Pulse Oximeter that Diagnoses Sleep Apnea

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The Problem

Obstructive sleep apnea is estimated to affect about 4% of men and 2% of women. It is probably more common than either of these numbers because the population is becoming more obese, and obesity worsens obstructive sleep apnea. More shocking is the estimate that only 10% of people with obstructive sleep apnea are currently receiving treatment and many patients with sleep apnea remain undiagnosed.

Diagnosis of apnea requires spending a night in a sleep clinic, which many people have neither the time nor the desire to do. In the sleep clinic, several monitoring devices are attached to the patient, and a sleep doctor uses their recordings to determine a “apnea-hypopnea index” (AHI) – a single digit number used to scale severity of apnea. Reimbursement for treatment depends on the AHI.

Additionally, in transportation industries, where operator wakefulness is essential, screening for sleep disorders is expensive and inconvenient.

Solution

Pulse oximeters (those devices clipped to your finger in the hospital, that measure your pulse, and also how much oxygen is in your blood) are commodity medical devices, that range from low-end consumer devices, to more sophisticated devices used in hospitals.

Using data gathered from ~1500 patients who spent the night in the sleep clinic, the inventors developed an algorithm to convert a night’s pulse oximeter recordings into an AHI measurement. They then validated the algorithm in 750 patients.

Markets

The market for pulse oximeters was ~$300M in 2013. The market is highly competitive, especially among high-end pulse oximeter manufacturers. Patent litigation is not infrequent as they fight to obtain and maintain market edges on one another. Incorporating the algorithm into a pulse oximeter would be a differentiator, and an opportunity to dramatically expand the market for these devices, and for apnea treatment, by diagnosing the approximately 90% of apnea patients who remain undiagnosed.

<table>
<thead>
<tr>
<th>AHI of ≥5/hr.</th>
<th>Sensitivity% (CI)</th>
<th>Specificity% (CI)</th>
<th>PPV% (CI)</th>
<th>NPV% (CI)</th>
<th>Accuracy% (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>95 (94-97)</td>
<td>77 (72-82)</td>
<td>88 (85-90)</td>
<td>91 (87-95)</td>
<td>89 (86-91)</td>
<td></td>
</tr>
<tr>
<td>AHI of ≥10/hr.</td>
<td>88 (85-92)</td>
<td>91 (88-94)</td>
<td>88 (84-92)</td>
<td>91 (89-94)</td>
<td>90 (88-92)</td>
</tr>
<tr>
<td>AHI of ≥15/hr.</td>
<td>82 (77-87)</td>
<td>95 (94-97)</td>
<td>89 (85-93)</td>
<td>92 (90-94)</td>
<td>91 (89-93)</td>
</tr>
<tr>
<td>AHI of ≥30/hr.</td>
<td>73 (65-82)</td>
<td>98 (97-99)</td>
<td>88 (81-94)</td>
<td>96 (94-97)</td>
<td>95 (93-96)</td>
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Stratified results for the Pred AHI algorithm

PPV=positive predictive value, NPV=negative predictive value, CI=95% confidence interval

Contact

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