohol. There is no one pressure, and I certainly want to say that we should abandon the idea of a single one-pressure-fits-all determination. In particular, there is one patient in that group who had a dramatically lower pressure both high and low on the self-setting device than the one pressure measured in the lab.

C. Guilleminault: Did you try to use the chin strap to avoid the leak? I know that in our own experience with a similar type of device it worked probably no more than 60 percent of the time and we don't know what to do any more.

M. Berthon-Jones: We used a super chin strap to reasonable effect, a chin strap that was more like a lip sealer. The chin strap came up and pressed the bottom lip against the top lip. This seemed to work particularly well in obese patients, but it was not reliable and didn't work in everybody.

M. Sanders: In Pittsburgh, we sort of can keep the mandible opposed to the maxilla, but the absence of teeth really presents a problem. The spaces just let the air right through. But what we have done is we have been using a full face mask for a number of years now and have accumulated well over 50 people. We have talked about this before at previous meetings. These work real well and people are frequently more comfortable with them. They have got their option of presumably whether they can breathe through their mouth or their nose. We are engaged in other studies looking at that right now so a full face mask of one variety or another is also an option.

C. Zwillich: Michael, how many of these leak problems are solved by the full face mask?

M. Berthon-Jones: It depends on how well you make the full face mask seal to the face.

D. Millhorn: I wish that I was far enough along to present data like this, but I think there are two very important things. First of all, the question that was asked earlier, I think, deserves some commentary about using something like arousal. I think you asked it, Cliff. The whole concept here is not to have something you use in the laboratory, but something which continues to work and which has no other connection than that which we have already found to be somewhat limited by your own data in the home. You want something that is nothing more than the mask. You don't want an oximeter. You don't want EEG leads. You really want something which is going to work off of what is already there or preferably even less than what is already there.

M. Berthon-Jones: Thank you for mentioning that because our device, in fact, is totally noninvasive.

D. Millhorn: That's clear. I was just responding to the question that was asked earlier to emphasize that. That's clearly what has to be done. The other point is that I don't think we should judge the approach by the success of one algorithm or another because very clearly a 60 percent failure rate or a 40 percent failure rate is going to be a big problem if you try to implement it. But the concept of finding something which will respond to the patient's requirement for CPAP instead of basing one night and then treating the patient for the next 10 years with that pressure is what we are talking about here. I think that these devices are going to illustrate how different it is. Those of us who have been doing some mini version of what Dr. Miles presented looking throughout the night are already aware that in the first part of the night and the latter part of

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the night you may get different optimal pressures, and if you restudy your patients you may see that. We are all aware that there is a need for a changing setting, and these devices may give us information of what parameters it is that contribute to the disease also.

M. Kryger: Why is there necessarily a need for changing pressures if a pressure already works, or are we having technology drive? What we are doing?

M. Berthon-Jones: I think the first answer is that patients feel uncomfortable at high CPAP pressures. If the patient only needs 5 centimeters of water pressure, then making it 4.5 isn't going to achieve anything; but if they need 20 centimeters of water on their back in REM after three schooners of beer, then they are not going to notice that 20 centimeters of water while they are deeply unconscious but they are going to object violently to it while they are wide awake trying to go to sleep on an ordinary night. Another possible thing which I probably shouldn't mention is that it may be possible ultimately to do away with the pressure determination night altogether so that the cost of the extra technology is absorbed by the saving of hospital beds. I don't want to push that argument.

C. Zwillich: The way I understand that, Michael, is that on the one hand you may come up with a more lower pressure which will be more comfortable for the patient, particularly when they are awake, which may result in a higher compliance and better CPAP therapy than may result from a very high pressure being set in the lab which is too high and is objectionable; or even a very low pressure set in the lab because the person hasn't been drinking, but a higher pressure is necessitated by his usual lifestyle which happens to be moderate to heavy alcohol use and a smart CPAP instrument would negate or it would decrease the problem of an insufficiently treated patient who looked beautiful during a polysomnographic pressure determination which resulted in a pressure of eight but in actuality that person needed 14 because it's always 100 milligrams percent on board because of his alcohol consumption.

C. Guilleminault: There was a study done in Europe when I was on sabbatical where the patients were monitored nearly every night and recalibrated. I believe that some of the reports indicating that nasal CPAP doesn't improve the MSLT can be very easily explained by what happened and what we are talking about right now. When you do your study, if you count micro-arousal you are going to see that your patients on nasal CPAP are going to have much more micro-arousals one night and much less on another night. Then if you recalibrate and do that on a regular basis, you see that when you have a lot of micro-arousal it's because that night the nasal CPAP was not adjusted. Pressures can be too high or too low. The too low settings usually are also associated with complete awakening for one minute or two, and at too high pressures it's the micro-arousals which really disturb sleep.

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