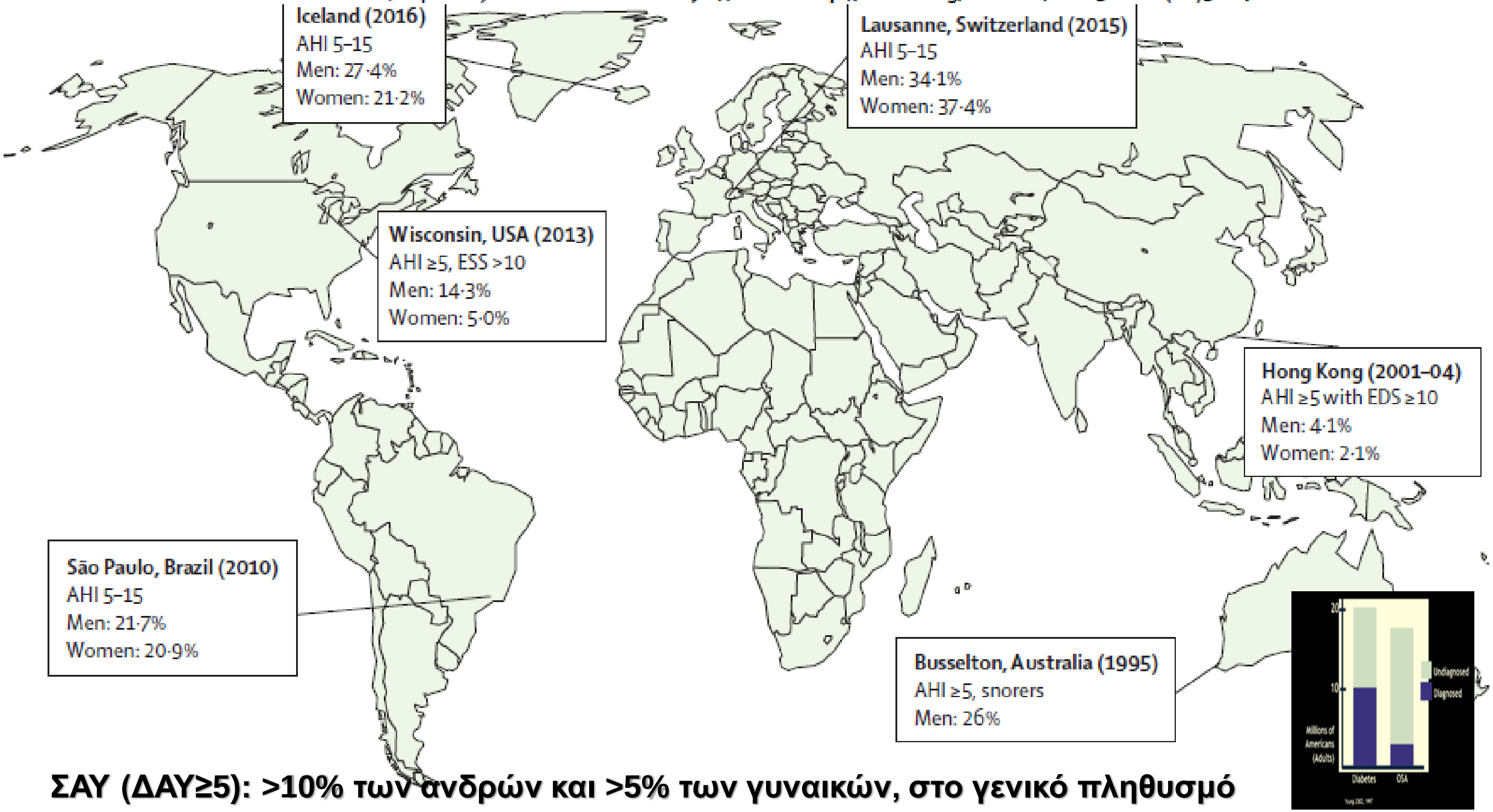
ΚΑΤ' ΟΙΚΟΝ ΠΕΡΙΟΡΙΣΜΕΝΟΥ ΤΥΠΟΥ ΚΑΤΑΓΡΑΦΕΣ ΣΤΟ Σ.Α.Υ. (Home Sleep Apnea Test)

ΤΡΑΚΑΔΑ Π. ΓΕΩΡΓΙΑ

ΘΕΡΑΠΕΥΤΙΚΗ ΚΛΙΝΙΚΗ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ ΕΘΝΙΚΟΥ ΚΑΙ ΚΑΠΟΔΙΣΤΡΙΑΚΟΥ ΠΑΝΕΠΙΣΤΗΜΙΟΥ ΑΘΗΝΩΝ

www.thelancet.com/respiratory Published online May 27, 2016 http://dx.doi.org/10.1016/S2213-2600(16)30146-1



ΣΑΥ (ΔΑΥ≥5): >10% των ανδρών και >5% των γυναικών, στο γενικό πληθυσμό

διαγνωστικά κριτήρια αποφρακτικής άπνοιας ύπνου ενηλίκων – ICSD-3

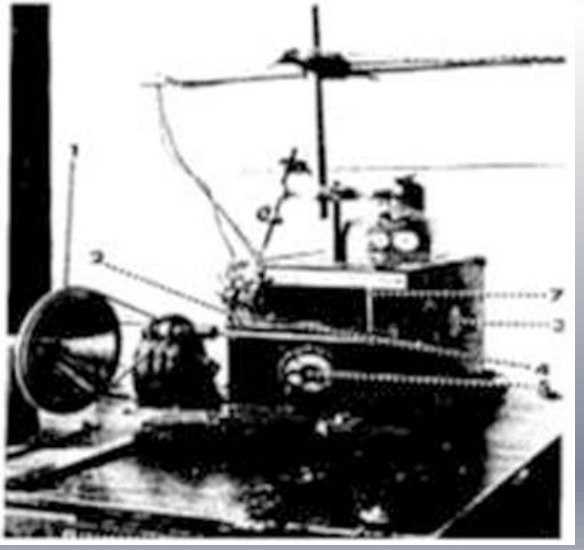
American Academy of Sleep Medicine. International classification of Sleep Disorders, 3rd edn. American Academy of Sleep Medicine, Darien, IL, 2014.

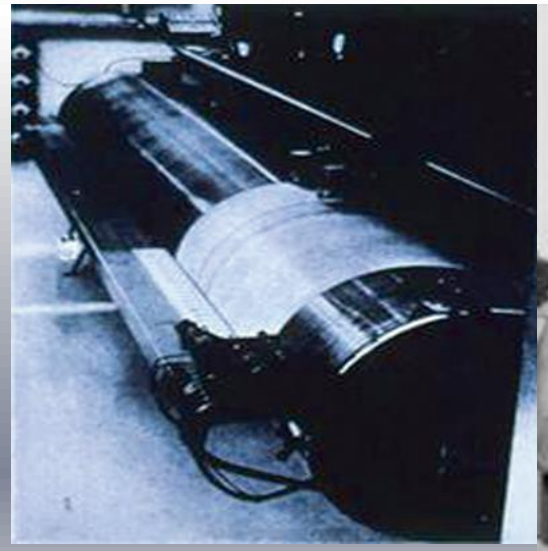
Α και Β ή Γ

- **Α** παρουσία ενός ή παραπάνω από: συμπτώματα υπνηλίας, μη αποδοτικού ύπνου, κόπωσης ή αϋπνίας, νυχτερινές αφυπνίσεις λόγω δύσπνοιας, αναφορά από σύντροφο για ροχαλητό ή/και άπνοιες, διάγνωση υπέρτασης, συναισθηματικής διαταραχής, άνοιας, στεφανιαίας νόσου, αγγειακού εγκεφαλικού επεισοδίου, καρδιακής ανεπάρκειας, πτερυγισμού ή σακχαρώδη διαβήτη ΙΙ
- **Β** δεδομένα πολυσωματο- ή πολυκαταγραφικής μελέτης ύπνου: ≥5 αποφρακτικά επεισόδια ανά ώρα ύπνου ή καταγραφής (αποφρακτικές και μεικτές άπνοιες, υπόπνοιες, αφυπνίσεις λόγω αναπνευστικής προσπάθειας – RERAs)

ή

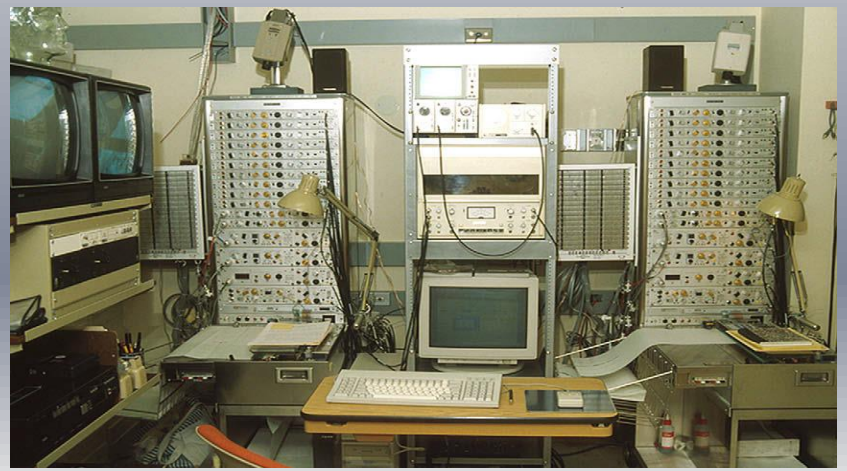
- **Γ** ≥15 αποφρακτικά επεισόδια ανά ώρα ύπνου ή καταγραφής (αποφρακτικές και μεικτές άπνοιες, υπόπνοιες, αφυπνίσεις λόγω αναπνευστικής προσπάθειας – RERAs)



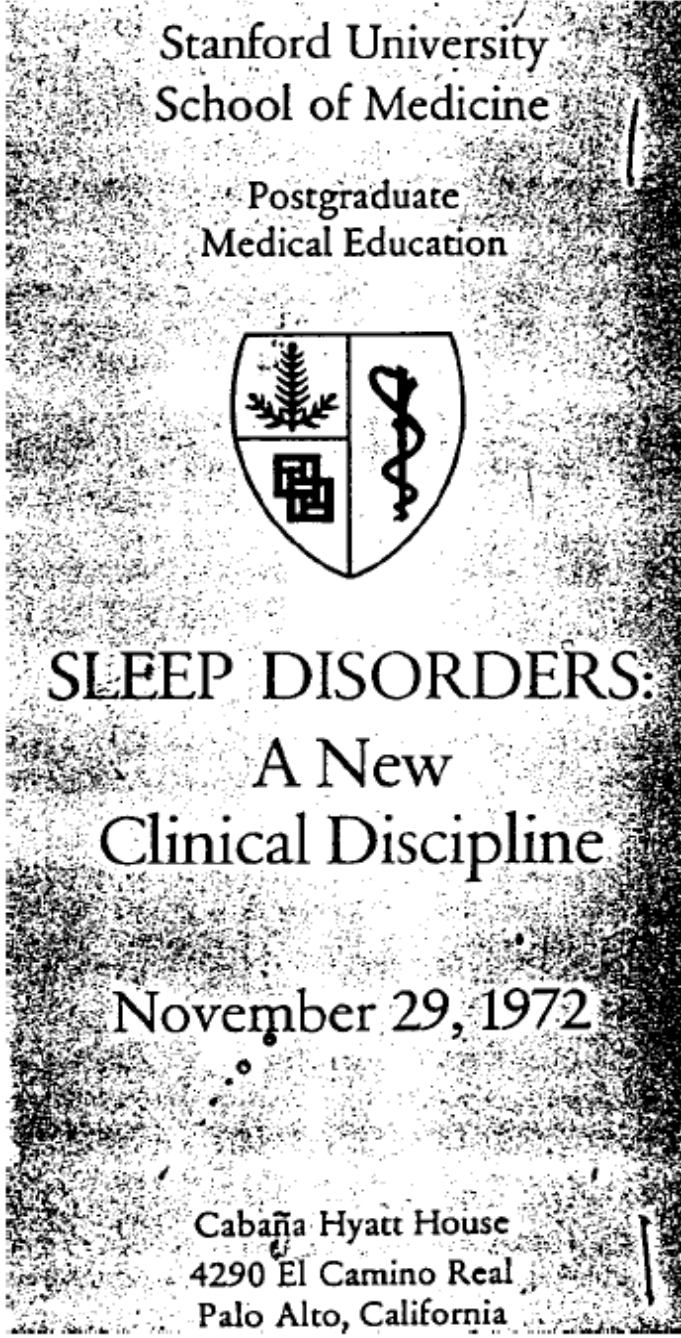


Loomis, Alfred L., E. Newton Harvey, and G. A. Hobart. "Cerebral states during sleep, as studied by human brain potentials." Journal of experimental psychology. 21.2 (**1937**): 127

Gastaut H, Tassinari CA, Duron B. [Polygraphic study of diurnal and nocturnal (hypnic and respiratory) episodal manifestations of Pickwick syndrome]. Rev Neurol (Paris) **1965**;112(6):568–79 [in French].



Analog sleep system. Two-bed sleep laboratory at the University of Wisconsin, **1988**. (Courtesy of S. Weber, Madison, WI.)



Stanford University
School of Medicine

Postgraduate
Medical Education

SLEEP DISORDERS:
A New
Clinical Discipline

November 29, 1972

Cabaña Hyatt House
4290 El Camino Real
Palo Alto, California

Figure 1 A replica of the original brochure announcing clinical course on "Sleep Disorders: a New Clinical Discipline".

ΤΥΠΟΙ ΚΑΤΑΓΡΑΦΩΝ

Portable studies for sleep apnea evaluation: classification scheme (6-hour overnight recording minimum)

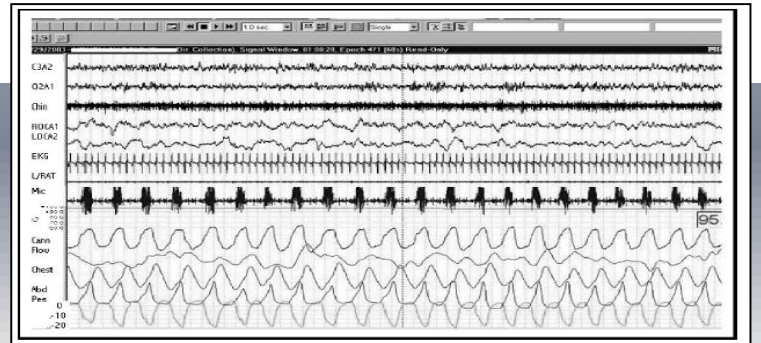
	Level 1: Standard PSG	Level 2: Comprehensive Portable PSG	Level 3: Modified Portable Apnea Testing	Level 4: Continuous Single or Dual Parameter Recording
Parameters	Minimum of 7: EEG, EOG, chin EMG, ECG, airflow, respiratory effort, oximetry	Minimum of 7: EEG, EOG, chin EMG, ECG or HR, airflow, respiratory effort, oximetry	Minimum of 4: ventilation (respiratory movement and airflow) HR or ECG, oximetry	Minimum of 1 (typically oximetry or airflow)
Body position	Documented or objectively measured	Can be objectively measured	Can be objectively measured	Not measured
Leg movement	EMG or motion sensor (optional)	EMG or motion sensor (optional)	May be recorded	Not recorded
Personnel attendance	Constant	None	None	None
Interventions Possible	Yes	No	No	No

Abbreviations: ECG, electrocardiogram; EEG, electroencephalogram; EMG, electromyogram; EOG, electrooculogram; HR, heart rate.

From Ferber R, Millman R, Coppola M, et al. Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. Sleep 1994;17(4):378–92.

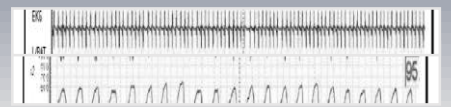
Peripheral Arterial Tonometry (PAT)?

1, 2



3

4



- **Η διάγνωση του ΣΑΥ πρέπει να πραγματοποιείται ΠΑΝΤΑ σε συνδυασμό με κλινική αξιολόγηση <u>πριν</u> και μακροχρόνια παρακολούθηση της θεραπείας <u>μετά</u>.**

- **Διαγνωστικά εργαλεία, ερωτηματολόγια και προγνωστικοί αλγόριθμοι δεν πρέπει να χρησιμοποιούνται ως αποκλειστικά μέσα για τη διάγνωση του ΣΑΥ, χωρίς συνοδό μελέτη ύπνου στο εργαστήριο (ΠΜΥ) ή νυχτερινή καταγραφή κατ' οίκον (ΦΜΥ). (STRONG)**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

- **ΠΜΥ ή ΦΜΥ με τεχνικά επαρκές καταγραφικό μηχάνημα πρέπει να χρησιμοποιείται για τη διάγνωση του ΣΑΥ σε μη επιπλεγμένους ασθενείς, με συμπτώματα και σημεία ενδεικτικά αυξημένου κινδύνου μετρίου ή βαρέος ΣΑΥ. (STRONG)**

κλασσική οδός

εναλλακτική οδός

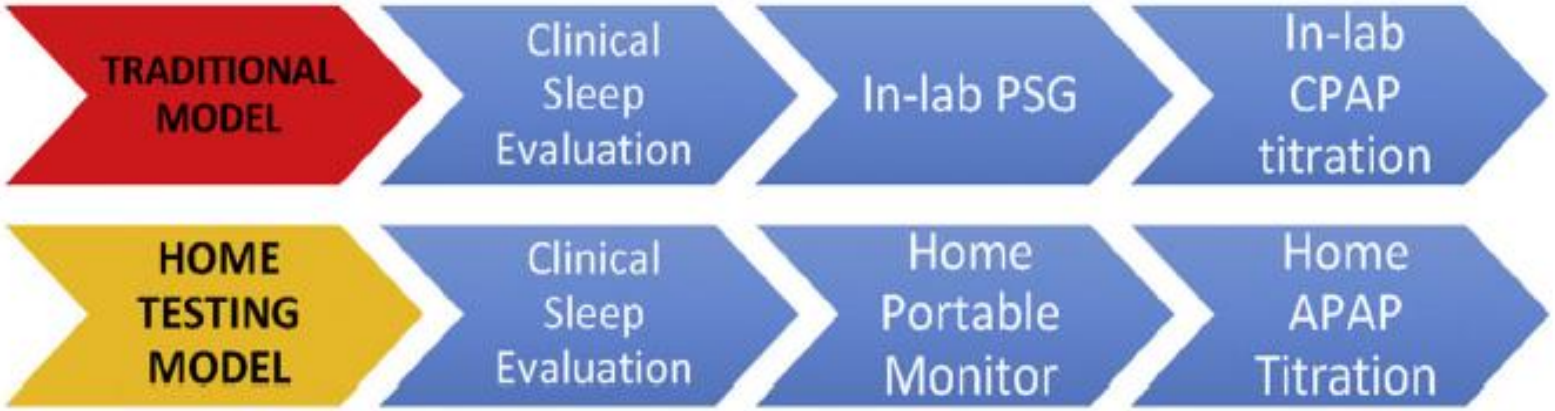


Fig. 1.
Traditional in-laboratory and home PT pathways for the diagnosis of OSA, based on 90th percentile APAP pressure. (*Adapted from* Cooksey JA, Balachandran JS. Portable monitoring for thediagnosis of OSA. Chest 2016;149:1074–81.)

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

Ως ανεπίπλεκτος ασθενής θεωρείται όποιος δεν έχει:

- **άλλα νοσήματα με αυξημένο κίνδυνο μη αποφρακτικών διαταραχών της αναπνοής στον ύπνο, όπως κεντρική άπνοια του ύπνου, υποαερισμό ή νυχτερινή υποξαιμία: βαριά καρδιοαναπνευστική νόσος, πιθανή μυϊκή ατονία στα πλαίσια νευρομυϊκού νοσήματος, ιστορικό ΑΕΕ ή χρόνια χρήση οπιοειδών.**

- **άλλες – μη αναπνευστικές - διαταραχές ύπνου που χρήζουν περαιτέρω αξιολόγησης, όπως διαταραχές κεντρικής υπερυπνίας, παραυπνίες, ή κινήσεις άκρων ή που μπορεί να επηρεάσουν την ποιότητα της καταγραφής, όπως σοβαρή αυπνία.**

- **περιβαλλοντικοί ή προσωπικοί παράγοντες του ασθενή.**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

- **Αυξημένο κίνδυνο μετρίου ή βαρέος ΣΑΥ έχει ο ασθενής με εκσεσημασμένη ημερήσια υπνηλία και τουλάχιστον 2 από τα παρακάτω κριτήρια: συχνό δυνατό ροχαλητό, αναφερόμενες άπνοιες ή αίσθημα πνιγμονής ή αφυπνίσεις λόγω δύσπνοιας, διαγνωσμένη υπέρταση.**

- **ΦΜΥ διενεργείται υπό την αιγίδα πιστοποιημένου κέντρου ύπνου και υπό την εποπτεία εξειδικευμένου ιατρού του ύπνου (board-certified sleep medicine physician, or a board-eligible sleep medicine provider).**

- **Μια μόνο ΦΜΥ πραγματοποιείται κατά τη διάρκεια μιας νύχτας.**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

- **Χρόνος καταγραφής (Monitoring time - MT): Συνολικός χρόνος καταγραφής μείον των περιόδων με τεχνικά σφάλματα και του χρόνου που ο ασθενής ήταν σε εγρήγορση, όπως διαπιστώνεται από την ακτιγραφία, τη θέση σώματος, το πρότυπο της αναπνοής ή το ημερολόγιο του ασθενή.**

- **Δείκτης αναπνευστικών συμβαμάτων (Respiratory event index - REI): Συνολικός αριθμός αναπνευστικών συμβαμάτων×60 διά του χρόνου καταγραφής.**

✓ **άπνοιες και υπόπνοιες σκοράρονται με βάση τη ροή του αέρα και τις αναπνευστικές κινήσεις**

✓ **αναπνευστικά συμβάματα σκοράρονται στο PAT με βάση τον περιφερικό αρτηριακό τόνο, τον αποκορεσμό του οξυγόνου και τις αλλαγές του καρδιακού ρυθμού στο οξύμετρο**

- **Τεχνικά επαρκές καταγραφικό μηχάνημα περιλαμβάνει τουλάχιστον τους παρακάτω αισθητήρες: ρινική κάνουλα, ζώνες θώρακα και κοιλιάς και οξυμετρία ή εναλλακτικά PAT, με οξυμετρία και ακτιγραφία.**

- **Τεχνικά επαρκής μελέτη περιλαμβάνει τουλάχιστον 4 ώρες καταγραφής οξυμετρίας και δεδομένων ροής αέρα, στα πλαίσια μίας μελέτης που έγινε κατά τη συνήθη περίοδο ύπνου.**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

- **τα περισσότερα καταγραφικά μηχανήματα δε διαχωρίζουν ύπνο έναντι εγρήγορσης**
- **χρόνος καταγραφής αντί χρόνος ύπνου**
- **δεν καταγράφονται υπόπνοιες που συσχετίζονται μόνο με μικροαφύπνιση**
- **αποκόληση αισθητήρων, πτωχό σήμα**

<u>υποεκτίμηση “πραγματικού” ΔΑΥ</u>

- **Αν η ΦΜΥ είναι αρνητική ή μη διαγνωστική ή μη επαρκής τεχνικά, πρέπει να επαναλαμβάνεται ΠΜΥ για τη διάγνωση του ΣΑΥ. (STRONG)**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

- **ΠΜΥ και όχι ΦΜΥ πρέπει να πραγματοποιείται για τη διάγνωση ΣΑΥ σε ασθενείς με σοβαρή καρδιοαναπνευστική νόσο, πιθανή μυϊκή ατονία επί νευρομυϊκού νοσήματος, ημερήσιο υποαερισμό ή υποψία νυχτερινού υποαερισμού, χρόνια χρήση οπιοειδών, ιστορικό ΑΕΕ ή σοβαρή αυπνία. (STRONG)**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

8,127 studies identified through PubMed and Embase.
Search 1: (PubMed) January 1, 2005 to July 26, 2012
(Embase) January 1, 2005 to September 13, 2012
Search 2: (PubMed) July 27, 2012 to December 23, 2013
(Embase) September 13, 2012 to December 23, 2013
Search 3: (PubMed) December 24, 2013 to June 29, 2016

140 studies identified through "spot check"

8,267 studies screened by title → 875 duplicates removed

7,392 studies reviewed for inclusion/exclusion criteria → 7,294 studies excluded.

Reason for exclusion:
a. Treatment paper, not about diagnosis
b. No OSA
c. Pediatric patients
d. PICO 2: Initial sample size < 25 per condition, 50 total
e. All other PICOs: Initial sample size < 10 per condition, 20 total
f. Wrong publication type (review, editorial, methodological, non-RCT or non-observational study)
g. Other sleep comorbidities besides OSA
h. Hospitalized or general surgery
i. Diagnostic test not in PICO question
j. Time between HSAT and PSG >4 weeks
k. HSAT used in-lab
l. HSAT used simultaneously with PSG in-lab
m. MSLT, MWT, and other nap tests

98 studies included in evidence base for recommendations → **86** studies included in meta-analysis

Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(3):479–504.

Journal of Clinical Sleep Medicine

Clinical suspicion of OSA[a,b]

Does the patient have signs and symptoms that indicate an increased risk of moderate to severe OSA?[c]
(See Recommendation 2)

No → Perform PSG

Yes → Does the patient have: significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or high risk of sleep related hypoventilation, history of stroke, chronic opioid medication use, severe insomnia, symptoms of other significant sleep disorder(s), or environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT?

Yes → Perform PSG by an accredited sleep center under the supervision of a board-certified sleep physician.
Follow a split-night protocol, if clinically appropriate and feasible.[f,g]
(See Recommendations 4, 5)

No → Perform HSAT, administered by an accredited sleep center under the supervision of a board-certified sleep physician[d,e]
(See Recommendation 2)

Positive diagnosis and adequate results?[h]

Yes → **INITIATE TREATMENT OF OSA[i]**

No → Evaluate for other sleep disorders OR perform PSG when OSA has not yet been ruled out.
Follow a split-night protocol, if clinically appropriate and feasible.[f,g]
(See Recommendations 3 and 6)

Positive diagnosis and adequate results?[h]

Yes → **INITIATE TREATMENT OF OSA[i]**

No → Reevaluate for other sleep disorders OR repeat in-lab PSG[j]

Follow-up after treatment initiation[k]

Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(3):479–504.

Table S37—Summary of Findings table for Type 2 HSAT vs. PSG to diagnose OSA in Suspected Adults (AHI ≥ 5)

References: Campbell 2011 (A); Banhiran 2014 (B)

Range of sensitivities Type 2 HSAT: 0.88 to 0.97 | **Range of specificities Type 2 HSAT**: 0.50 to 0.56
Range of sensitivities Attended: 1.00 to 1.00 | **Range of specificities Attended**: 1.00 to 1.00 **Accuracy (high risk)**: 84% to 91% **Accuracy (low risk):** 73% to 77%

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 87%		Prevalence 55%		
		Type 2 HSAT	Attended	Type 2 HSAT	Attended	
True positives (patients with OSA)	⊕⊕⊕⊕ HIGH	766 to 844	870 to 870	484 to 534	550 to 550	116 (2) [A,B]
		26 to 104 fewer TP in Type 2 HSAT		**16 to 66 fewer TP in Type 2 HSAT**		
False negatives (patients incorrectly classified as not having OSA)		26 to 104	0 to 0	16 to 66	0 to 0	
		26 to 104 more FN in Type 2 HSAT		**16 to 66 more FN in Type 2 HSAT**		
True negatives (patients without OSA)	⊕⊕⊕⊕ HIGH	65 to 73	130 to 130	225 to 252	450 to 450	116 (2) [A,B]
		57 to 65 fewer TN in Type 2 HSAT		**198 to 225 fewer TN in Type 2 HSAT**		
False positives (patients incorrectly classified as having OSA)		57 to 65	0 to 0	198 to 225	0 to 0	
		57 to 65 more FP in Type 2 HSAT		**198 to 225 more FP in Type 2 HSAT**		

Table S38—Summary of Findings table for Type 2 HSAT vs. PSG to diagnose OSA in Suspected Adults (AHI ≥ 15)

References: Campbell 2011 (A); Banhiran 2014 (B)

Range of sensitivities Type 2 HSAT: 0.94 to 0.95 | Range of specificities Type 2 HSAT: 0.76 to 0.77
Range of sensitivities Attended: 1.00 to 1.00 | Range of specificities Attended: 1.00 to 1.00 Accuracy (high risk): 88% to 88% Accuracy (low risk): 81% to 81%

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 64%		Prevalence 25%		
		Type 2 HSAT	Attended	Type 2 HSAT	Attended	
True positives (patients with OSA)	⊕⊕⊕⊕ HIGH	602 to 608	640 to 640	235 to 238	250 to 250	116 (2) [A,B]
		32 to 38 fewer TP in Type 2 HSAT		**12 to 15 fewer TP in Type 2 HSAT**		
False negatives (patients incorrectly classified as not having OSA)		32 to 38	0 to 0	12 to 15	0 to 0	
		32 to 38 more FN in Type 2 HSAT		**12 to 15 more FN in Type 2 HSAT**		
True negatives (patients without OSA)	⊕⊕⊕⊕ HIGH	274 to 277	360 to 360	570 to 578	250 to 250	116 (2) [A,B]
		83 to 86 fewer TN in Type 2 HSAT		**172 to 180 fewer TN in Type 2 HSAT**		
False positives (patients incorrectly classified as having OSA)		83 to 86	0 to 0	172 to 180	0 to 0	
		83 to 86 more FP in Type 2 HSAT		**172 to 180 more FP in Type 2 HSAT**		

Table S39—Summary of Findings table for Type 3 HSAT vs. PSG to diagnose OSA in Suspected Adults (AHI ≥ 5)

References: Gjevre 2011 (A); Masa 2011 Thorax (B); Polese 2012 (C); Santos-Silva 2009 (D); Yin 2006 (E); Planes 2010 (F); Masa 2013 (G)

Range of sensitivities Type 3 HSAT: 0.90 to 1 | **Range of specificities Type 3 HSAT**: 0.30 to 0.67
Range of sensitivities Attended: 1.00 to 1.00 | **Range of specificities Attended**: 1.00 to 1.00 **Accuracy (high risk)**: 84% to 91% **Accuracy (low risk):** 70% to 78%

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 87%		Prevalence 55%		
		Type 3 HSAT	Attended	Type 3 HSAT	Attended	
True positives (patients with OSA)	⊕⊕⊕◯ MODERATE[1]	783 to 870	870 to 870	495 to 550	550 to 550	1001 (7) [A-G]
		0 to 87 fewer TP in Type 3 HSAT		**0 to 55 fewer TP in Type 3 HSAT**		
False negatives (patients incorrectly classified as not having OSA)		0 to 87	0 to 0	0 to 55	0 to 0	
		0 to 87 more FN in Type 3 HSAT		**0 to 55 more FN in Type 3 HSAT**		
True negatives (patients without OSA)	⊕⊕⊕◯ MODERATE[1]	39 to 87	130 to 130	135 to 302	450 to 450	1001 (7) [A-G]
		43 to 91 fewer TN in Type 3 HSAT		**148 to 315 fewer TN in Type 3 HSAT**		
False positives (patients incorrectly classified as having OSA)		43 to 91	0 to 0	180 to 315	0 to 0	
		43 to 91 more FP in Type 3 HSAT		**148 to 315 more FP in Type 3 HSAT**		

[1]Wide range of values for specificity

Table S40—Summary of Findings table for Type 3 HSAT vs. PSG to diagnose OSA in Suspected Adults (AHI ≥ 15)

References: Garcia-Diaz 2007 (A); Gjevre 2011 (B); Polese 2012 (C); Santo Silva 2009 (D); Yin 2006 (E); Planes 2010 (F)

Range of sensitivities Type 3 HSAT: 0.62 to 0.94 | **Range of specificities Type 3 HSAT**: 0.25 to 0.97
Range of sensitivities Attended PSG: 1.00 to 1.00 | **Range of specificities Attended PSG**: 1.00 to 1.00 **Accuracy (high risk)**: 65% to 91% **Accuracy (low risk):** 59% to 90%

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 64%		Prevalence 25%		
		Type 3 HSAT	Attended PSG	Type 3 HSAT	Attended PSG	
True positives (patients with OSA)	⊕⊕⊕◯ MODERATE[1]	397 to 602	640 to 640	155 to 235	250 to 250	457 (6) [A-F]
		38 to 243 fewer TP in Type 3 HSAT		**15 to 95 fewer TP in Type 3 HSAT**		
False negatives (patients incorrectly classified as not having OSA)		38 to 243	0 to 0	15 to 95	0 to 0	
		38 to 243 more FN in Type 3 HSAT		**15 to 95 more FN in Type 3 HSAT**		
True negatives (patients without OSA)	⊕⊕⊕◯ MODERATE[1]	90 to 349	360 to 360	188 to 728	750 to 750	457 (6) [A-F]
		11 to 270 fewer TN in Type 3 HSAT		**22 to 562 fewer TN in Type 3 HSAT**		
False positives (patients incorrectly classified as having OSA)		11 to 270	0 to 0	22 to 562	0 to 0	
		11 to 270 more FP in Type 3 HSAT		**22 to 562 more FP in Type 3 HSAT**		

[1]Wide range of values for specificity and sensitivity

Table S41—Summary of Findings table for Type 3 HSAT vs. PSG to diagnose OSA in Suspected Adults (AHI ≥ 30)

References: Garcia-Diaz 2007 (A); Gjevre 2011 (B); Masa 2011 (C); Planes 2010 (D); Polese 2012 (E)

Pooled sensitivity Type 3 HSAT: 0.87 (95% CI: 0.77 to 0.93) | **Pooled specificity Type 3 HSAT**: 0.88 (95% CI: 0.59 to 0.97)
Pooled sensitivity Attended PSG: 1.00 (95% CI: 1.00 to 1.00) | **Pooled specificity Attended PSG**: 1.00 (95% CI: 1.00 to 1.00)
Accuracy (high risk): 88% (95% CI: 81 to 94%) **Accuracy (low risk):** 88% (95% CI: 71 to 95%)

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 36%		Prevalence 10%		
		Type 3 HSAT	Attended PSG	Type 3 HSAT	Attended PSG	
True positives (patients with OSA)	⊕⊕◯◯ LOW[1,2]	313 (277 to 335)	360 (360 to 360)	87 (77 to 93)	100 (100 to 100)	545 (5) [A-E]
		47 fewer TP in Type 3 HSAT		**13 fewer TP in Type 3 HSAT**		
False negatives (patients incorrectly classified as not having OSA)		47 (25 to 83)	0 (0 to 0)	13 (7 to 23)	0 (0 to 0)	
		47 more FN in Type 3 HSAT		**13 more FN in Type 3 HSAT**		
True negatives (patients without OSA)	⊕⊕◯◯ LOW[1,2]	563 (378 to 621)	640 (640 to 640)	792 (531 to 873)	900 (900 to 900)	545 (5) [A-E]
		77 fewer TN in Type 3 HSAT		**108 fewer TN in Type 3 HSAT**		
False positives (patients incorrectly classified as having OSA)		77 (19 to 262)	0 (0 to 0)	108 (27 to 369)	0 (0 to 0)	
		77 more FP in Type 3 HSAT		**108 more FP in Type 3 HSAT**		

[1]Wide confidence intervals for sensitivity and specificity
[2]Wide range of values for sensitivity and specificity

5 μελέτες σύγκριναν ΦΜΥ 2–3 παραμέτρων έναντι ΠΜΥ:

- **σε πληθυσμό αυξημένου κινδύνου με ΔΑΥ ≥5, ≥15, και ≥30, διαγνωστική ακρίβεια 81%-93%, 72%-87%, και 71%-90%, αντίστοιχα.**
- **σε πληθυσμό χαμηλού κινδύνου κινδύνου με ΔΑΥ ≥5, ≥15, και ≥30, διαγνωστική ακρίβεια 77%-88%, 68%-95%, και 88%-91%, αντίστοιχα.**

όταν σύγκριναν ΦΜΥ 2–3 παραμέτρων έναντι μη παρακολουθούμενης ΠΜΥ:

- **σε πληθυσμό αυξημένου κινδύνου με ΔΑΥ ≥15, και ≥30, διαγνωστική ακρίβεια 86% και 83%-91%, αντίστοιχα**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

Table S53—Summary of Findings table for Oximetry vs. In-home PSG to diagnose OSA in Suspected Adults (AHI ≥ 30)

References: Chung 2012 (A)

Single study sensitivity Oximetry: 1.00 (95% CI: 1.00 to 1.00) | **Single study specificity Oximetry**: 0.59 (95% CI: 0.54 to 0.63)
Single study sensitivity In-home PSG: 1.00 (95% CI: 1.00 to 1.00) | **Single study specificity In-home PSG**: 1.00 (95% CI: 1.00 to 1.00) **Accuracy (high risk)**: 74% (95% CI: 71 to 76%) **Accuracy (low risk):** 63% (95% CI: 59 to 67%)

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 36%		Prevalence 10%		
		Oximetry	In-home PSG	Oximetry	In-home PSG	
True positives (patients with OSA)	⊕⊕⊕◯ MODERATE[1]	360 (360 to 360)	360 (360 to 360)	100 (100 to 100)	100 (100 to 100)	243 (1)[A]
		0 fewer TP in Oximetry		**0 fewer TP in Oximetry**		
False negatives (patients incorrectly classified as not having OSA)		0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	
		0 fewer FN in Oximetry		**0 fewer FN in Oximetry**		
True negatives (patients without OSA)	⊕⊕⊕◯ MODERATE[1]	378 (346 to 403)	640 (640 to 640)	531 (486 to 567)	900 (900 to 900)	243 (1)[A]
		262 fewer TN in Oximetry		**369 fewer TN in Oximetry**		
False positives (patients incorrectly classified as having OSA)		262 (237 to 294)	0 (0 to 0)	369 (333 to 414)	0 (0 to 0)	
		262 more FP in Oximetry		**369 more FP in Oximetry**		

[1]Indirect evidence as study includes patients scheduled for inpatient surgery

Table S57—Summary of Findings table for Watch-PAT vs. In-lab PSG to diagnose OSA in Suspected Adults (AHI ≥ 30)

References: Pittman 2004 (A)

Single study sensitivity Watch-PAT: 0.92 (95% CI: 0.62 to 1.00) | **Single study specificity Watch-PAT**: 0.82 (95% CI: 0.57 to 0.96) **Accuracy (high risk)**: 83% (95% CI: 58 to 97%) **Accuracy (low risk):** 83% (95% CI: 58 to 96%)

Test result	Quality of the Evidence (GRADE)	Number of results per 1000 patients tested (95% CI)				Number of participants (studies)
		Prevalence 36%		Prevalence 10%		
		Watch-PAT	In-Lab PSG	Watch-PAT	In-Lab PSG	
True positives (patients with OSA)	⊕⊕⊕◯ MODERATE[1]	331 (223 to 360)	360 (360 to 360)	92 (62 to 100)	100 (100 to 100)	29 (1) [A]
		29 fewer TP in Watch-PAT		**8 fewer TP in Watch-PAT**		
False negatives (patients incorrectly classified as not having OSA)		29 (0 to 137)	0 (0 to 0)	8 (0 to 38)	0 (0 to 0)	
		29 more FN in Watch-PAT		**8 more FN in Watch-PAT**		
True negatives (patients without OSA)	⊕⊕⊕◯ MODERATE[1]	525 (365 to 614)	360 (360 to 360)	738 (513 to 864)	100 (100 to 100)	29 (1) [A]
		165 more TN in Watch-PAT		**638 more TN in Watch-PAT**		
False positives (patients incorrectly classified as having OSA)		115 (26 to 275)	0 (0 to)	162 (36 to 87)	0 (0 to 0)	
		115 more FP in Watch-PAT		**162 more FP in Watch-PAT**		

[1]Wide confidence intervals for sensitivity and specificity

Table S58—HSAT compared to PSG for adults suspected of OSA

References: Andreu 2012 (A); Antic 2009 (B); Berry 2008 (C); Kuna 2011 (D); Mulgrew 2007 (E); Rosen 2012 (F); Skomro 2010 (G)

Patient or population: adults suspected of OSA
Setting: Home, lab
Intervention: HSAT
Comparison: Attended PSG

Outcomes	Quality of the evidence (GRADE)	Anticipated absolute effects* (95% CI) MD between HSAT and PSG		№ of participants (studies)	Comments
Sleepiness* (ESS)	⊕⊕⊕⊕ HIGH	The mean difference in sleepiness (ESS) after treatment was 0.38 less (1.07 less to 0.32 less) with HSAT		764 (7 RCTs) [A-G]	
QOL (FOSQ)*	⊕⊕⊕⊕ HIGH	The mean difference in QOL (FOSQ) after treatment was 0.10 lower (0.42 higher to 0.61 lower) with HSAT		550 (4 RCTs) [A,B,D,F]	
QOL (SAQLI)*	⊕⊕⊕⊕ HIGH	The mean difference in QOL (SAQLI) after treatment was 0.11 greater (0.15 lower to 0.38 greater) with HSAT		271 (3 RCTs) [E,F,G]	
QOL (SF-36 Vitality Score)*	⊕⊕⊕⊕ HIGH	The mean difference in QOL (SF-36 Vitality Score) after treatment was 1.03 greater (1.88 lower to 3.94 greater) with HSAT		382 (3 RCTs) [B,F,G]	
QOL (SF-12/SF-36 Physical Component Summary)*	⊕⊕⊕◯ MODERATE[1]	The mean difference in QOL (SF-12/SF-36 Physical Component Summary) after treatment was 1.45 greater (2.92 fewer to 5.82 greater) with HSAT		243 (2 RCTs) [D,G]	
QOL (SF-12/SF-36 Mental Component Summary)*	⊕⊕⊕◯ MODERATE[1]	The mean difference in QOL (SF-12/SF-36 Mental Component Summary) after treatment was 0.73 lower (1.56 greater to 3.01 lower) with HSAT		413 (3 RCTs) [B,D,G]	
CPAP Adherence (h/night)*	⊕⊕⊕◯ MODERATE[2]	The mean CPAP Adherence (h/night) in the intervention group was 0.25 h more (0.21 less to 0.71 more) with HSAT		705 (6 RCTs) [B-G]	
		Relative Effect Baseline Risk	Comparative risk		
Compliance (No. of nights > 4 h)*	⊕⊕⊕⊕ HIGH	525 per 1000	**588 per 1000** (515 to 656) **OR 1.29** (0.96 to 1.73)	823 (5 RCTs) [A,C,D,F,G]	

*Critical Outcomes
[1]Quality of evidence for QOL as measured by the SF-36 was downgraded due to imprecision (i.e., 95% CI of mean difference crosses clinical decision threshold of 3 points for SF-36 physical and mental component summary scores and the origin of the plot)
[2]Quality of evidence for adherence was downgraded due to imprecision (i.e., 95% CI of mean difference crosses clinical decision threshold of 0.5 h/night and the origin of the plot)

Figure S24—HSAT vs. PSG (CPAP Adherence, h/night)

Study or Subgroup	HSAT Mean	HSAT SD	HSAT Total	PSG Mean	PSG SD	PSG Total	Weight	Mean Difference IV, Random, 95% CI
Antic 2009	4.11	2.7	94	4.56	2.7	83	16.4%	-0.45 [-1.25, 0.35]
Berry 2008	5.2	1.8	40	5.25	2.4	39	13.8%	-0.05 [-0.99, 0.89]
Kuna 2011	3.5	2.5	96	2.9	2.3	86	18.5%	0.60 [-0.10, 1.30]
Mulgrew 2007	6	1.5	31	5.4	2	30	14.6%	0.60 [-0.29, 1.49]
Rosen 2012	4.7	2.1	75	3.7	2.4	61	17.0%	1.00 [0.23, 1.77]
Skomro 2010	5.4	1	33	5.6	1.7	37	19.7%	-0.20 [-0.85, 0.45]
Total (95% CI)			**369**			**336**	**100.0%**	**0.25 [-0.21, 0.71]**

Heterogeneity: Tau² = 0.17; Chi² = 10.45, df = 5 (P = 0.06); I² = 52%
Test for overall effect: Z = 1.06 (P = 0.29)

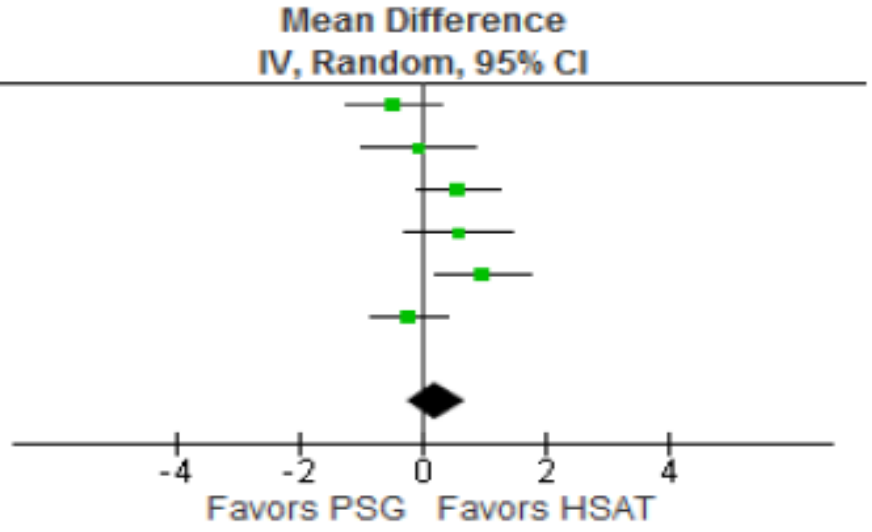
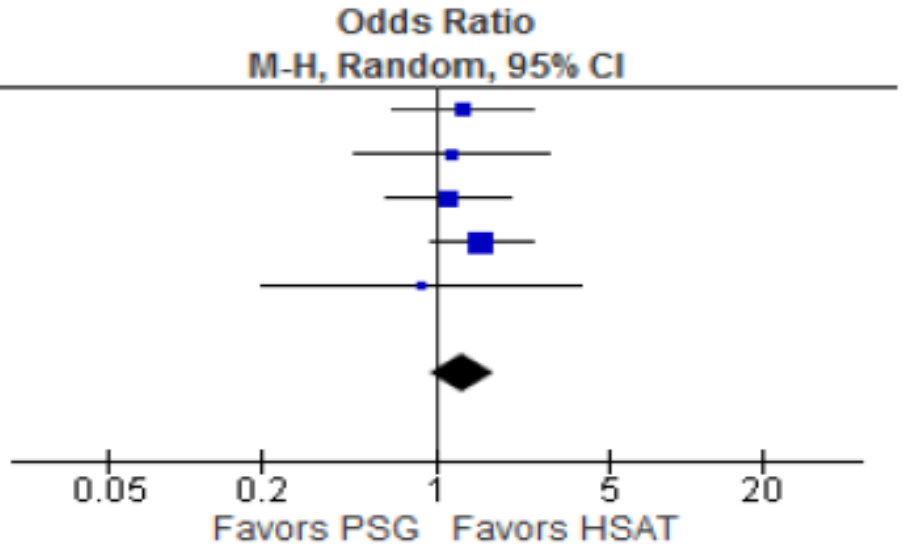


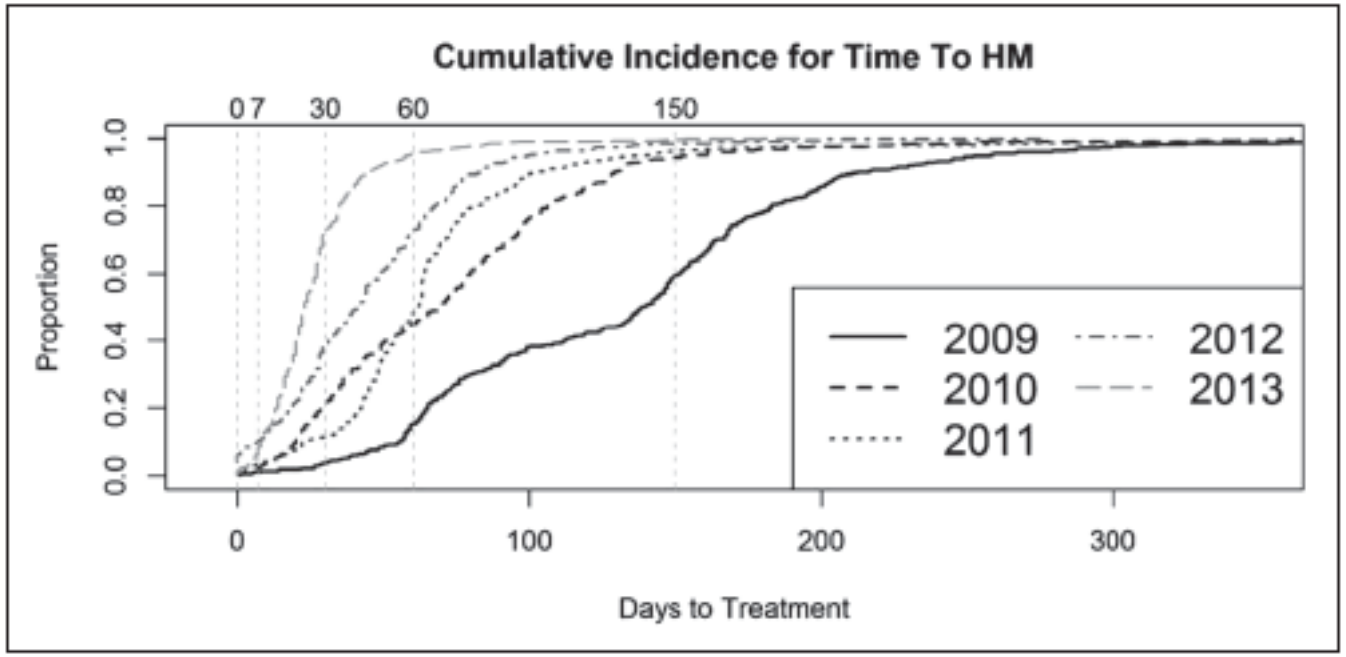
Figure S25—HSAT vs. PSG (CPAP Adherence, no. nights > 4 h)

Study or Subgroup	HSAT Events	HSAT Total	PSG Events	PSG Total	Weight	Odds Ratio M-H, Random, 95% CI
Andreu 2012	93	129	44	66	21.1%	1.29 [0.68, 2.45]
Berry 2008	24	40	22	39	10.8%	1.16 [0.47, 2.84]
Kuna 2011	53	96	45	86	25.3%	1.12 [0.63, 2.01]
Rosen 2012	72	163	46	134	38.8%	1.51 [0.94, 2.43]
Skomro 2010	29	33	33	37	4.0%	0.88 [0.20, 3.83]
Total (95% CI)		**461**		**362**	**100.0%**	**1.29 [0.96, 1.73]**
Total events	271		190			

Heterogeneity: Tau² = 0.00; Chi² = 0.97, df = 4 (P = 0.91); I² = 0%
Test for overall effect: Z = 1.70 (P = 0.09)



- **Οι ΦΜΥ βελτίωσαν το χρόνο αναμονής των ασθενών ως προς τη διάγνωση και τη θεραπεία, από μια διάμεση διάρκεια αναμονής 152 ημερών το 2009 σε 92 ημέρες το 2012 (P<0.0001).**



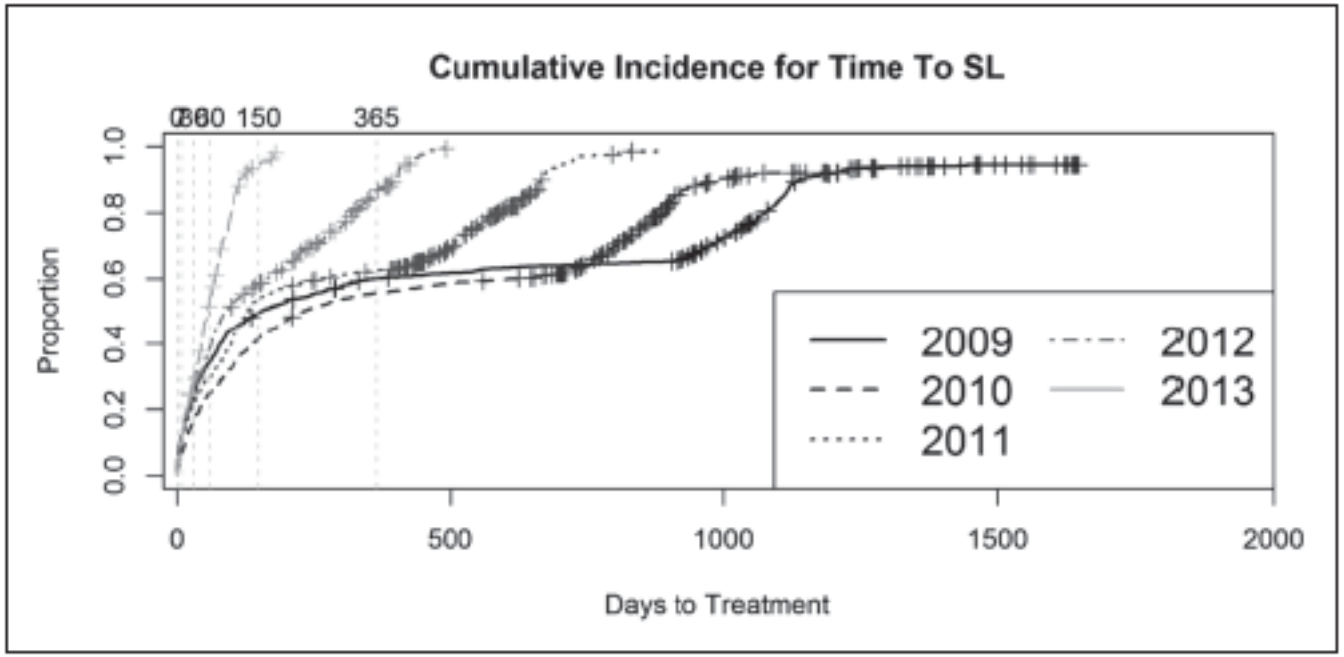


Figure 3) *Wait times for in-laboratory polysomnography (sleep lab [SL])*

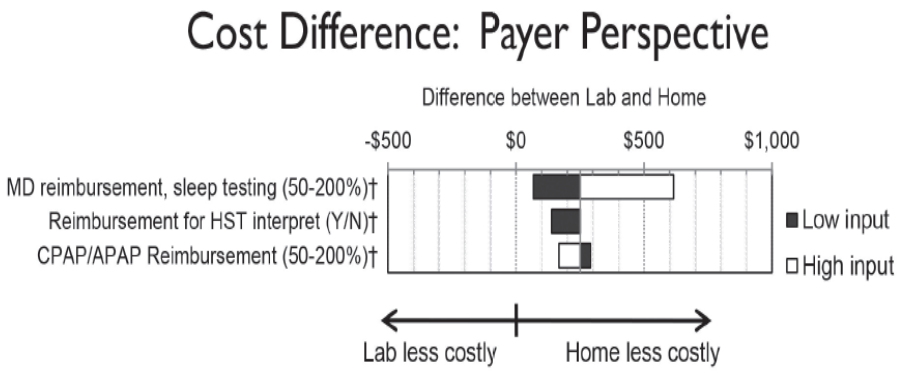
SA Stewart, R Skomro, J Reid, et al. Improvement in obstructive sleep apnea diagnosis and management wait times: A retrospective analysis of a home management pathway for obstructive sleep apnea. Can Respir J 2015;22(3):167-170

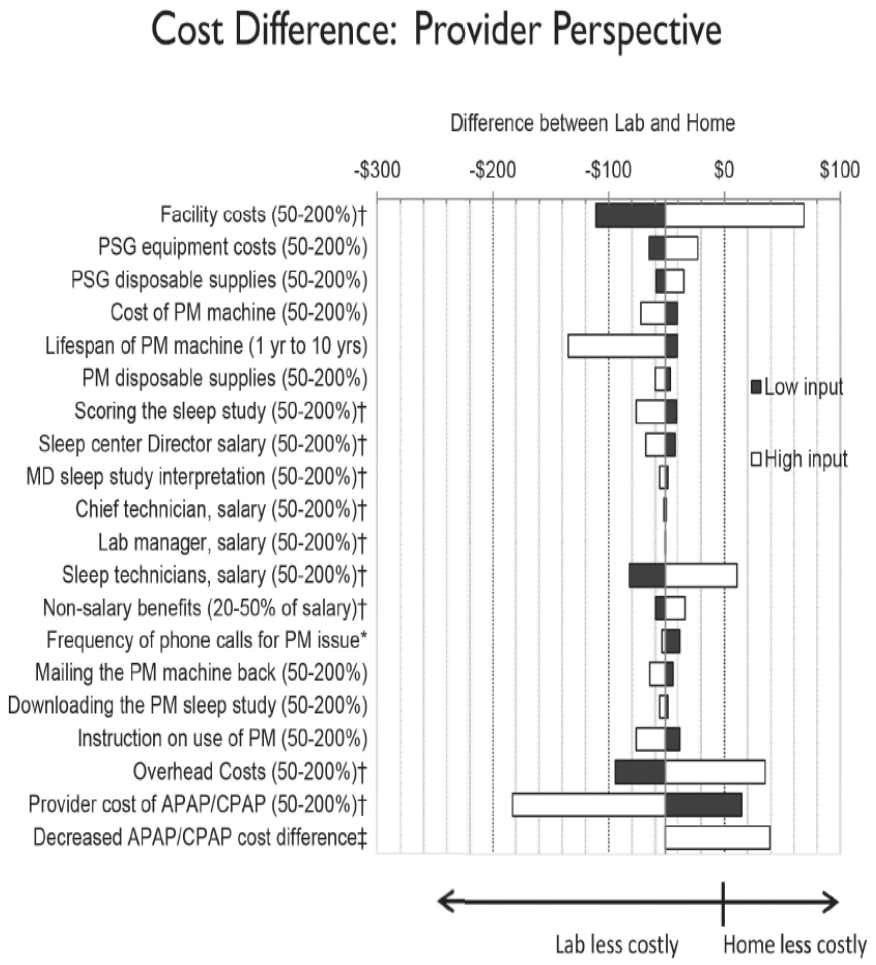
κόστος / όφελος ΦΜΥ έναντι ΠΜΥ για τη διάγνωση του ΣΑΥ

373 υψηλού κινδύνου για μέτριο / βαρύ ΣΑΥ

- **από την πλευρά του ασφαλιστικού παρόχου: κόστος ανά ασθενή με ΠΜΥ $1,840 ($1,660-$2,015) έναντι $1,575 ($1,439-$1,716) για ΦΜΥ – εξοικονόμηση $264 ($39-$496, P = 0.02) με ΦΜΥ**
- **από την πλευρά του παρόχου υπηρεσιών υγείας: κόστος ανά ασθενή με ΠΜΥ $1,697 ($1,566-$1,826) έναντι $1,736 ($1,621-$1,857) για ΦΜΥ, διαφορά of $40 (−$213-$142, P = 0.66) υπέρ του εργαστηρίου**
- **από την πλευρά του παρόχου υπηρεσιών υγείας: περιθώριο κέρδους $142 ($85-$202,P < 0.01) στο εργαστήριο, έναντι απώλειας −$161 (−$202-−$120, P < 0.01) κατ' οίκον**

SLEEP 2015;38(7):1027–1037.





ΠΛΕΟΝΕΚΤΗΜΑΤΑ έναντι μειονεκτημάτων για τον ασθενή:

- **άνεση, ελευθερία, αυξημένη δυνατότητα πρόσβασης, μειωμένο κόστος επί ορθής χρήσης**
- **στο οικείο περιβάλλον, με λιγότερους αισθητήρες, καλύτερος ύπνος**
- **δυνατότητα ελέγχου μη μετακινούμενου ασθενή**
- **διαφορετικοί τρόποι διάγνωσης ανάλογα με τις προτιμήσεις του ασθενή, ικανοποίηση**

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

ΜΕΙΟΝΕΚΤΗΜΑΤΑ έναντι πλεονεκτημάτων για τον ασθενή:

- **ανάγκη για επιπρόσθετο διαγνωστικό έλεγχο επί μη αποτελέσματος και υψηλής υποψίας, άρνηση**

- **μη διαγνωσμένος ασθενής με ΣΑΥ**

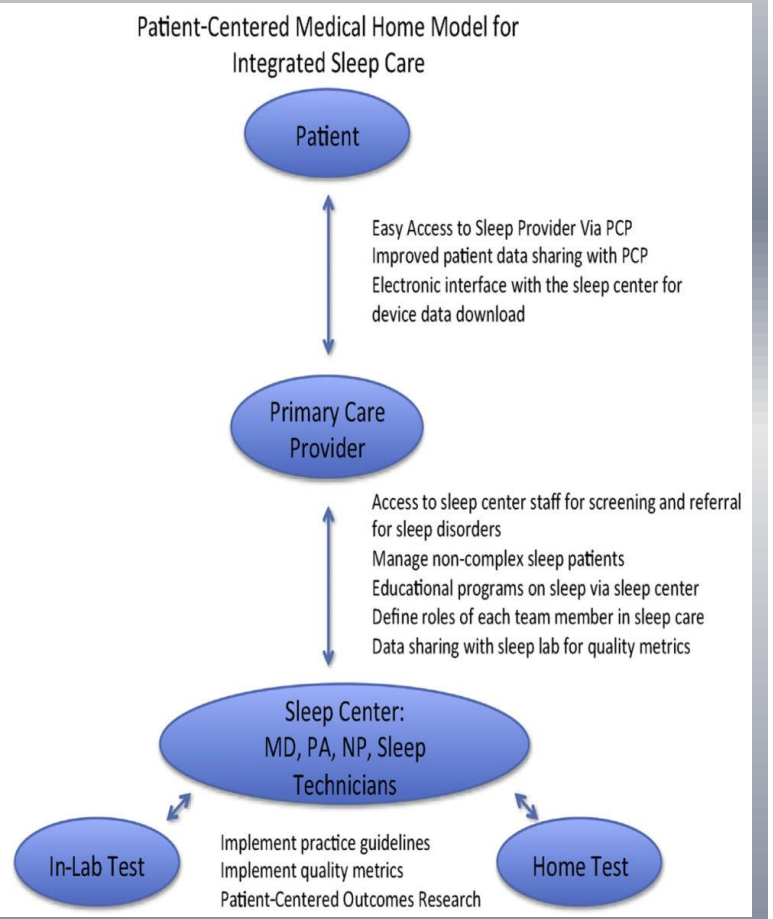
Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504

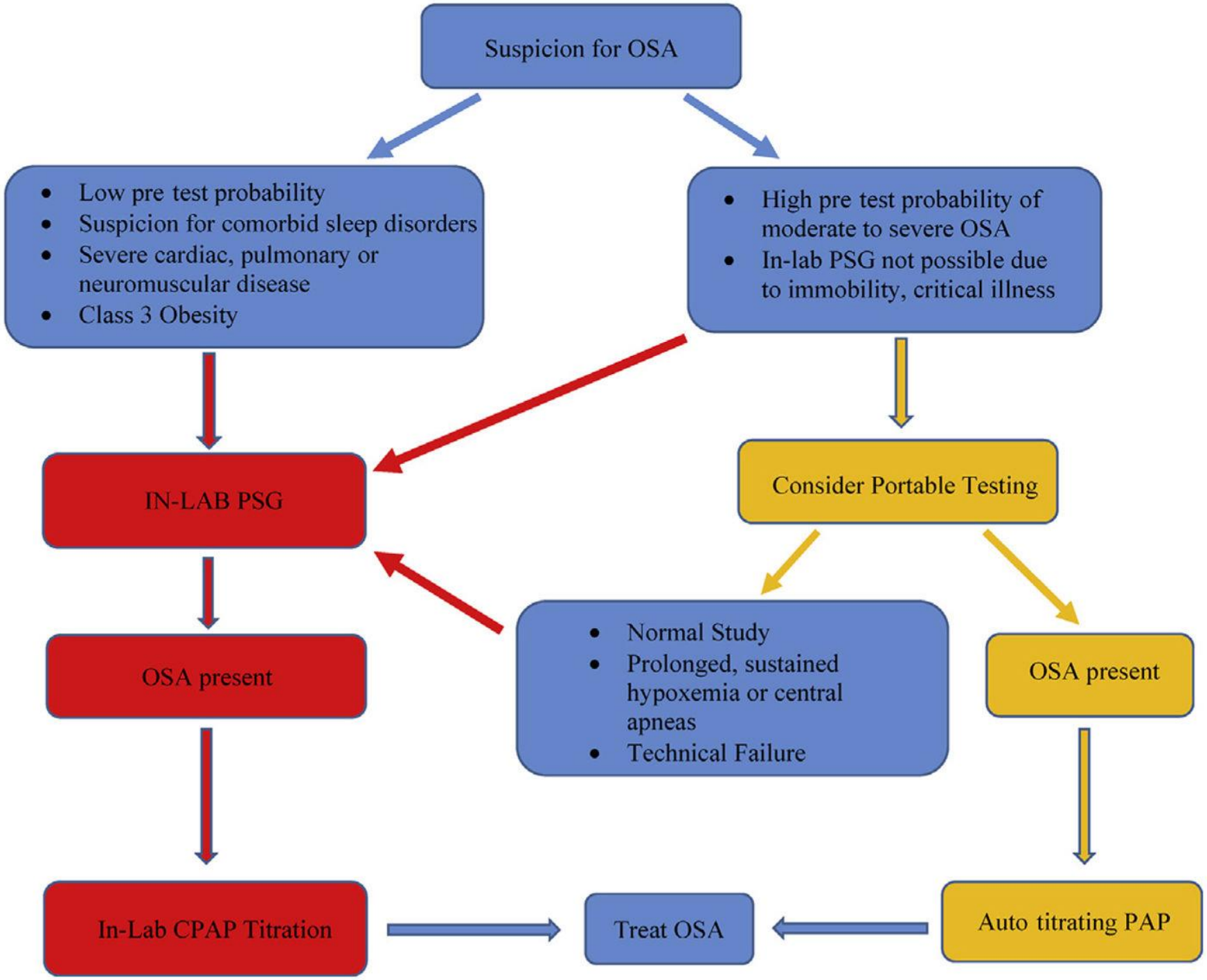
- **Η ΦΜΥ είναι λογική εναλλακτική διαγνωστική προσέγγιση σε ασθενή με υψηλή πιθανότητα για μέτριο / βαρύ ΣΑΥ.**

- **Δεν ενδείκνυται σε ασθενείς με άλλες διαταραχές ύπνου, νοσογόνο παχυσαρκία και σοβαρή καρδιοαναπνευστική νόσο.**

- **Επί αρνητικής ΦΜΥ ακολουθεί ΠΜΥ σε οργανωμένο εργαστήριο.**

- **Το κόστος / όφελος είναι μεγαλύτερο σε ΦΜΥ για τον ασφαλιστικό πάροχο και μπορεί να βελτιωθεί περαιτέρω με τη συνεργασία με οργανωμένο εργαστήριο ύπνου και την τακτική παρακολούθηση του ασθενή, έτσι ώστε να εξασφαλίζεται η συμμόρφωση στη θεραπεία**


Patient-Centered Medical Home Model for Integrated Sleep Care
Patient
Easy Access to Sleep Provider Via PCP
Improved patient data sharing with PCP
Electronic interface with the sleep center for device data download
Primary Care Provider
Access to sleep center staff for screening and referral for sleep disorders
Manage non-complex sleep patients
Educational programs on sleep via sleep center
Define roles of each team member in sleep care
Data sharing with sleep lab for quality metrics
Sleep Center: MD, PA, NP, Sleep Technicians
In-Lab Test
Implement practice guidelines
Implement quality metrics
Patient-Centered Outcomes Research
Home Test


Suspicion for OSA
Low pre test probability
Suspicion for comorbid sleep disorders
Severe cardiac, pulmonary or neuromuscular disease
Class 3 Obesity
High pre test probability of moderate to severe OSA
In-lab PSG not possible due to immobility, critical illness
IN-LAB PSG
Consider Portable Testing
OSA present
Normal Study
Prolonged, sustained hypoxemia or central apneas
Technical Failure
OSA present
In-Lab CPAP Titration
Treat OSA
Auto titrating PAP

Home Sweet Home