

**RCT**  
**Potential PURL Review Form**  
**PURL Jam Version**

**PURLs Surveillance System**  
**Family Physicians Inquiries Network**

**SECTION 1: Identifying Information for Nominated Potential PURL**  
**[to be completed by PURLs Project Manager]**

- A. Citation: Corral J, Sánchez-Quiroga MÁ, Carmona-Bernal C, Sánchez-Armengol Á, de la Torre AS, Durán-Cantolla J, Egea CJ, Salord N, Monasterio C, Terán J, Alonso-Alvarez ML, Muñoz-Méndez J, Arias EM, Cabello M, Montserrat JM, De la Peña M, Serrano JC, Barbe F, Masa JF; Spanish Sleep Network. Conventional Polysomnography Is Not Necessary for the Management of Most Patients with Suspected Obstructive Sleep Apnea. Noninferiority, Randomized Controlled Trial. *Am J Respir Crit Care Med.* 2017 Nov 1;196(9):1181-1190. doi: 10.1164/rccm.201612-2497OC. PubMed PMID: 28636405.
- B. Link to PubMed Abstract: <https://www.ncbi.nlm.nih.gov/pubmed/?term=28636405>
- C. First date published study available to readers: 12/24/2016
- D. PubMed ID: 28636405
- E. Nominated By: Jim Stevermer
- F. Institutional Affiliation of Nominator: University of Missouri-Columbia
- G. Date Nominated: 12/6/2017
- H. Identified Through: Evidence Updates
- I. PURLs Editor Reviewing Nominated Potential PURL: Dean Seehusen
- J. Nomination Decision Date: 11/6/2017
- K. Potential PURL Review Form (PPRF) Type: RCT
- L. Assigned Potential PURL Reviewer: Scott Earwood
- M. Reviewer Affiliation: Eisenhower Army Medical Center
- A. Abstract: RATIONALE:  
Home respiratory polygraphy may be a simpler alternative to in-laboratory polysomnography for the management of more symptomatic patients with obstructive sleep apnea, but its effectiveness has not been evaluated across a broad clinical spectrum.

**OBJECTIVES:**

To compare the long-term effectiveness (6 mo) of home respiratory polygraphy and polysomnography management protocols in patients with intermediate-to-high sleep apnea suspicion (most patients requiring a sleep study).

**METHODS:**

A multicentric, noninferiority, randomized controlled trial with two open parallel arms and a cost-effectiveness analysis was performed in 12 tertiary hospitals in Spain. Sequentially screened patients with sleep apnea suspicion were randomized to respiratory polygraphy or polysomnography protocols. Moreover, both arms received standardized therapeutic decision-making, continuous positive airway pressure (CPAP) treatment or a healthy habit assessment, auto-CPAP titration (for CPAP indication), health-related quality-of-life questionnaires, 24-hour blood pressure monitoring, and polysomnography at the end of follow-up. The main outcome was the Epworth Sleepiness Scale measurement. The noninferiority criterion was -2 points on

the Epworth scale.

#### MEASUREMENTS AND MAIN RESULTS:

In total, 430 patients were randomized. The respiratory polygraphy protocol was noninferior to the polysomnography protocol based on the Epworth scale. Quality of life, blood pressure, and polysomnography were similar between protocols. Respiratory polygraphy was the most cost-effective protocol, with a lower per-patient cost of 416.7€.

#### CONCLUSIONS:

Home respiratory polygraphy management is similarly effective to polysomnography, with a substantially lower cost. Therefore, polysomnography is not necessary for most patients with suspected sleep apnea. This finding could change established clinical practice, with a clear economic benefit. Clinical trial registered with [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT 01752556).

B. Pending PURL Review Date: 9/24/2018

### **SECTION 2: Critical Appraisal of Validity [to be completed by the Potential PURL Reviewer]**

- A. Number of patients starting each arm of the study?  
218 HRP and 212 PSG
- B. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)  
Inclusion (adults between 18-70yo referred to pulmonologist for suspected OSA), snoring or sleep apneas observed by a partner, ESS 10 or greater, and absence of clinical suspicion of any other sleep pathology like narcolepsy).  
Exclusion (psychophysical inability to complete questionnaires, documented structural or coronary cardiopathy that was not controlled by medical treatment, Cheyne-Stokes syndrome, patients with hx of UPPP, very severe nasal obstruction, inability to give informed consent).  
Setting majority male obese patients referred to pulmonologists in tertiary care centers for suspected OSA in Spain.
- C. Intervention(s) being investigated? The non-inferiority of home respiratory polygraphy verses in-laboratory polysomnography to diagnose, develop treatment plan, and produce long-term effectiveness.
- D. Comparison treatment(s), placebo, or nothing?  
home respiratory polygraphy verses in-laboratory polysomnography
- E. Length of follow-up? (Note specified end points, e.g., death, cure, etc.)  
6 months
- F. What outcome measures are used? List all that assess effectiveness.  
ESS-Primary  
Health-related quality of life (HRQL), Functional Outcomes of Sleep Questionnaire, Short Form-36, EuroQol 5D, Thermometer, a visual analog well being scale (VAWS), 24 hour BP monitor (ABPM), hourly compliance from CPAP devices, work or traffic accidents (6 months before and after randomization), hospital admissions, days of admission, ER visits, and the mean incident

rate of new cardiovascular events during the follow-up period.

G. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CU, p-values, etc.  
The P values for the primary and secondary outcomes were not significant with the exception of the VAWS which had a P value of 0.035 in favor of PSG.

H. What are the adverse effects of intervention compared with no intervention?  
None identified

I. The study addresses an appropriate and clearly focused question.  
(select one) Well covered  
Comments:

J. Random allocation to comparison groups:  
(select one) Well covered  
Comments:

K. Concealed allocation to comparison groups:  
(select one) Well covered  
Comments: blinded PCM's

L. Subjects and investigators kept "blind" to comparison group allocation:  
(select one) Not applicable  
Comments:

M. Comparison groups are similar at the start of the trial:  
(select one) Well covered  
Comments:

N. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential sources of bias. (select one) Well covered  
Comments: No

O. Were all relevant outcomes measured in a standardized, valid, and reliable way?  
(select one) Well covered  
Comments:

P. Are patient oriented outcomes included? If yes, what are they? yes  
Health-related quality of life (HRQL), Functional Outcomes of Sleep Questionnaire, Short Form-36, EuroQol 5D, Thermometer, a visual analog well being scale (VAWS), 24 hour BP monitor (ABPM), hourly compliance from CPAP devices, work or traffic accidents (6 months before and after randomization), hospital admissions, days of admission, ER visits, and the mean incident rate of new cardiovascular events during the follow-up period.

Q. What percent dropped out, and were lost to follow up? Could this bias the results? How?  
8% in HRP group and 14% in PSG group, unlikely to bias

- R. Was there an intention-to-treat analysis? If not, could this bias the results? How?  
yes
- S. If a multi-site study, are results comparable for all sites?  
Unable to say as this data not included.
- T. Is the funding for the trial a potential source of bias? If yes, what measures were taken to ensure scientific integrity? 3 foundations funded and 1 durable medical equipment company, Air Liquide, which could lead to bias as this company is interested in having more patients diagnosed with OSA; do not believe there was bias here but it is possible.
- U. To which patients might the finding apply? Include patients in the study and other patients to whom the findings may be generalized.  
All patients who are medically stable with no severe nasal obstruction or hx of having a UPPP who have intermediate to high suspicion of OSA.
- V. In what care settings might the finding apply, or not apply? Outpatient Family physician office setting as we are the ones making the referral.
- W. To which clinicians or policy makers might the finding be relevant?  
All primary care physician who have adult patients with suspected OSA

### **SECTION 3: Review of Secondary Literature**

**[to be completed by the Potential PURL Reviewer]**

**[to be revised by the Pending PURL Reviewer as needed]**

**Citation Instructions:** For up-to-date citations, use style modified from [http://www.uptodate.com/home/help/faq/using\\_UTD/index.html#cite](http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite) & AMA style. Always use Basow DS on editor & current year as publication year.

Example: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: <http://www.uptodate.com>. {Insert date modified if given.} Accessed February 12, 2009. [whatever date PPRF reviewer did their search.]

For DynaMed, use the following style:  
Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at <http://www.DynamicMedical.com>. Last updated February 4, 2009. {Insert date modified if given.} Accessed June 5, 2009. {search date}

- A. DynaMed excerpts

## Home testing (portable monitors)

- AASM recommendations on PSG for evaluation of suspected OSA
  - [PSG](#) or home sleep apnea testing with technically adequate device indicated for diagnosis of OSA in uncomplicated adult patients with suspected moderate-to-severe OSA ([AASM Strong](#))
    - uncomplicated patient defined as absence of
      - conditions that increase risk of nonobstructive sleep-disordered breathing (central sleep apnea, hypoventilation, and sleep-related hypoxemia), such as
        - significant cardiorespiratory disease
        - potential respiratory muscle weakness due to neuromuscular condition
        - awake hypoventilation or suspected sleep-related hypoventilation
        - chronic opioid use
        - history of stroke
      - clinical conditions, such as
        - significant nonrespiratory sleep disorders requiring evaluation (disorders of central hypersomnolence, parasomnias, sleep-related movement disorders)
        - those that may interfere with home sleep apnea testing, such as severe insomnia
      - environmental or personal factors that preclude adequate acquisition and interpretation of data from home sleep apnea testing
    - technically adequate diagnostic test defined as  $\geq 4$  hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period
  - if single home sleep apnea test yields negative, inconclusive, or technically inadequate results, PSG recommended ([AASM Strong](#))
  - PSG preferred over home sleep apnea testing in patients with ([AASM Strong](#))
    - significant cardiorespiratory disease
    - potential respiratory muscle weakness due to neuromuscular condition
    - awake hypoventilation or suspected sleep-related hypoventilation
    - chronic opioid use
    - history of stroke or severe insomnia
  - Reference - AASM clinical practice guideline for diagnostic testing for adult obstructive sleep apnea ([J Clin Sleep Med 2017 Mar 15;13\(3\):479](#))

B. DynaMed citation/ Obstructive sleep apnea(OSA) in adults. Alexander Rae-Grant, MD, Carolyn M D'Ambrosio. In: DynaMed [database online]. Available at: <http://www.dynamed.com/topics/dmp~AN~T115600/Ostructive-sleep-apnea-Osa-in-adults#sec-testing-portable-monitors>  
access date 24 Sep 2018 [www.DynamicMedical.com](http://www.DynamicMedical.com) Last Updated: 13 Sep 2018.  
Accessed

C. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)

Home sleep apnea testing with a technically adequate device is indicated for diagnosis of OSA in uncomplicated adult patients with suspected moderate-to-severe OSA.

D. UpToDate excerpts

- a. Home sleep apnea testing (HSAT), also referred to as out-of-center sleep testing or portable monitoring, is a diagnostic test used to diagnose obstructive sleep apnea (OSA), a disorder characterized by repetitive episodes of apnea or reduced inspiratory airflow due to upper airway obstruction during sleep. It has evolved as an alternative to overnight, attended, in-laboratory polysomnography (PSG) in selected patients.
- b. Advantages of HSAT include its convenience (it can be performed in the patient's home or in a hospital room) and its potential to lower costs, since most HSAT devices are less costly than complete polysomnography systems and the attendance of a technologist is not required. A disadvantage is that for most of these devices, fewer physiologic variables are measured than with PSG, which can lead to misinterpretation of the results. Other advantages and disadvantages are listed in the table ([table 1](#)).
- c. The United States Centers for Medicare and Medicaid Services (CMS) guidelines state that results from HSAT can be used to support a prescription for positive airway pressure therapy [1]. The American Academy of Sleep Medicine (AASM) has also released clinical practice guidelines to guide clinicians in the use of HSAT [2-4].
- d. **Patients who are suitable candidates for HSAT** – HSAT can be used for the diagnosis of OSA in patients with a high pre-test probability of moderate to severe OSA. Risk of moderate to severe OSA is indicated by the presence of daytime hypersomnolence, and at least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping/choking, or diagnosed hypertension.
- e. **Patients not suitable for HSAT** – HSAT should **not** be used in patients with the following:
  - i. Comorbid medical conditions – Patients who have comorbid medical conditions that predispose to sleep-related breathing disorders. This includes patients with significant respiratory disease such as chronic obstructive pulmonary disease (COPD; GOLD stage II or higher ([table 3](#))) patients with class III or IV heart failure ([table 4](#)) (because they are predisposed to Cheyne-Stokes breathing), and patients with hypoventilation syndromes (eg, obesity hypoventilation, central sleep apnea syndromes). The accuracy of HSAT in these patients is unknown.
  - ii. Comorbid sleep disorders – HSAT should not be used when there is clinical suspicion for comorbid sleep disorders such as narcolepsy or other hypersomnia disorders, insomnia, parasomnias, or periodic limb movement

disorder. The devices used for HSAT are only meant to diagnose OSA, and patients at risk for other disorders should be referred for attended PSG.

iii. Mission-critical employment – Additionally, patients in mission-critical employment, such as airline pilots, are not appropriate candidates for home sleep testing, since current technologies do not certify that the data are generated from that specific individual; this creates the potential for fraud.

f. HSAT can also be used to evaluate the efficacy of an oral appliance or upper airway surgery for OSA. Another potential use is to guide the titration of positive airway pressure therapy if the chosen mode of positive airway pressure is either continuous positive airway pressure (CPAP) or autotitrating positive airway pressure.

g. There are several types of HSAT devices. Type 3 and 4 devices have highly variable diagnostic performance and most do not include a conventional measure of sleep, which has many drawbacks. This was supported by a technology evaluation that found that some devices clearly perform better than others. The SCOPER categorization system provides a more detailed description of individual devices than traditional categorization schemes. An adequate device is one that, at minimum, measures nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry. Alternatively, devices that use peripheral arterial tonometry (PAT) with oximetry and actigraphy are appropriate.

h. Pulse oximetry is a widely accepted and important component of both polysomnography and HSAT. However, it should NOT be used alone for the diagnostic evaluation of suspected OSA.

E. UpToDate citation/ Always use Basow DS as editor & current year as publication year. Access date Title. Author. In: UpToDate [database online]. Available at: <http://www.uptodate.com>. Last updated: 07 NOV 2017. Accessed 26 SEP 2018

Collop, Nancy MD. Home sleep apnea testing for obstructive sleep apnea in adults. In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2018. Available at <http://www.uptodate.com>. 07 NOV 2017. Accessed 26 SEP 2018.

F. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)  
Home sleep studies are a cost effective acceptable alternative to in lab sleep studies for most patients without significant comorbidities with high probability of OSA. There are various types of home monitoring devices; acceptable devices must measure nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry.

- G. Other excerpts (USPSTF; other guidelines; etc.) - Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine

Based on a review of literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) makes the following recommendations: unattended portable monitoring (PM) for the diagnosis of obstructive sleep apnea (OSA) should be performed only in conjunction with a comprehensive sleep evaluation. Clinical sleep evaluations using PM must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination. PM may be used as an alternative to polysomnography (PSG) for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA. PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of PM. PM is not appropriate for the diagnostic evaluation of patients suspected of having comorbid sleep disorders. PM is not appropriate for general screening of asymptomatic populations. PM may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness. PM may also be indicated to monitor the response to non-CPAP treatments for sleep apnea. At a minimum, PM must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in PM. The Task Force recommends that PM testing be performed under the auspices of an AASM-accredited comprehensive sleep medicine program with written policies and procedures. An experienced sleep technologist/technician must apply the sensors or directly educate patients in sensor application. The PM device must allow for display of raw data with the capability of manual scoring or editing of automated scoring by a qualified sleep technician/technologist. A board certified sleep specialist, or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, must review the raw data from PM using scoring criteria consistent with current published AASM standards. Under the conditions specified above, PM may be used for unattended studies in the patient's home. A follow-up visit to review test results should be performed for all patients undergoing PM. Negative or technically inadequate PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

- H. Citations for other excerpts

Collop NA, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *Journal of Clinical Sleep Medicine*. 2007 Dec 15; 3(7): 37-47.

- I. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

Home polygraphy is acceptable for patients with high probability of OSA without significant comorbidities if monitoring includes at least airflow, respiratory effort and blood oxygenation.

#### **SECTION 4: Conclusions**

**[to be completed by the Potential PURL Reviewer]**

**[to be revised by the Pending PURL Reviewer as needed]**

- A. **Validity:** Are the findings scientifically valid?      Yes
- B. If **A** was coded "Other, explain or No", please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?



C. **Relevance:** Is the topic relevant to the practice of family medicine and primary care practice, including outpatient, inpatient, obstetrics, emergency and long-term care? Are the patients being studied sufficiently similar to patients cared for in family medicine and primary care in the US such that results can be generalized?

Yes

D. If **C** was coded “Other, explain or No”, please provide an explanation.

E. **Practice changing potential:** If the findings of the study are both valid and relevant, are they not a currently widely accepted recommendation among family physicians and primary care clinicians for whom the recommendation is relevant to their patient care? Or are the findings likely to be a meaningful variation regarding awareness and acceptance of the recommendation?

Yes

F. If **E** was coded as “Yes”, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit. The home respiratory polygraphy was found non-inferior and much cheaper than conventional polysomnography in the diagnosis and management settings for suspected OSA patients with an Epworth Sleepiness scale score of 10 or greater, who are medically stable, do not have severe obstruction of the nasal passages, and have not undergone UPPP. This result should change primary care physicians’ diagnostic evaluation for obstructive sleep apnea. Family physicians can potentially refer patients for home evaluation, thru a sleep certified physician who could make recommendations from a remote site based on results from the home evaluation.

G. **Applicability to a Family Medical Care Setting:**

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc.), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, education or counseling a patient; or creating a system for implementing an intervention? Yes

H. Please explain your answer to **G**.

Family physicians can potentially refer patients for home evaluation, via a sleep certified physician who could make recommendations from a remote site based on results from the home evaluation.

I. **Immediacy of Implementation:**

Are there major barriers to immediate implementation? No – assuming insurance would cover. Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? No. Are there regulatory issues that prohibit implementation? I don’t know. Is the service, device, drug, or other essentials available on the market? Yes

J. If **I** was coded “Other, explain or No”, please explain why.

**K. Clinically meaningful outcomes or patient oriented outcomes:**

Do the expected benefits outweigh the expected harms? Are the outcomes patient oriented (as opposed to disease oriented)? Are the measured outcomes, if true, clinically meaningful from a patient perspective?

Yes

L. If **K** was coded "Other, explain or No", please explain why.

M. In your opinion, is this a pending PURL? Yes

1. Valid: Strong internal scientific validity; the findings appear to be true.
2. Relevant: Relevant to the practice of family medicine.
3. Practice Changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
4. Applicability in medical setting.
5. Immediacy of implementation

N. Comments on your response for question M.

OSA is common and can have significant morbidity due to increased risk for both cardiovascular disease and motor vehicle accidents. The ability to aid in diagnosis via home sleep studies rather than in lab sleep studies could help family physicians working in rural settings with little access to sleep laboratories as well as increase patient compliance as sleep labs often have a significant wait time for evaluation and are time consuming. Additionally, home testing is more cost effective for diagnosis. The option to have a home study to diagnose and direct management settings for patients could alleviate the barriers described above as well as save health care dollars as it is significantly cheaper than the conventional sleep laboratory option and may aid in diagnosing and treating more OSA patients thereby also decreasing associated morbidity with untreated or poorly managed OSA.