Are Portable Monitors Cost Effective?

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Finding a Home for Portable Monitor Testing in Sleep Apnea

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Outline

• What do we already know about the economics of OSA?
• How do we plan to add to this knowledge base with the trial: Cost-Effective Strategy to Evaluate Veterans with Sleep Apnea?

Cost of Undiagnosed Sleep Apnea

• Several studies have reported on the cost of undiagnosed obstructive sleep apnea
• Kapur et al.
  – Undiagnosed OSA may add $1,335 per year (1996 U.S dollars) in medical costs compared with age and gender matched controls
  – Nationally, it may cause $3.4 billion in additional medical costs
• Ronald et al.
  – Undiagnosed OSA may add as little as $427 per year (1985 through 1995 Canadian dollars) to physician claims and hospitalization cost
Potential Savings from Treatment of Sleep Apnea

- Several observational studies have attempted to estimate potential savings that may be result from treatment for OSA
  - Peker et al.
    - Treatment may reduce cardiovascular and pulmonary disease costs by $2800 per year (measured in Swedish Kroner, but expressed in U.S. dollars)
  - Bahamman et al.
    - Treatment may reduce physician claims and hospitalization cost by $655 (1990 through 1995 Canadian dollars)

Diagnosis

- A number of studies have reported on the cost-effectiveness of in-lab vs home diagnosis
  - Three of the studies used decision analysis (i.e., no direct observation; three used data from randomized trials or prospective cohort studies
  - Chervin et al.
    - Used decision analysis and reported that polysomnography is more costly and more effective than either home testing or empiric therapy
    - Found that polysomnography has acceptable point estimates for the ratio of the cost per quality-adjusted life year gained compared with home testing (13,400) and empiric therapy (9200)

Diagnosis (2)

- Reuveni et al.
  - Used decision analysis, and reported that the combination of polysomnography and attended partial monitoring is the most cost-effective approach to sleep evaluation
  - Reported that unattended home sleep monitoring was the most-expensive (because of the need for repeated sleep studies due to data loss and diagnostic disagreement)
Diagnosis (3)

- Golpe et al.
  - Within-subject comparison of in-lab versus either unattended or attended home diagnostic testing
  - Home testing with technician least expensive, followed by home testing without technician, and in-lab testing
  - Observed a 33% failure rate on unattended home testing

Immediate Home Testing vs Delayed In-Lab

- Pelletier-Fleury et al. reported that earlier diagnosis and treatment was cost-effective compared with waiting for in-lab diagnosis

Other Sleep-Therapy Related Questions

- Mar et al.
  - Compared with no treatment, nasal CPAP has an acceptable point estimate for the ratio of the cost per quality-adjusted life year gained (<6,000 Euros)
- Planès et al.
  - Home initiation of nasal CPAP produced significant improvements in sleep respiratory parameters that were similar to those produced with in-lab initiation
  - Initiation at home reached the final adjustment in significantly less time and for significantly less cost (savings of 355 Euros) than did in-lab initiation
Other Sleep-Therapy Related Questions (2)

• Ayas et al.
  – Used decision analysis and reported that continuous positive airway pressure therapy for moderate to severe OSA has a cost per quality-adjusted life year saved between $314 and $3354 per quality-adjusted year of life saved from the social and third party payer perspective, respectively.

• Tan et al.
  – In a replication study found that this therapy had a cost per QALY ratio of $3626 Canadian from the third party payer perspective.

Other Sleep-Therapy Related Questions (3)

• Guest et al.
  – Used decision analysis and reported that the cost per QALY ratio depended upon the length of projection.
    – For 1 year projection, ratio > £20,000; after 2 years, expected to be ~£10,000; after 13 years, less costly and more effective.

Do We Know What We Need to Know?

• Given the large number of studies, why hasn’t the question been satisfactorily answered?
  – Little to no direct observation of benefit; mainly decision analysis
  – Inputs needed for a modeling analysis are uncertain
  – When trials have been conducted, a large number of therapies that our intuition tells us should be good value haven’t turned out to be
Cost-Effective Strategy to Evaluate Veterans with Sleep Apnea

- Prospective randomized, clinical non-inferiority trial, consecutive patients referred to the sleep centers at the Philadelphia VAMC and VA Pittsburgh Health-care System for evaluation for OSA will be randomized to either exclusively in-lab (Group 1) or home (Group 2).

**Group 1 Algorithm**

- Participants randomized to in-lab testing will be scheduled for an in-lab polysomnogram.
- If the apnea-hypopnea index is greater than 20 events/hr on the first two hours of sleep, a split-night study will be performed.
- Subjects in whom the split-night polysomnogram establishes the diagnosis of OSA and determines an optimal fixed CPAP setting will be initiated on CPAP treatment.

**Group 1 Algorithm (cont.)**

- If no split-night study is performed, a full-night diagnostic polysomnogram will be performed.
- Those with an apnea-hypopnea index >15 events/hr will be scheduled for a full-night manual CPAP titration polysomnogram.
- Those with an index <15 events/hr will be scheduled for a follow-up appointment in sleep clinic.
- If the sleep physician and patient decide to pursue CPAP treatment, the patient will be scheduled for an in-lab manual CPAP titration polysomnogram.
Group 2 Algorithm

- Participants randomized to home testing will perform a self-administered, overnight unattended sleep study at home with Stardust II® to diagnose OSA.
- Individuals with an apnea-hypopnea index ≥15 will be scheduled for a 1-week autoCPAP titration to determine the fixed pressure for initiation of CPAP treatment.
- Those with a failed home sleep study (less than 4 hours of oximetry recording) will repeat the study once.
- Those subjects with an apnea-hypopnea index <15 on the home sleep study and those subjects with two failed home sleep studies will be scheduled for an in-lab polysomnogram.

Group 2 Algorithm (cont.)

- Group 2 subjects in whom the in-lab polysomnogram is able to be split will be initiated on CPAP treatment; those in whom it cannot be split will have a full night diagnostic polysomnogram.
- Participants with an in-lab apnea-hypopnea index ≥15 events/hr will be scheduled for a home autoCPAP titration study. Those who have an inadequate autoCPAP study, will be scheduled for a full-night manual CPAP titration polysomnogram.
- Those with an apnea-hypopnea index <15 events/hr will be scheduled for a follow-up appointment in sleep clinic; if on that clinic visit, the sleep physician and patient decide to pursue CPAP treatment, the home autoCPAP titration study will be conducted.

Anticipated Enrollment and Follow-up

- Expected enrollment is 132 / group at 2 VA sites.
- Enrollment will take approximately 2 years; follow-up on all patients will continue for 3 months after the last patient is enrolled.
  - Thus, minimum follow-up time will be 3 months; approximate maximum follow-up time will be 2.25 years.
- If equal numbers of participants are enrolled monthly, median follow-up will be 1.125 years.
Economic Analysis

- The economic aim of the trial is to compare the differences in cost and quality-adjusted life years saved (QALYS) between home and in-lab testing by estimation of the ratio of the cost per QALYS saved
- Hypotheses:
  - Average total health-care delivery cost is lower for veterans tested at home versus those tested in-lab
  - Because we believe home testing will have lower costs and equivalent outcomes, we predict that the 90% upper limit of the cost per QALY ratio comparing home versus in-lab testing will be less than $100,000 (i.e., we will have 90% confidence that it is good value for the cost)

Cost Measures

- We will assess testing cost, treatment cost, and other medical cost
- Testing Cost
  - In-lab and home testing cost including the use of the at-home sleep monitor for patients receiving autoCPAP titration
  - Study participants and study personnel are asked to keep track of the time they spend performing activities related to such testing (e.g., time for set-up and patient education)
- VA sleep-study and treatment medical service use will be derived from the case report form; and will be costed out using VA acquisition costs

Cost Measures

- Other medical service use will be derived from VA administrative records
- Non-VA medical service use will be derived from patient interview and will be costed out using federal reimbursement schedules
- Costs will be stratified by whether or not they are related to the diagnosis and treatment of OSA
  - We will also collect all sleep-related costs pertaining to non-OSA sleep-related disorders (e.g. medication costs for restless leg syndrome)
Patient Preferences

- **Health Utilities Index 2 (HUI).** HUI will be the primary outcome measure of general public’s preferences. This self-administered questionnaire includes a generic comprehensive health status classification (i.e., profile) system and a generic HRQL utility scoring system.
- The HUI includes 7 attributes: Sensation, Mobility, Emotion, Cognition, Self-Care, Pain, and Fertility. Each attribute has 3-5 levels. HUI scores meet or exceed the criteria for calculating quality-adjusted life years (QALY) and are responsive to changes in health status over time.
- The questionnaire takes 5-10 min to finish.

Patient Preferences (cont.)

- **EuroQol.** The EuroQol (EQ-5D) will be used as the measure of patient’s preferences.
  - The self-report questionnaire includes the respondent’s self-rated health status on a vertical graduated (1-100) visual analogue scale.
  - In addition, a multi-attribute utility scale comprises 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and produces a single index score for each state of health.
  - Each dimension comprises 3 levels (no problems, some/moderate problems, extreme problems). A unique score is defined by combining 1 level from each of the 5 dimensions.

Analysis

- We will use univariate and multivariable estimation of costs and QALYs to estimate the resulting cost effectiveness ratios.
- Univariate statistics will include mean costs (total and stratified by whether or not they are sleep-related), standard deviations, differences in means (sleep-related and total), and 95% CI for these differences.
- They will also include mean QALYs (from the general public’s [HUI] and the patients’ [EuroQol] perspective), standard deviations, differences in means (HUI and EuroQol), and 95% CI for these differences.
Multivariable Analysis

- Multivariable analysis will also be used to assess differences in costs and QALYS.
- These models assess the effect of the interventions while holding constant other factors such as severity of disease and prior service use.
- For cost and QALYS we will use general linear models (GLM) with the family and link determined by the distribution of the data.

Cost-Effectiveness

- We will calculate cost-effectiveness ratios based on the results of the multivariable models.
- Our primary ratio will be derived by use of GLM estimates of sleep-related costs and QALYS derived by use of the HUI.
- Other ratios will be reported in sensitivity analysis.
- Sampling uncertainty will be assessed by use of 90% CI for the cost-effectiveness ratio and acceptability curves.

Decision Analysis

- One potential advantage of home versus in-lab testing is the reduction in waiting time.
- In the trial, we do not allow for differential waiting times.
- We will use the clinical and economic results of the trial to construct a decision model to assess the likely effect of delay due to in-lab waiting times.
- We will model different average durations of delay of in-lab sleep studies (e.g., 2-month, 4-month, and 6-month) during which time in the in-lab arm will be assumed to have costs and QALYS similar to those they experienced prior to randomization.
- The decision model will also allow us model the effect of variations in prevalence of OSA.
Summary

• There is a large literature on the cost-effectiveness of diagnosing and treating OSA
• Little to none is based on direct observation of different methods of diagnosis and treatment
• The Department of Veterans Affairs trial “Cost-Effective Strategy to Evaluate Veterans with Sleep Apnea” should provide direct evidence of the differences in cost and effect of in-lab versus home testing for OSA