USING TECHNOLOGY TO IMPROVE OUTCOMES IN SLEEP DISORDERED BREATHING

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Saturday, January 19, 2019 – 10:40 a.m. – 11:10 a.m.

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Conflict of Interest Statement

I do not have any relationships with any entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Due to the nature of the talk, commercial products are discussed; no endorsement is made.
Learning Objectives

- Review outcomes-related data with respect to use of technologies to enhance the treatment of sleep disordered breathing
- Review delivery models combining telemonitoring and telemedicine
- A look towards the future of consumer facing devices

The Landscape

- Sleep medicine is a poster child for dramatic change in models of care delivery and technology
- In recent years, home sleep testing has replaced a portion of laboratory sleep studies for the diagnosis of obstructive sleep apnea
- Consumer wearables and trackers, mobile applications, and health interfaces abound
- Remote device monitoring has advanced and is widely available on newer and a broader range of devices
Opportunities

- **New Treatments**
  - Devices more adaptive than in the past
  - NIPPV for complicated or advanced respiratory disorders exist – patients with higher risk profile
  - Use of such devices often requires more proactive, nimble management
    - Patients highly reliant on devices
    - More rapid disease state change
- **New superhighways of patient-derived data**
  - Patient assessments and HST data can be remotely and securely scored and routed
  - Advent of usage data on cloud-based portals augments ability to manage patients remotely
    - Preset triggers to detect who might be struggling
    - Not just for CPAP/ BL; ST, IVAPS, AVAPS, Trilogy, Astral available
  - Websites & mobile applications to increased patient-facing information, tracking, and engagement
- **New models of sleep center proximity, access**
  - Remote in-home testing
  - Increasing use of telehealth platforms, remote provider access, etc
  - Value based alternative payment models

Approach

- Remote Data collection/ telemonitoring
- Telehealth/ Telemedicine: principles & data
- Diagnostics and tracking: Consumer health vs medical tool?

Remote PAP Monitoring: “The Cloud”

Industry-Sponsored Portals

- Latest devices have wireless access to remote device data
- Most of the data available from a traditional “download” in clinic:
  - Hours of usage
  - Device-calculated proxies of AHl, leak, ventilation measures, patient-triggered breaths
  - In some scenarios, breath-to-breath data, leak, and event scoring
- Caution: different manufacturers detect and report differently
  - Stay tuned for sessions at 1:40 and 2:20 today!
- Patients can have access to some/most of this data via smartphone apps or websites
- Also potential for alerts to patient or clinician if problems detected
- Independent outcomes data demonstrating consistent benefits of using patient-facing informatics on adherence to therapy largely absent until recently; also assessed by industry
Industry-Sponsored Portals

- Resmed: AirView (web-based; for provider); MyAir (patient; web-based and/or mobile)
- Phillips Respironics: EncoreEverywhere (web-based; for provider; transitioning to CareOrchestrator); DreamMapper (patient; web-based and/or mobile)
- Fisher and Paykel: Infosmart Web (web-based)
Sleepyhead

- https://sleepyhead.jedi mark.net
- freeware enables review of data on SD cards
- flow, pressure, leak, inspiratory and expiratory times, and mean and median of respiratory rate, tidal volume, and minute ventilation


Early studies of remote PAP monitoring: depends what happens with the data...

The impact of telemonitoring on CPAP adherence is dependent on pre-existing ‘usual care’ in the control arm as well as what type of intervention is employed based on telemimonitored data

Remote PAP monitoring: What happens next?

- Early detection of problems
- Facilitation of appropriate interventions
- Improve early experience

Empowering PAP adherence through *patient-facing* telemonitoring data (website access to CPAP usage data)

Kuna et al. Web-Based Access to Positive Airway Pressure Usage with or without an Initial Financial Incentive Improves Treatment Use in Patients with Obstructive Sleep. Sleep. 2015;38(8):1229-1236.
Improved adherence when given access to website-based PAP usage data

Table 2—Positive airway pressure device data in first week and 3-mo treatment period.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Usual Care (n = 52)</th>
<th>Web Access (n = 45)</th>
<th>Web Access with Fl (n = 39)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>First week results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average days used</td>
<td>5.5 ± 2.6</td>
<td>6.7 ± 0.8</td>
<td>6.6 ± 1.3</td>
</tr>
<tr>
<td>Average daily h of use</td>
<td>4.7 ± 3.3</td>
<td>6.3 ± 2.5</td>
<td>5.9 ± 2.5</td>
</tr>
<tr>
<td>Average daily h of use on days used</td>
<td>6.0 ± 2.4</td>
<td>6.6 ± 2.2</td>
<td>6.3 ± 2.0</td>
</tr>
<tr>
<td>Average AHImax (events/h)</td>
<td>3.6 ± 3.8</td>
<td>4.7 ± 4.8</td>
<td>3.8 ± 3.7</td>
</tr>
<tr>
<td>Average air leak (LPM)</td>
<td>36.8 ± 22.7</td>
<td>34.6 ± 11.3</td>
<td>34.3 ± 13.6</td>
</tr>
<tr>
<td>3-mo results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average days used</td>
<td>4.7 ± 2.96</td>
<td>5.6 ± 2.3</td>
<td>5.6 ± 2.3</td>
</tr>
<tr>
<td>Average daily h of use</td>
<td>3.8 ± 3.3</td>
<td>5.0 ± 3.2</td>
<td>4.8 ± 3.0</td>
</tr>
<tr>
<td>Average daily h of use on days used</td>
<td>5.6 ± 2.4</td>
<td>6.2 ± 2.3</td>
<td>5.9 ± 2.0</td>
</tr>
<tr>
<td>Average AHImax (events/h)</td>
<td>3.2 ± 3.7</td>
<td>3.4 ± 4.3</td>
<td>2.9 ± 3.3</td>
</tr>
<tr>
<td>Average air leak (LPM)</td>
<td>39.0 ± 26.1</td>
<td>33.1 ± 13.0</td>
<td>35.3 ± 19.8</td>
</tr>
</tbody>
</table>

P values compare estimated means from each intervention group (Web access and Web access with financial incentive) to usual care via a generalized linear model. AHI, apnea-hypopnea index; Fl, financial incentive; LPM, liters per minute; SD, standard deviation.

Kuna et al. Web-Based Access to Positive Airway Pressure Usage with or without an Initial Financial Incentive Improves Treatment Use in Patients with Obstructive Sleep Apnea. Sleep. 2015;38(8):1229-1236.
Pairing Telemonitoring and Telemedicine

Telemedicine

- “Delivery of health care services at a distance”, using information and communication technology.
  - **Telehealth**: Electronic exchange of medical information to improve a patient’s health status. Broader concept than telemedicine.
  - **Telemedicine**: A legal patient/clinician encounter using electronic communication.
- Major rationales for introduction: decreased costs, improved efficiency; increased access in health care delivery; potential for improved outcomes
- Sleep-specific rationales:
  - Increased opportunities to increase adherence rates in sleep disorder treatment management;
  - OSA – HST; PAP data downloads and feedback
  - Evaluation of home environment - assessing sleep dysfunction such as equipment problems, aspects of poor sleep hygiene, lighting, etc.
Sample Telemedicine Workflow for OSA Patients

Consultation can be Traditional or via Telemedicine
+ Symptoms
+ Findings
+ Consistent decision-making in accordance with clinical practice guidelines

Diagnostic Testing at Home or In-lab
+ HSAT
+ PSG/Split night
+ Use of Auto-PAP

Follow-up can be Traditional or via Telemedicine
+ Result review
+ Device downloads
+ Management

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Majority of Sleep Patients Willing to Try Telemedicine

Acceptance using Telemedicine Platforms for OSA Management


Equivalent PAP Adherence Using Telemedicine Platforms

Feasibility and Acceptance

- Prospective, parallel-group randomized pilot study
- Assessed feasibility of telemedicine for OSA evaluation and management vs. traditional, in-person care
- 60 Veterans at 3 affiliated VA locations
- Video vs in-person visit; HST; APAP; phone follow up at 1w; phone (w download) vs. in-person at 1m, and 3m
- PAP adherence NS between groups
- ESS improvement NS between groups
- TM highly accepted in this population


Access

- Single-hospital VA study found telemedicine resulted in an average travel savings of 145 miles and 142 minutes per visit;
- Patients to take less time off from work, associated with high levels of patient satisfaction

REVAMP Trial

- VA-sponsored trial, n=350 participants
- Randomized, open label
- Access to interactive website Veterans complete intake and follow-up questionnaires
- Unattended home sleep test (HST) without in-person instructions.
- Sleep specialists review the findings with the patient during an initial phone clinic.
- REVAMP auto-populates templated progress notes that are exported to EMR
- Veterans diagnosed with OSA are treated with APAP
- Telemonitoring data available to both Veterans and practitioners, thereby promoting patient self-management and productive patient-practitioner interactions.
- End point is non-inferior care; also measures of access; wait times.

clinicaltrials.gov; ClinicalTrials.gov Identifier: NCT03007745

Home sleep testing; Built-in alerts for sleep tests; Sleep health questionnaires
Submit requests for PAP supplies; Sleep tracking graphs; Send and receive secure messages with your sleep care team
Telemonitoring and Telemedicine in OSA:
Patient-Facing App

- Retrospective study funded by Resmed
- Patients initiated PAP therapy between 2009-2014
- Managed either using telemedicine (AirView™; “proactive care” group) or telemedicine + patient engagement app (AirView™ + myAir™, “patient engagement”)
- Proactive care: homecare provider telephoned patients if compliance during the first 2 weeks of PAP therapy fell below the required level (<4 h/day).
  - 2 weeks - 6 months: patients were telephoned again if continued periods of no or low usage were identified from telemonitoring data.
  - 6 months+: patients were notified via telephone call or letter if telemonitoring data showed that PAP device usage dropped significantly or did not reach the required threshold (average of 4 h/night).
  - When contacted, patients were provided with detailed information on use of their PAP therapy device and management of side effects (eg, upper airway dryness, pressure, etc).

Data at 180 days of therapy

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Addition of Engagement Tool to Telemonitored, Proactive Care Led to Higher Device Usage

<table>
<thead>
<tr>
<th>Proactive care (n = 500)</th>
<th>Patient engagement (n = 500)</th>
<th>Difference</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of nights with usage &lt;4 h, %</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>63 ± 32</td>
<td>77 ± 25</td>
<td>14 ± 41</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>73 (55, 91)</td>
<td>87 (64, 97)</td>
<td></td>
</tr>
<tr>
<td>Average usage on nights used, hours/night</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>5.5 ± 1.7</td>
<td>6.2 ± 1.4</td>
<td>0.7 ± 2.2</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>5.8 (4.5, 6.7)</td>
<td>6.5 (5.4, 7.2)</td>
<td></td>
</tr>
<tr>
<td>Average usage over first 180 days, hours/night</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>4.2 ± 2.4</td>
<td>5.4 ± 1.9</td>
<td>1.2 ± 3.1</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>4.6 (2.2, 6.2)</td>
<td>5.8 (4.2, 6.8)</td>
<td></td>
</tr>
<tr>
<td>Proportion of nights used, %</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>79 ± 24</td>
<td>88 ± 17</td>
<td>9 ± 30</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>90 (68, 98)</td>
<td>96 (84, 99)</td>
<td></td>
</tr>
<tr>
<td>Number of nights with usage &gt;0</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>127 ± 55</td>
<td>151 ± 35</td>
<td>25 ± 66</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>152 (94, 172)</td>
<td>166 (139, 176)</td>
<td></td>
</tr>
<tr>
<td>Days without observation, n</td>
<td>Mean ± SD</td>
<td>Median (IQR)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Main ± SD</td>
<td>29 ± 35</td>
<td>20 ± 28</td>
<td>-9 ± 45</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>15 (4, 43)</td>
<td>8 (2, 28)</td>
<td></td>
</tr>
</tbody>
</table>

IQRI, interquartile range (25th and 75th percentile values); SD, standard deviation.


Telemonitoring and Telemedicine in OSA

- N = 1455, mean age 49 ± 12.5 years, RCT
  - 956 underwent HST
  - 556 prescribed CPAP
- 2 telemedicine interventions were tested:
  - Web-based OSA education (Tel-Ed)
  - PAP telemonitoring with automated patient feedback (Tel-TM)
- 4-arm randomized trial
  - Usual care
  - Tel-Ed
  - Tel-TM
  - Tel-Ed + Tel-TM


Table 3. CPAP Use and Subjective Outcomes 90 Days after CPAP Dispensation

Results

- Usage significantly higher in the Tel-TM and Tel-both groups versus usual care ($P = 0.0002$ for both) but not for Tel-Ed ($P = 0.10$).
- Telemedicine-based education did not improve CPAP adherence but did increase clinic attendance for OSA evaluation.
- CPAP telemonitoring with automated feedback messaging improved 90-day adherence in patients with OSA.
- The improvement was observed without requiring additional provider intervention.


Chronic Disease Management

![Graph showing adherence over time](image)
Patient-facing interventions alone?

Resmed Active Patient Engagement

- Retrospective; 128,037 pts analyzed
- APE = MyAir
- MyAir score, usage based praise, badges, etc
- Tips on making PAP more comfortable
- Personalized coaching and reinforcement sent via email
- Increase self management reward success, resolve basic issues
- Primary outcome: % compliance in first 90 days

Adherence: APE 87.3% vs UC 70.4%


DreamMapper

N ~ 173,000 pts

- PAP with DreamMapper vs not
- 90-day compliance 78% (vs 63%)
- Average usage 1.1 hours longer

Consumer health space and diagnostics?

Is the future of medicine a smartphone?

The Saturday Essay
The Future of Medicine Is in Your Smartphone: New tools are tilting health-care control from doctors to patients  By Eric J. Topol  Jan. 9, 2015
Advancement of Consumer-Facing Tools

- Use of smartphone to detect OSA for almost 15 years
- Ever-growing number of consumer devices in the sleep space
- Smartphones: fast processing, ability to monitor ambient light and noise, accelerometry, low cost oximetry probes (HR and O2 sat) – requires beat to beat processing


Ex: Smartphone applications to track sleep without external sensors

Like a sleep lab that fits in your pocket

SleepTune™ is the smallest wearable that can monitor how your breathing and position impact your sleep quality.

FDA-Listed Solution Supported By Leading Sleep Physicians

Wearable Sleep and Fitness Monitoring

Small, lightweight but packed with features

- OLED screen to track and analyze oxygen levels and sleep quality
- Vibrates when it detects a drop of oxygen saturation in the blood
- Two modes: sleep mode monitors (SpO2) level, heart rate and movement during sleep
- Panic mode monitors (SpO2) level, heart rate and counts steps during light exercise
- Customizable settings, alerts and vibration level
- Pair with devices via standalone app and Bluetooth
- Includes see-saw back-up sensor and cradle charging cable
- Rechargeable via USB and included cable
- Set tight and tuck it into – part 1 of 2

The SleepTune™ is flexible and has a heart sensor to track heart rate and movement, and a skin sensor to track skin temperature. The device is waterproof and can be used in the shower. It comes with a free mobile app that allows you to view your sleep data and trends over time. The app also provides insights on your sleep quality, including duration, sleep efficiency, and REM sleep. You can set alarms and goals for your sleep and receive notifications to help you achieve your sleep goals. The SleepTune™ is also compatible with Apple Health and Google Fit.
Clinical Use of a Home Sleep Apnea Test: An Updated American Academy of Sleep Medicine Position Statement


Maintains:
- Only a license practitioner can diagnose a medical condition
- HSTs should not be used for screening the asymptomatic
- Diagnosis should not be made solely on automatically scored HST; raw data must be reviewed by BC sleep MD

Integrating new tools into a Patient-Centered Approach

Summary

“It is ironic that the least complex and most healthy individuals get the maximum oversight – CPAP compliance is vigorously tracked in OSA patients, with a pathologically obsessive fixation on four hours of use per night regardless of severity, comorbid illnesses, or native sleep times, and the device “taken away” if adequate use is not demonstrable. Biological and clinical efficacies are nearly irrelevant. Patients in respiratory failure can obtain a bilevel ventilator with no polysomnographic data or long-term tracking requirements... In this day and age, our management should be data driven – clinical and device, of the highest quality and resolution, and dynamically tracked (over time). Blind assumptions of device efficacy raise the likelihood of harm. Once we try to manipulate respiratory drive and rhythm, adaptive and maladaptive outcomes are possible and readily recognizable, if the raw data are reviewed and analyzed.”


Thank you!