Treatment Adherence and Outcomes in Flexible versus Standard Continuous Positive Airway Pressure

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Introduction

Background
- Obstructive sleep apnea (OSA) is associated with neuropsychological and cardiovascular sequelae.
- Continuous Positive Airway Pressure (CPAP) improves daytime functioning, quality of life and blood pressure.
- Despite its reported efficacy, nightly adherence to CPAP is suboptimal.
- Technological advances in airflow delivery such as Auto-titrating CPAP and Bi-level airway pressure devices aim to improve patient adherence, comfort, and effectiveness for reducing inspiratory flow limitation.
- These advances have been variably effective for improving treatment adherence compared to CPAP.
- C-Flex™ is a recent technologic advance in which airway pressure is reduced during early exhalation and then increased at end-exhalation on a breath-by-breath basis (Fig. 1).
- In theory C-Flex™ is associated with similar efficacy but increased comfort during exhalation and may improve adherence compared to conventional CPAP.

Objective
- To compare C-Flex™ and traditional CPAP on adherence, treatment outcomes and attitudes toward treatment of OSA.

Methods

Study Population/Procedures
- 89 participants (64 men 24 women, ages 25-80 yrs) with OSA were recruited prior to starting CPAP.
- OSA was diagnosed by full in-lab overnight polysomnography and adequate CPAP settings, (defined by the absence of apneas/hypopneas and snoring), were determined on a separate full night titration study.
- All participants were referred to the same home healthcare company.
- All CPAP devices (REMstar® Pro) were equipped with objective monitors of CPAP use and heated humidification.
- Participants enrolled 4/2002-4/2003 (n = 41) received conventional CPAP machines; those from 4/2003 –3/2004 (n = 48) received CPAP machines with C-Flex™ technology.

Measurements

Adherence
- Monitored with SmartCard™ technology.
- Reported as the total number of hours used at the prescribed pressure per 24-hour period.
- Data are collected at week 1, week 2-4, week 6-8 and week 9-12 after starting on CPAP or C-Flex.

PSG Variables
- Apnea- hypopnea index
- Time spent below SaO2 of 90% (min.)

Treatment Outcomes
- Epworth Sleepiness Scale
- Functional Outcomes of Sleep Questionnaire (FOSQ)
- Self-Efficacy Scale - Measures patient’s confidence about his/her ability to use CPAP even under difficult circumstances (a higher score indicates greater confidence for use).

Analysis
- Adherence data and clinical outcomes for the CPAP vs C-Flex groups were compared over time with a repeated measures ANOVA and Bonferroni post-hoc test.
- Spearman rank correlation to examine predictive utility of self-efficacy on adherence.

Results

• Groups were not different on demographic or severity measures.
- Adherence over the 3 month follow up was higher in the C-Flex™ compared to the CPAP group (2-4 weeks: 4.2 ± 2.4 vs 3.5 ± 2.8 hours and at 9-12 weeks: 4.8 ± 2.4 vs 3.1 ± 2.8, p 0.003). Self-efficacy scores trended higher at follow-up in those treated with C-Flex™ compared to CPAP.

Demographics & OSA Severity

<table>
<thead>
<tr>
<th>Variable</th>
<th>CPAP</th>
<th>C-Flex™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>51.4 (10.8)</td>
<td>53.7 (11.0)</td>
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<tr>
<td>Education (hours)</td>
<td>14.4 (2.4)</td>
<td>14.7 (3.4)</td>
</tr>
<tr>
<td>AHI (events/h)</td>
<td>39.4 (25.9)</td>
<td>43.2 (22.7)</td>
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<tr>
<td>SA90 (%)</td>
<td>79.3 (99.2)</td>
<td>60.4 (79.6)</td>
</tr>
<tr>
<td>CPAP Pressure (cmH2O)</td>
<td>9.8 (2.9)</td>
<td>10.1 (2.0)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>31.7 (5.2)</td>
<td>32.0 (3.7)</td>
</tr>
<tr>
<td>Epworth (/24)</td>
<td>11.2 (4.8)</td>
<td>10.7 (4.7)</td>
</tr>
</tbody>
</table>

Self-efficacy (/25) 19.9 (3.3) 20.4 (3.1)

| Outcome Measures for the Groups |

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>3 month</th>
<th>Baseline</th>
<th>3 month</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epworth</td>
<td>11.2 (4.8)</td>
<td>9.4 (4.6)</td>
<td>10.7 (4.7)</td>
<td>8.3 (3.9)</td>
<td>0.56</td>
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<tr>
<td>FOSQ Total</td>
<td>9.9 (2.8)</td>
<td>8.0 (2.0)</td>
<td>9.6 (2.7)</td>
<td>7.7 (2.2)</td>
<td>0.99</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>19.9 (3.3)</td>
<td>19.6 (5.4)</td>
<td>20.4 (3.1)</td>
<td>21.9 (3.4)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

* p value for the change over time of variables by group

Figure 1. Raw Data from 1 subject: CPAP vs C-Flex

Conclusions

• C-Flex™ may improve overall adherence over three months compared to standard CPAP.
• Clinical outcomes do not improve consistently, but C-Flex™ users may be more confident about their ability to adhere to treatment.
• Randomized clinical trials are needed to replicate these findings.

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