

Home- vs. Laboratory-Based Management Of OSA: An Economic Review

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Abstract Obstructive sleep apnea (OSA) is a common condition that impairs quality of life and health. Diagnosis and treatment of OSA is cost-effective; however, the economics of various management strategies remain to be defined. Home sleep apnea tests (HSAT) provide an alternative to laboratory based polysomnography (PSG) and are less expensive than PSG on a per test basis; however, when utilized within a framework that has been demonstrated to provide comparable clinical outcomes, home testing pathways incur additional costs to compensate for failed studies and lower diagnostic accuracy. A cost-minimization analysis from a randomized controlled trial showed that the cost advantage of a home management pathway narrowed significantly when these additional costs are considered. Further, when the actual costs of providing HSAT rather than what is reimbursed by insurance were considered, the cost advantage was further attenuated. A comprehensive cost-effectiveness analysis (CEA), favored a lab over a home approach based on modeling that projected

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that the costs of erroneous diagnosis over a long time span for the home approach outweighed lower test costs. Studies have identified the following factors that influence costeffectiveness of home-based management: cost of untreated OSA, prevalence of OSA, performance characteristics of the selected test, time horizon, and whether backup PSG is used for failed HSAT. More clinical studies are needed to provide the inputs for more robust CEA regarding this issue.

Keywords Sleep apnea · Economics · Cost-effectiveness · Polysomnography · Home sleep testing

Abbreviations

- AASM American Academy of Sleep Medicine
- AHI Apnea-hypopnea index
- APAP Auto-titrating positive airway pressure
- CEA Cost-effectiveness analysis
- HSAT Home sleep apnea testing
- ICER Incremental cost-effectiveness ratio
- OSA Obstructive sleep apnea
- PAP Positive airway pressure
- PSG Polysomnography
- RCT Randomized controlled trial
- QALY Quality-adjusted life year
- QOL Quality of life

Introduction

Obstructive sleep apnea (OSA) is common, and when untreated, is associated with reduced quality of life, work productivity loss, motor vehicle accidents, and risk of cardiovascular disease [1–3]. Conventionally, diagnosis and treatment of OSA involves overnight laboratory-based diagnostic polysomnography (PSG) followed by a second night of positive airway pressure (PAP) titration PSG. This process, considered the gold standard method for diagnosis and initiation of PAP therapy, is time and labor intensive, and therefore costly [4–6]. Additionally, patients are inconvenienced by travel to testing sites, returning for a second night, and sleeping in an unfamiliar environment. In some settings, the availability of laboratory testing may be limited and this can lead to delays in care. For some patients, it is not technically feasible to conduct studies in the sleep center due to health conditions and limited mobility. The utilization of split-night protocols whereby diagnostic and PAP titration PSG occur on the same night alleviates some burdens associated with traditional testing with similar effectiveness [7–9].

Home sleep apnea tests (HSAT) offer the opportunity to improve access to care, simplify diagnosis of OSA, and reduce costs. The American Academy of Sleep Medicine (AASM) recommends that HSAT only be used in patients with high pretest probability of moderate to severe disease without other significant medical or sleep related comorbidities under the guidance of a sleep specialist within a management pathway that uses PSG to confirm diagnosis when HSAT findings are inconclusive or negative [10]. Use of auto-titrating positive airway pressure (APAP) devices can also streamline management of OSA by obviating the need to perform attended PSG PAP titration in some OSA patients [11]. Studies have shown equivalent outcomes using APAP compared to manual PAP titration in appropriately selected patients; medically stable patients at high risk for moderate to severe OSA who do not have significant cardiorespiratory comorbidities [12–16]. Combining HSAT and APAP, it is possible to construct a home-based OSA management strategy as an alternative to lab-based PSG and titration. Several recent randomized clinical trials (RCT) demonstrate non-inferior outcomes using home-based approaches [17-19, 20..]. The HomePAP study, a large multicenter trial with 373 participants, showed noninferior treatment adherence, PAP therapy acceptance, treatment pressures, and functional improvements at 3 months for the home arm $[20 \bullet \bullet]$.

OSA patients consume significant healthcare resources, and this results in an annual economic burden estimated to be in the billions of dollars just in the USA alone [21–23]. Costeffectiveness analysis (CEA), a technique that provides a framework for assessing value for money spent among alternative management strategies, shows that treatment of OSA with PAP is cost-effective compared to no treatment [22–24]. For example, one CEA showed societal incremental costeffectiveness ratio (ICER) of \$314 per quality-adjusted life year (QALY) gained which compares very favorably to other large, publically funded health interventions based on a willingness to pay a threshold of \$50,000 per QALY [24, 25]. The economics of home- relative to lab-based management of OSA is of considerable interest given the significant costs associated with the disorder as well as its diagnosis and treatment. We review recent literature to elucidate what is known on this topic (refer to Table 1 for summary of studies).

Cost Effectiveness Analyses

A potential advantage of the home-based diagnosis and treatment of OSA is lower resource utilization and lower costs [35, 36]. However, the most comprehensive CEA of this question found that a full night PSG followed by titration was the most cost-effective strategy, compared with split-night PSG and HSAT/APAP [26..]. In this analysis, both the split-night PSG and HSAT/APAP strategies had full night/titration backup. The analysis was taken from a third party payer perspective using Markov modeling over a lifetime horizon. The base model was composed of 50-year-old men with a 50 % pretest probability of moderate to severe OSA (AHI ≥15). Key assumptions made in this study include rates of patient attrition, PAP acceptance/ adherence, and quality of life (QOL) reduction for those on PAP due to a wrong diagnosis. Additional structural assumptions made in the model include the following: PAP discontinuation remaining in effect for the remaining time horizon, lack of attrition after diagnostic PSG, lack of PSG/titration failures, increased number of clinic follow-ups for HSAT/APAP pathway, and no change in probability of stopping PAP based on the accuracy of diagnosis (person with wrong OSA diagnosis was assumed to have the same probability of stopping PAP as correct OSA diagnosis). These assumptions favor the strategy with superior test performance (full night PSG and titration pathway) especially over the lifetime horizon, because costs related to wrong diagnoses persist over the entire time horizon. The CEA did find that all testing methods were cost-effective at a threshold of \$50,000 per QALY gained.

More recent CEAs have been more limited in scope; one modeled cost-effectiveness of three diagnostic/treatment strategies (do nothing, type 3 HSAT/PAP, or OSA screening inventory followed by split-night PSG/PAP) in a population with low prevalence and risk for OSA (active duty military personnel) [27•]. Uniquely, this study also considered costs of lost workplace productivity, whereas the prior CEA only focused on health care utilization and medical outcomes. This study found that the home testing approach was favored over the screen-then-test approach. Backup PSG was not considered for failed HSAT and all patients with AHI >5 proceeded to PAP therapy. Factors that favored the HSAT strategy were poor diagnostic performance of the screening inventory (leading to more PSGs) and lower costs incurred from missing OSA diagnoses due to low OSA prevalence. In contrast, screen/split-night PSG was favored at longer time horizons and with better screening inventory performance. The donothing approach was favored in low prevalence, low cost, and short time horizon settings. The base model assumed untreated OSA (5 % prevalence) incurs a 20 % reduction in work

Table 1 Summary of discussed stud	lies			
Study	Population	Intervention	Comparator	Results
Pietzsch 2011 [26] (2008 dollars, Medicare Reimbursement Rate)	Moderate to high risk for OSA	HSAT (type 3)+ APAP \$209 + \$209 per study	Lab PSG + Titration or split-night ± Titration \$811 + \$891 or \$891 ± \$891 per study	All strategies (full night PSG, split-night PSG, HSAT) are cost-effective, but ICER was lowest for the most accurate testing method at longer time horizons due to commonundel costs of missifeamosts
Bianchi 2014 [27•] (costs modeled after Pietzsch)	Low risk for OSA	HSAT (type 3) \$231 per person per night (accounts for 10 % failure rate)	Screening inventory followed lab split-night PSG \$891	In a low prevalence and low cost population, time horizon is less important (accumulated costs will remain low regardless of time), and the least expensive toxicor divisor is necessari
Moro 2015 [28••] (Costs modeled after Pietzsch and Deutsch)	Uncomplicated OSA	HSAT (type 3) + APAP \$200 + \$200	Lab PSG ± titration (assumes 50 % have split night) \$800 ± \$800	ussuig stategy is prototicut. HSAT/APAP approach was preferred when backup PSG/itration was used, but without backup the latter approach is preferend for longer time horizons due to minimization of costs related to mickiamosis
Kim 2015 [20••] (2011 Dollars, Medicare reimbursement rate)	High risk for moderate to severe OSA	HSAT (type 3) + APAP \$167 + \$0 per study + titration (payer) \$326 + \$307 per study + titration (provider)	Lab PSG ± titration \$782 ± \$782 per study (payer) \$967 ± \$967 per study (provider)	Direct ossis of HSAT protocol from payer and provider perspectives were 11 and 33 %, respectively, of PSG costs. For cost-minimization analysis, diagnostic (and overall) costs of HSAT from payer and provider perspectives were 67 (86)% and 93 (102)%, respectively, of PSG cost
Masa 2013a [30•] (2009 Euros)	Moderate to high risk for OSA	HSAT (type 3) (manual vs. sequential scoring) Total cost per patient—6136 vs. 121. For	Lab PSG Total cost per patient—€563. For equal	For equal diagnostic efficacy, costs of manual vs. sequential HSAT protocol were 69 and 64 %, respectively, of PSG
Masa 2013b [31•] (2009 Euros)	Suspected OSA patients	equal diagnostic enreacy—e.558 vs. 571. Empiric vs. elective HSAT (type 3) Total cost per patient—£135 vs. 320. For equal diagnostic and therapeutic efficacy—£476 vs.	diagnostic enforce/-e5// Lab PSG Total cost per patient£560. For equal diagnostic and therapeutic efficacy£574.	costs. For equal diagnostic and therapeutic decision efficacy, costs of empiric vs. elective HSAT protocol were 83 and 80 %, respectively, of PSG costs.
Masa 2014 [32•] (2012 Euros)	Moderate to high risk for OSA	HSAT (type 4) (manual vs. automatic scoring) (For AHI ≥ 15) Total cost per patient— $\varepsilon 53$ vs. 36. For equal diagnostic efficacy— $\varepsilon 271$ vs. 292.	Lab PSG Total cost per patient—€457. For equal diagnostic efficacy—€473.	For equal diagnostic efficacy, costs of manual vs. automatic protocol at AHI \geq 5 were 27 and 50 %, respectively, of PSG costs. At AHI \geq 15, costs were 57 and 62 %.
Guerrero 2014 [33•] (Euros, year not reported)	Mild to moderate risk for OSA or with other comorbidities	Three-night HSAT (type 3) Total cost per patient—€221. For equal diagnostic efficarv€757	Lab PSG Total cost per patient—6548. For equal diamostic efficary—6548	and oz. 70, respectively, or 1 50 costs. For equal diagnostic efficacy, costs of three nights HSAT protocol was 47 % of PSG costs.
Safadi 2014 [34•] (2007–2011 Dollars)	At risk for OSA	HSAT (WatchPAT) Cost per study—\$95	Lab PSG Cost per study—\$295 to 340. (not adjusted for inflation).	Switch to HSAT led to increased testing, decreased waiting time, increased PAP device purchases, and decreased OSA management costs.

efficiency that equates to loss of \$10,000 per year based on an annual military salary of \$50,000 over 20 service years (time horizon). The balance of potential cost savings from optimal job performance due to OSA treatment relative to costs associated with OSA management was analyzed for each strategy. The HSAT approach was favored in the base model in terms of per person costs (\$4516) vs. screen/split-night PSG (\$5468). Sensitivity analyses varying cost of untreated OSA, prevalence, time horizon, and cost of HSAT in most cases also favored the HSAT approach.

In a similar vein, another recent CEA explored the effects of the following: pretest probability, cost of untreated OSA, time horizon, and using backup PSG/ titration for failed HSAT/APAP, in an uncomplicated OSA population [28...]. It evaluated direct cost and cost-effectiveness from a third party payer perspective by simulating four strategies-treat no one, treat all, PSG and titration (50 % chance of being split), or HSAT/APAP. Studies were allowed to be repeated once if initial evaluation was indeterminate. Test costs and performance (sensitivity/specificity) assumptions were extrapolated from prior studies. Higher OSA prevalence favored HSAT, but also increased chances of meeting split-night criteria, favoring cost savings with PSG. Low OSA prevalence and low cost of untreated OSA favored the treat-no-one approach, whereas high OSA prevalence and high cost of untreated OSA favored the treat-all approach. If downstream consequences of missed OSA diagnoses and its associated costs were neglected and time horizon was short, the cheapest strategy is always preferred (i.e., no testing). HSAT/APAP approach was preferred when backup PSG/titration was used, but without backup, the PSG approach was preferred for longer time horizons due to minimization of costs related to misdiagnoses.

Randomized Controlled Trial-Based Cost Analysis

In contrast to the prior CEAs, a recent study performed a cost-minimization analysis using results from the HomePAP study and thus did not need to make assumptions regarding PAP acceptance, patient attrition, failed tests, and rates of successful titrations [29••]. This study was also unique in that it considered costs from a provider perspective in addition to third party payer perspective (as was considered in the prior CEAs); in other words, the resource inputs reflected in labor and capital costs of each OSA management pathway to the provider were estimated over a 1-year time horizon. The findings mirror cost-effectiveness since the trial demonstrated equivalent outcomes in home vs. lab strategies. A limitation of the trial design was that patients with AHI

<15 after diagnostic testing were excluded. To mimic a more realistic scenario, a model in which patients with AHI ≥5 were treated was also developed. Home program was always cheaper in all scenarios for the payer (\$1575 vs. \$1840 for the base case) in part due to higher cost of PSG and no reimbursement for APAP, but the gap shrank due to split-night PSG, backup PSG/titration for failed HSAT/APAP, higher number of failed HSAT/APAP, and larger number of patients treated with PAP. While for the provider, costs (capital, labor, overhead) were generally less for the home program, this was not true for all scenarios. Another important finding was that provider operating margin (payer cost or "reimbursement" minus provider cost) was negative for home program in all scenarios as Medicare reimbursement levels for HSAT are lower than provider costs. This disparity between home-based cost perspectives suggests that high quality HSAT programs may be unsustainable and potential lower quality (and possibly worse outcomes) programs may result as providers are forced to cut costs. The provider perspective highlighted the large number of cost components necessary to ensure high quality home-based OSA management, which narrowed the cost difference relative to lab management.

Equivalency Trials

A series of studies from Spain looked at cost implications under various scenarios from equivalency trials comparing outcomes in patients who underwent both HSAT and PSG [30•, 31•, 32•, 33•]. Cost data in this situation is not directly comparable because distinct testing strategies were not utilized, unlike in the previously discussed studies. Despite these limitations, these studies illustrate several key points about cost and outcomes between HSAT and PSG.

The first study looked at costs associated with achieving equivalent diagnostic efficiency comparing different HSAT scoring methodologies (manual vs. sequential scoring) vs. PSG and found that an individual HSAT is substantially less costly to perform (with some minor additional saving if not all HSAT studies are manually scored), but cost to achieve diagnostic equivalence with PSG results in less dramatic savings [30•]. There was better AHI agreement between PSG and manually scored HSAT compared to automated scoring. Total cost to reach diagnosis of OSA per patient in sequential and manual HSAT groups were 22 and 24 % of PSG, respectively. However, to achieve equal diagnostic efficacy, HSAT costs were 64 and 69 % of PSG for sequential and manual HSAT scoring, respectively. A second study, based on data from the same clinical trial as the first, indicated that empiric (test all patients) vs. elective (test patients at high clinical probability of OSA) HSAT with backup PSG resulted in similar cost savings relative to PSG to achieve equivalent diagnostic and therapeutic efficacy [31•]. Elective HSAT dramatically reduced the number of HSATs while only slightly increasing the number of backup PSGs required compared to empiric HSAT. Empiric vs. elective HSAT resulted in 24 and 57 % of PSG costs, respectively. For equal diagnostic and treatment efficacy, empiric and elective HSAT resulted in 83 and 80 % of PSG approach costs, respectively. Since elective HSAT had more appropriately selected high clinical probability patients that go on to diagnosis and treatment, there were less indeterminate results necessitating backup PSGs. Similarly, more backup PSGs were needed to achieve diagnostic and therapeutic efficacy in the empiric HSAT arm due to indeterminate and false positive/negative studies leading to higher costs.

Analysis of data from a Spanish multicenter, crossover study of adults at moderate to high risk for OSA concluded that manual scoring is less costly than automated scoring due to relatively better diagnostic efficacy than automated scoring at lower AHI levels [32•]. Though the total cost per test relative to PSG for automated (8 %) scoring was less than for manual scoring (12 %), to achieve equal diagnostic efficacy, HSAT costs for OSA diagnosis (AHI ≥15) was higher for automated scoring (62 %) than for manual scoring (57 %). At AHI ≥5, manual scoring resulted in even more cost savings relative to automatic scoring.

Finally, a Spanish trial that included patients without high risk of OSA, found that nothing was gained from extra nights of consecutive testing besides providing a fail-safe from invalid recordings on first night recording and that best treatment decision concordance was among sleep specialists who also tended to recommend more conservative treatment measures (cost savings) compared to other providers (respiratory specialists and residents with some training in sleep) [33•]. Total test cost of three nights of HSAT was 40 % of PSG cost and increased to 47 % for equivalent diagnostic efficacy based on AHI \geq 5. Due to better HSAT performance characteristics (sensitivity/specificity), few backup PSGs were needed, resulting in greater savings in this study compared to the other Spanish studies reviewed.

Impact on Healthcare System

A retrospective analysis from a large Israeli health system that recently transitioned from lab- to home-based management of OSA, reported decreased diagnostic costs despite more patients being evaluated for OSA over a 4-year period [34•]. In this study, the homebased management used HSAT in uncomplicated patients with suspected OSA, but allowed PSG for those with serious comorbidities unsuited for HSAT. When data from 2007-2008 (100 % PSG) was compared to 2010-2011 (24 % PSG), there was a 90 % increase in the number of sleep studies performed (1471 vs. 2794), an increase in CPAP purchases (597 vs. 831), and a decrease in waiting times for any sleep study (9.9 vs. 1.1 weeks). Patients surveyed prospectively in a random sample reported equivalent satisfaction, less discomfort with HSAT, and a preference for HSAT. Despite more testing during 2010-2011, overall total direct costs of testing from third party payer perspective were 20 % less due to increased utilization of HSAT (\$95) vs. PSG (\$295-340). This study does not address the effectiveness of the new strategy from a societal perspective and the relative cost-effectiveness of the new strategy vs the prior one. Factors such as the impact of misdiagnoses and their consequences could impact relative costeffectiveness of the two strategies.

Conclusion

The availability of a home-based strategy for management of OSA is transforming the practice of sleep medicine. Evidence from RCT supporting that a home-based pathway can achieve comparable outcomes to a labbased pathway in select clinical populations along with the potential for reduced costs have influenced payers to allow and, in some cases mandate, use of a home-based strategy. However, the economic consequences of home testing strategies remain to be adequately evaluated.

The cost of a single HSAT is unequivocally lower than a PSG, though this cost advantage is reduced by additional costs incurred to compensate for the reduced accuracy of HSAT. Further clouding a comprehensive economic evaluation is the potential for inferior clinical outcomes with HSAT. Important factors in determining the cost-effectiveness of home management of OSA include prevalence of OSA, clinical characteristics of the patient population, performance characteristics of HSAT, details of the management pathway such as whether backup PSG is used for failed HSAT, the time horizon over which costs are considered, and the cost of untreated OSA.

Moving forward, additional data from traditional randomized controlled trials as well as data from real-world studies that span longer time horizons and capture clinical effectiveness and cost data are needed to clarify the economic impact of HSAT. Data from these types of studies will allow more robust CEA by minimizing modeling assumptions, and help identify factors that will optimize cost-effectiveness of a home-based management of OSA.

Compliance with Ethical Standards

Conflict of Interest Ken He, Richard Kim, and Vishesh K. Kapur declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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