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Peer-Reviewed Published Study Validates WristOx[®] 3100 Ease of Use and Diagnostic Accuracy in Predicting Sleep Apnea/Hypopnea Syndrome (SAHS)

Study:

Validation of the WristOx 3100[™] oximeter for the diagnosis of sleep apnea/hypopnea syndrome

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Study Background:

Carlos Alberto Nigro is staff Pulmonary Physician and Coordinator of the Sleep Laboratory in Buenos Aires, Argentina with multiple peer-reviewed journal articles to his credit. This study was conducted and published independent of Nonin Medical, Inc.

The study's objective was to evaluate the diagnostic accuracy of the WristOx[®] and nVISION[®] software in patients suspected to have sleep apnea/hypopnea syndrome (SAHS). The motivation for the study was to identify a SAHS screening method which was less costly and more accessible than Polysomnography (PSG). After evaluating four other brands of oximetry equipment that were stated as "sparsely portables..." [large and bulky], the investigators settled specifically on WristOx and nVISION software for suitability for use in the home due to lightweight design and ability to be worn comfortably on the wrist.

Study Design Overview:

- Prospective, simultaneous comparison of WristOx and PSG.
- Recruitment: n=168 adult patients selected with suspicion of SAHS. Patients were excluded if they already used CPAP or some form of noninvasive mechanical respiratory assistance.
- Experienced medical staff manually performed the PSG readings, and the operator analyzing the oximetry with nVISION was blind to the devices being read.
- Outcomes assessed:
 - Mean adjusted desaturations per hour—number of events more than 2% and more than 3%.
 - Accumulated time below 90% SpO₂.
 - Number of apneas and hypopneas per hour of sleep through PSG.

Conclusions and Implications:

- Ability to identify SAHS independent of PSG: Results demonstrate the ease and reliability of the WristOx oximetry tool for a high likelihood of getting a good reading the first time—92% (n=154) of participants were included in the study with 4% removed due to a poor PSG signal independent of oximetry readings.
- Consistency and reliability: Unlike the limited availability, high cost and technical expertise required of PSGs, which is causing bottlenecks in the healthcare system, the WristOx was cited in the study as “*simple, cheap, portable and validated technology.*” that proves to be an alternative to placing all patients on the waiting list for PSG. The nVISION software automated the process in data interpretation, eliminating the requirement of trained specialists to review and interpret data.
- Better patient care: The study cited internationally that wait time for patients to have PSG performed can range from 2-60 months. WristOx can provide a valuable screening or decision tool to triage patients and get high risk patients in for PSG validation of SAHS. In this particular study, 40% of the PSGs could have been redirected toward patients with a high likelihood of SAHS for more rapid confirmation and overall cost savings.
- Overall findings were that the WristOx was highly sensitive in correctly identifying the vast majority of SAHS, allowing for better patient care and earlier intervention. Additionally, 40% of PSGs could have been prevented with 30 cases that could have quickly been excluded without PSG and 31 cases that clearly showed need for CPAP.

Discussion Points:

- Overnight pre-screening studies with the WristOx and nVISION software can get the highest risk patient population with suspected SAHS into PSG faster to confirm and begin treatment.
- This is a great proof source and demonstration of applications for effective use of the WristOx device and nVISION software along with the high reliability of results.

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