Decentralisation of Polysomnography Role of home sleep studies and Actigraphy

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Seminar Overview

- Introduction
- Decentralisation of polysomnography (PSG)
- Need of home sleep studies
- Comparison of type 1 and type 3 PSG in diagnosis of Obstructive Sleep Apnea (OSA)
- Positive airway pressure (PAP) titration
- Comparison of type 1 and type 3 PSG in PAP titration
- Actigraphy

Introduction

- Community prevalence of Obstructive Sleep Apnea Syndrome (OSAS) in India is 2.4-4.96% in males and 1-2.03% in females

- Worldwide 4% in males and 2% in females

INOSA Guidelines 2014

Introduction

- Sleep-related breathing disorders (SRBD)
  - OSA
  - CSA
  - OHS
  - Upper airway resistance syndrome
  - Nocturnal hypoventilation/hypoxemia secondary to cardiopulmonary or neuromuscular diseases

- Obstructive sleep apnea is the most common type of SRBD

Introduction

- Polysomnography (PSG) » diagnosis of suspected SRBD and for positive airway pressure (PAP) titration to choose an effective level of PAP for treatment

Chesson AL Jr et al. Sleep 1997;20:423-87
Kushida CA et al. Sleep 1995;28:499-521
Littner MR. Semin Respir Crit Care Med 2005; 26:56-67
Gay PC et al. Respir Care 2010;55:66-75

Introduction

- OSA and other SRBD evaluations have been occurring at an increasing rate over the last several years

- Expenditure on PSG in USA alone increased from $62 million in 2001 to $235 million in 2009 (CMS data)

http://oig.hhs.gov/publications/workplan/2011/FY11_WorkPlan-All.pdf

Reasons for 4-fold ↑ over 8 yrs

- Worsening epidemic of obesity

- Increasing availability (>2000 centres accredited by AASM till 2010)

- Increasing awareness amongst people

Disadvantages of type 1 PSG

- Located at urban center » testing of scattered or rural populations more difficult, access in a timely manner is limited or delayed
- Costly
- Labour-intensive
- Time-consuming
- Highly trained personnel

Disadvantages…….

- Overnight attendance and monitoring by technical staff
- So limited channel sleep studies (type 3) have come up nowadays, called portable monitoring (PM) or home sleep testing (HST)

What is decentralisation of PSG?

- This newer concept of limited sleep channel studies for the benefit of patients at large have led to the origin of decentralisation of PSG

- Venue shifted from in-lab to patient's home or elsewhere

- 4-7 channel study

Positive Airway Pressure (PAP)

- PAP is a standard treatment for pts with OSA

- Current standard of practice : after pt diagnosed with OSA » perform attended PSG » to achieve optimal pressure for upper airway patency

- 2 forms of PAP : Continuous positive airway pressure (CPAP) and Bilevel positive airway pressure (BiPAP)

Physiological effects of PAP Therapy
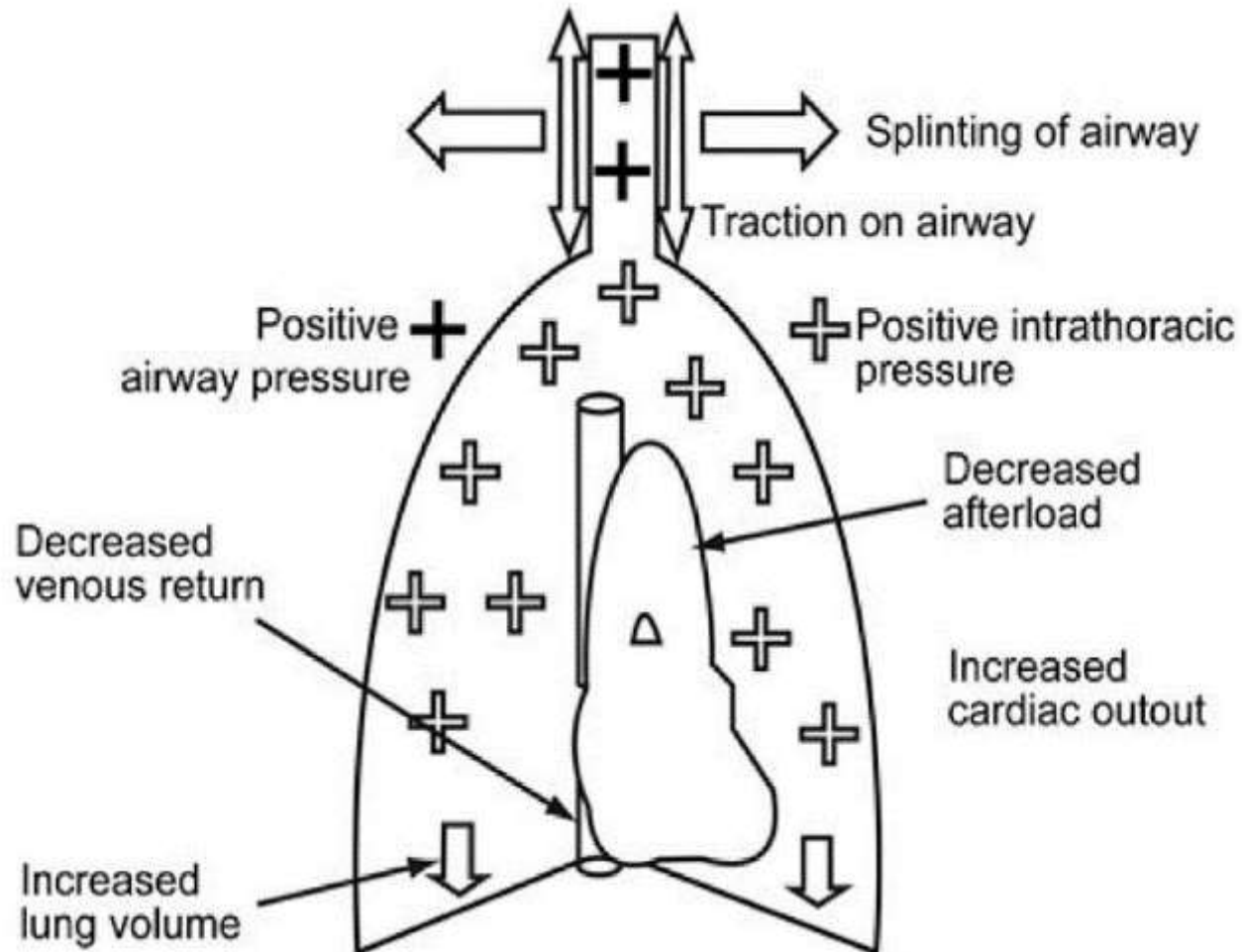
PAP delivery system

- Consists of 3 main components :

  » a PAP device

  » a nasal, oral, or oronasal interface (i.e., nasal mask, nasal pillows, full-face mask) held snug to the face by headgear and

  » a flexible hose that connects the device to the interface

PAP device

- An air pump (fan-driven or turbine system) that draws in external, filtered air and delivers pressurized airflow, adjustable by varying the pressure valve diameter or fan/turbine speed

- 4 basic types depending on their pressure delivery system :

  » Continuous positive airway pressure (CPAP)

  » Bilevel positive airway pressure (BiPAP)

  » Autotitrating positive airway pressure (APAP)

  » Adaptive servoventilation (ASV)

CPAP device

BiPAP device

Auto-PAP device

ASV device

Home Sleep Testing (HST)

History of home sleep testing (HST)

- Early 1990s : Scarce data ; devices not used in large scale

- 1994 : A review performed by the American Sleep Disorders Association (a precursor to the American Academy of Sleep Medicine) suggested the following criteria for performing home sleep testing-

Ferber R et al. Sleep 1994;17:378-92

- Patients with severe symptoms or when treatment is urgent and PSG is not readily available

- Patients unable to be studied in the laboratory

- Follow-up study after diagnosis established by PSG to evaluate response to therapy

History……

- 1997 : A repeated review suggested same recommendations stating there was not enough validated data for *"unattended"* use of home sleep testing devices

Chesson et al. Sleep 1997;20:423-87

History……

- 2003 : A Tri-Society (American Academy of Sleep Medicine, American Thoracic Society, American College of Chest Physicians) Practice Parameter stated that type 3 studies (limited channel home sleep tests) were acceptable :

  » in the *attended* setting, but not in *unattended* settings,

  » for general screening, or

  » for patients with comorbid conditions

Flemons et al. Chest 2003;124:1543-1579

History……

- 2007 : The Portable Monitoring Task Force of the AASM approved the use of HST with the condition that raw data be displayed on the devices for manual scoring prior to automated analysis & reviewed by a board certified sleep specialist during interpretation & reporting

What comprises type 3 testing?

- Uses portable monitors ; done at patient's home or elsewhere

- Type 3 devices record atleast 3 channels of data e.g. oximetry, airflow, and respiratory efforts

Type 3 testing

- More accessible and less expensive alternative to in-lab PSG

- Limitations » unlike type 1, cannot measure the duration of sleep, number of arousals or sleep stages, or detect non-respiratory sleep disorders, high chance of study failures as unsupervised
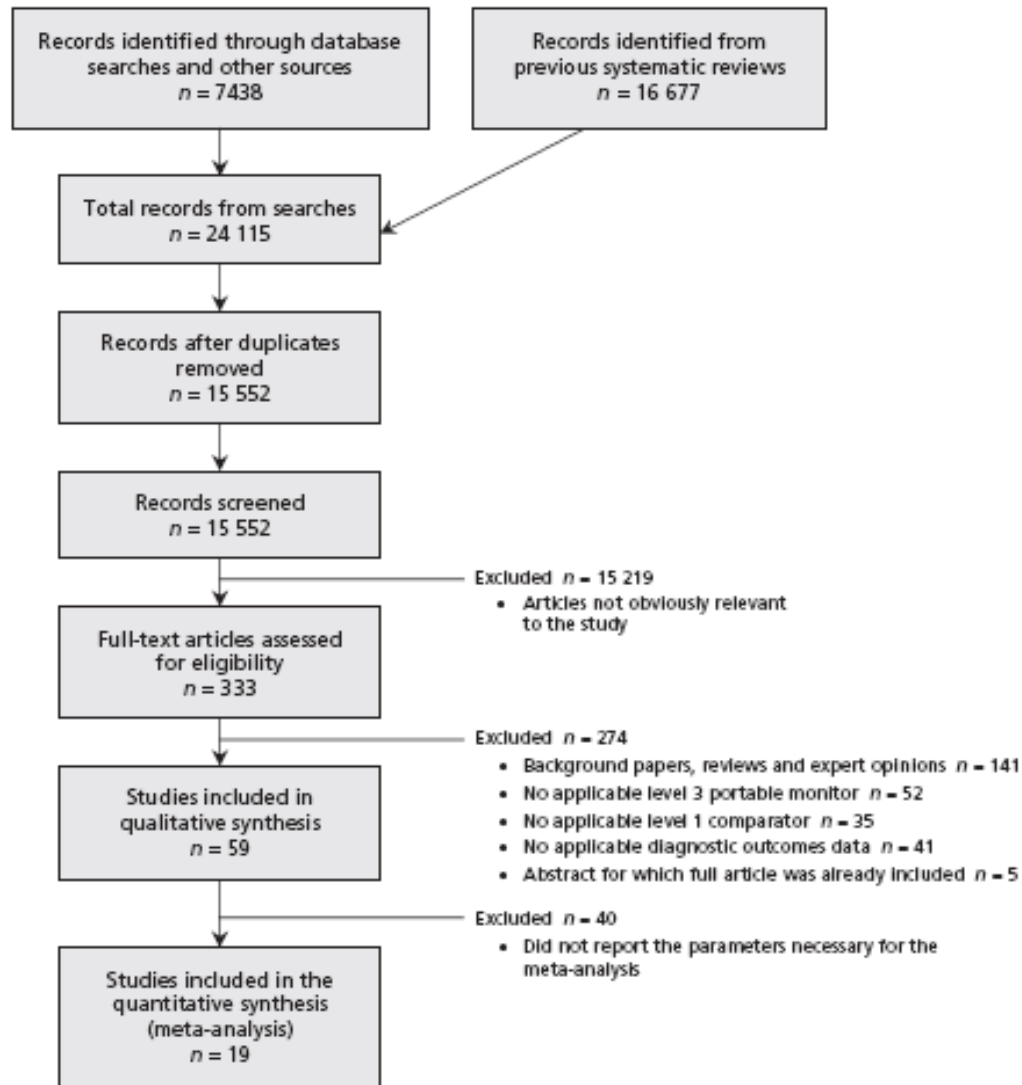
Blackman A et al. Can Respir J 2010;17:229-32

Mohsenin V. Am J Med 2013;126:el-3

Diagnostic accuracy of level 3 portable sleep tests versus level 1 polysomnography for sleep-disordered breathing: a systematic review and meta-analysis

Mohamed El Shayeb MD MSc, Leigh-Ann Topfer MLS, Tania Stafinski PhD, Lawrence Pawluk MD, Devidas Menon PhD

Selection of studies for inclusion in the review and meta-analysis

Records identified through database searches and other sources
$n = 7438$

Records identified from previous systematic reviews
$n = 16\ 677$

Total records from searches
$n = 24\ 115$

Records after duplicates removed
$n = 15\ 552$

Records screened
$n = 15\ 552$

Excluded $n = 15\ 219$
- Articles not obviously relevant to the study

Full-text articles assessed for eligibility
$n = 333$

Excluded $n = 274$
- Background papers, reviews and expert opinions $n = 141$
- No applicable level 3 portable monitor $n = 52$
- No applicable level 1 comparator $n = 35$
- No applicable diagnostic outcomes data $n = 41$
- Abstract for which full article was already included $n = 5$

Studies included in qualitative synthesis
$n = 59$

Excluded $n = 40$
- Did not report the parameters necessary for the meta-analysis

Studies included in the quantitative synthesis (meta-analysis)
$n = 19$

- The 59 studies included in the qualitative synthesis were classified as_

  1). Combination studies (10, 572 evaluable pts.)

  2). Simultaneous studies (20, 1152 evaluable pts.), and

  3). Separate studies (29, 3302 evaluable pts.)

Patient characteristics

- Included studies recruited patients with suspected OSA
- Patients were referred for PSG after a pretest assessment that included sleep questionnaires, history, and clinical examination

Patient characteristics

- Mean age of 50.8 yrs, a mean ESS score of 11.6, and a mean BMI of 30.4

- Male : female = 2.9:1

- A total of 1382 comorbidities were reported :

  » Cardiovascular conditions the most common (1080 pts., 78.1% of total comorbidities)

Patient characteristics

- HTN most frequently reported (574 pts), f/b stable CHD (142 pts), and CAD (113 pts)

- Respiratory comorbidities (0.7% of total) were limited to asthma (1 pt) and COPD (9 pts)

Study characteristics

- 4 channels were measured in all studies : nasal airflow, thoracoabdominal movement, oxygen saturation, and body position

- 2 studies reported adverse events with in-lab type 3 tests (1 hypertensive crisis, and 1 pacemaker interference)

Abraham WT et al. Congest Heart Fail 2006;12:241-7

Santos-Silva R et al. Sleep 2009;32:629-36

Study characteristics

- 1 study reported sensor irritation in 27 pts.

Abraham WT et al. Congest Heart Fail 2006;12:241-7

- Technical failures affected 0.44% of pts. in type 1 tests ; 1.30% pts (in-lab) and 10.25% pts (home) in type 3 tests.

www.cmaj.ca/cmaj.130952

Results

- 59 studies included, involving 5026 evaluable pts. (mostly those s/o OSA), only 19 were included in the meta-analysis owing to the lack of parameters necessary for the meta-analysis

- The estimated area ↓ROC curve was high ranging between 0.85-0.99 across different levels of disease severity

Results

- Summary sensitivity ranged between 0.79-0.97, and summary specificity ranged between 0.60-0.93 across different AHI cut-offs

- No significant difference in the clinical management parameters between pts who ↓either test to receive their diagnosis

Conclusion

- Type 3 sleep studies are safe and convenient for diagnosing OSA in pts with a high pretest probability of moderate to severe forms of the condition without substantial comorbidities

- Type 1 PSG remains the cornerstone for the diagnosis in pts s/o comorbid sleep disorders, unstable medical conditions, or complex SRBD

Conclusion…..

- Further studies assessing the use of portable sleep studies in pts with conditions other than OSA, and in pts with OSA and comorbidities, are needed

Auto-PAP titration

- Intelligent devices with in-built microprocessors
- Different names » self-adjusting/automatic/auto-adjusting/ smart CPAP/auto-titrating PAP

APAP machines

Revolution of APAP devices

- Older generation » sensors measured only the pressure inflections (vibrations) caused by snoring

- Next generation » could sense flow-based changes like apnea, hypopnea, or inspiratory flow limitation based on the inspiratory flow contour

Revolution……

- Newer generation » possess multiple functions :
- ➢ differentiate central from obstructive apneas
- ➢ identify Cheyne-Stokes respiration
- ➢ identify hypoventilation
- ➢ compensate for air-leaks
- ➢ measure both upper & lower airway resistance

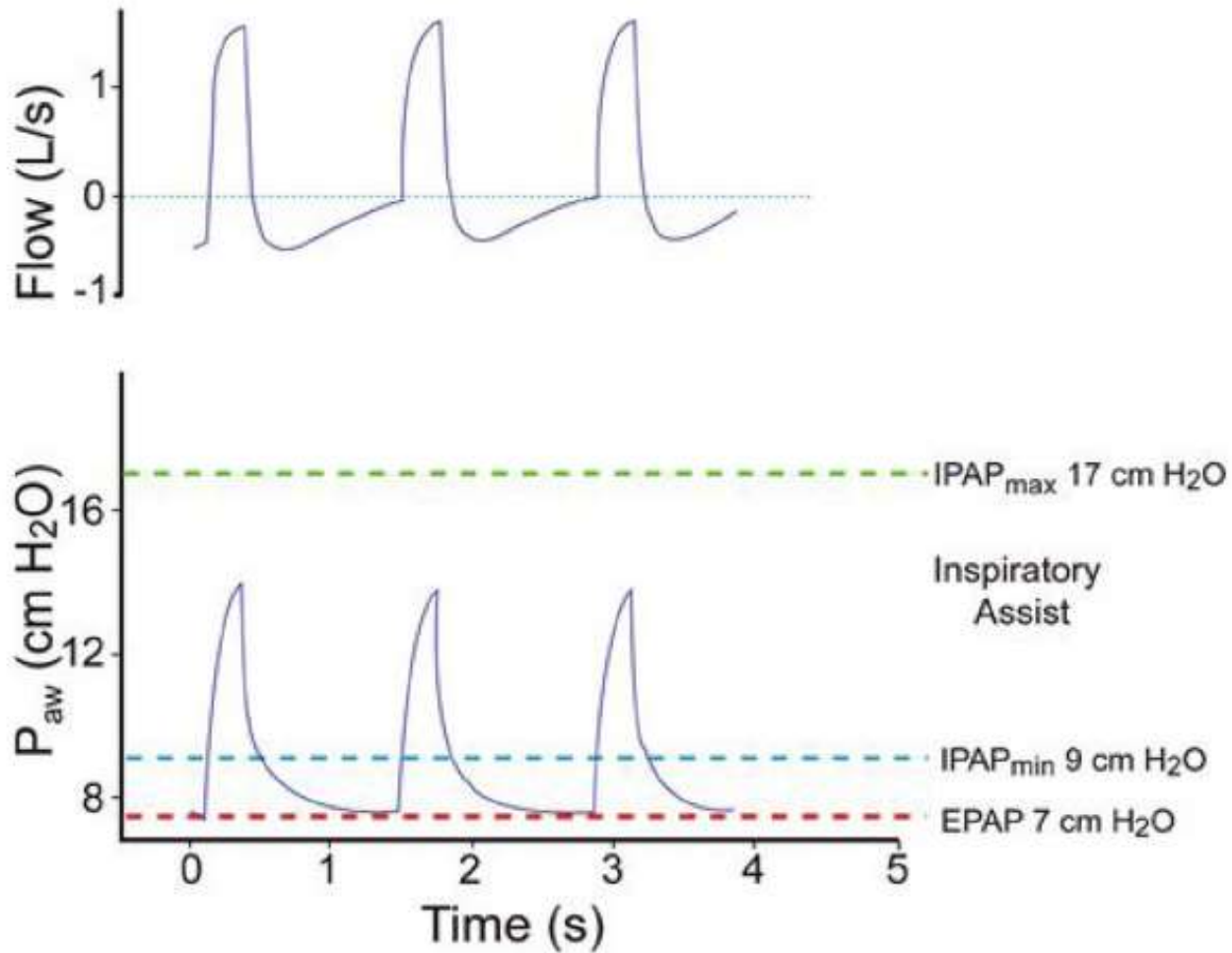# Technology of APAP devices

- Functions of APAP devices :

   (a). sensing of SRBD events (sensors)

   (b). automated computing & analysis of the sensed signals (analysis)

   (c). hierarchal set of algorithms » determines the action taken by the APAP device in response to the conditions exposed (effectors)

Principles of operation of servo ventilation
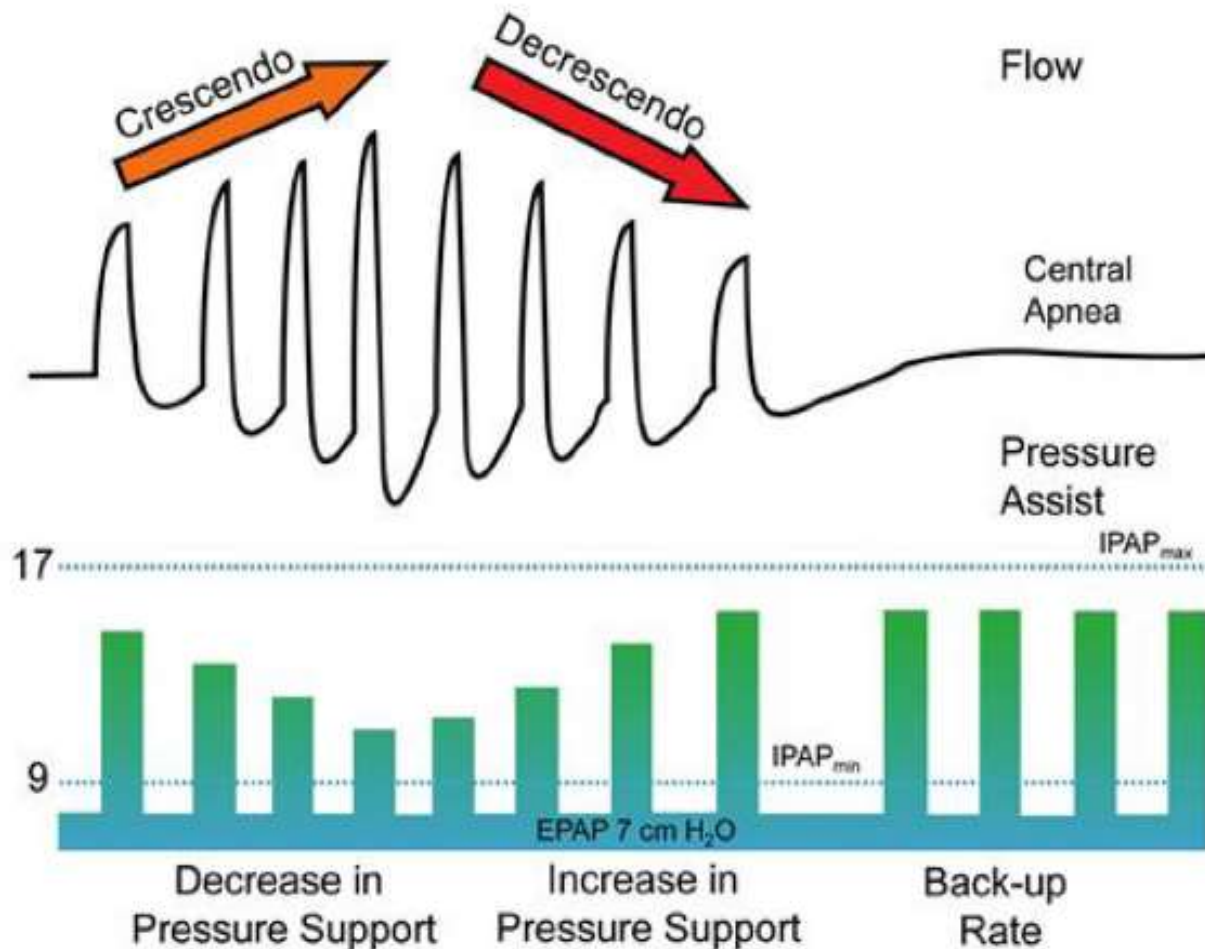
Settings of servo ventilator

Comparison studies on PAP titration

Reference	Population	Methodology	Outcome	Comments
Mulgrew et al. Ann Intern Med 2007; 146:157-66.	68 pts.with ↑pretest probability of mod-severe OSA (AHI > 15/h) identified by sequential application of the ESS score, Sleep Apnea Clinical Score, & overnight oximetry.	Pts. randomly assigned to PSG or ambulatory titration using combination of auto-CPAP & overnight oximetry; observed for 3 mths.	At 3mths f/u, no differences in the primary outcome; adherence to CPAP therapy was better in the ambulatory group than in the PSG group.	1).In pts. with ↑probability of OSA, PSG confers no advantage over ambulatory approach in terms of diagnosis & CPAP titration. 2).Ambulatory approach may improve adherence to treatment. 3).When access to PSG is inadequate, ambulatory approach can be used to expedite M_x.

Reference	Population	Methodology	Outcome	Comments
Cross et.al. Sleep, Vol.29, No.11, 2006	200 CPAP-naïve pts. with OSAHS requiring CPAP treatment Regional sleep centre & patient's home	Prospective, randomized, single-blind, parallel-group, controlled trial 100 pts » standard 1-night in-hosp auto-CPAP titration 100 pts » 3 night's home auto-CPAP titration	CPAP pressures at titration, no.of mask leaks, initial acceptance rates similar in both the groups At 3mths f/u, no significant difference in CPAP use, ESS score, OSLER, functional outcomes of Sleep Questionnaire, or SF-36 between both the groups	Home-based automated CPAP titration is as effective as in-lab automated titration in initiating treatment for OSAHS

Reference	Population	Methodology	Outcome	Comments
Rosen et.al. Sleep, Vol.35, No.6, 2012	373 consecutive new referrals, age ≥ 18yrs with high probability of mod-severe OSA (AHI ≥ 15/h) identified by clinical algorithm & ESS score ≥ 12	Randomized, open-label, parallel group, unblinded, multicenter Approx. equal no.of pts in both arms HST f/b 1wk auto-PAP with fixed pressure CPAP prescription based on the 90% pressure from auto-PAP therapy compared with attended, in-lab studies	At 3mths f/u, PAP usage & adherence were higher in both groups Acceptance of PAP therapy, titration pressures, effective titrations, time to treatment, ESS score change did not differ between both the groups	Home-based strategy for diagnosis & treatment compared with in-lab PSG not inferior in terms of acceptance, adherence, time to treatment & functional improvements

Reference	Population	Methodology	Outcome	Comments
Skomro et.al. Chest 2010;138(2): 257-263	102 subjects randomly recruited	Randomized trial HST f/b 1wk auto-CPAP & fixed pressure CPAP based on the 95% pressure derived from the auto-CPAP device & in-lab PSG with CPAP titration	After 4wks of CPAP therapy » no significant differences in ESS, PSQI, SAQLI, SF-36 vitality, SF-36, BP No difference in CPAP adherence in both the groups	Diagnosis & treatment in sleep lab not superior to HST in terms of improvement of sleepiness scores, sleep quality, quality of life, BP, CPAP adherence

Recommendations in INOSA Guidelines 2014

- Type 1 sleep study is the "gold standard" for evaluation of SRBD **(Evidence Quality A, Strong Recommendation)**

- Lab attended PSG is not necessary in all pts s/t have OSA

INOSA Guidelines….

- Portable monitoring or OCST with type 3 or 4 devices (airflow, oxygen, & respiratory effort) is adequate for diagnosis when :

  » used in conjunction with comprehensive sleep evaluation
  » in pts with high pretest probability of moderate to severe OSA

  » without comorbid sleep disorders or medical disorders like pulmonary disease, neuromuscular disease, or congestive heart failure

  (Evidence Quality A, Strong Recommendation)

Actigraphy

- Has been used to study sleep/wake patterns for over 20 yrs
- Advantage over PSG » can conveniently record continuously for 24 hrs a day for longer periods

- Not indicated for routine diagnosis or assesment

- Useful adjunct for diagnosis of insomnia, circadian rhythm disorders or excessive sleepiness

Sleep 1995;18:285-287

- Several review papers have concluded :

  » Wrist actigraphy can approximate sleep vs wake state during 24 hrs

  » Can be used for monitoring insomnia, circadian sleep/wake disturbances, and periodic limb movement disorder

Broughton R et al. J Clin NeuroPhysiol 1996;13(4):272-284

Teicher MH. Harvard Review of Psychiatry 1995;3(1):18-35

- Actigraphs » devices placed on the wrist, ankle, or trunk to record body movements
- Collected data are downloaded to a computer for display and analysis of activity/inactivity » analyzed to estimate wake/sleep

- First actigraphs were developed in the early 1970s

- Several modifications over the years

- Digital types used today

- Modern day actigraphs have movement detectors » accelerometers

- Sufficient memory to record for upto several weeks

Actigraphs

Validation Studies on Actigraphy

Study/Year	Population (mean age in yrs)	Subjects	Comparison Methodology	Outcome/ Comments
Wang et.al/2010	**39 (61.5)**	**Pts with NSCLC**	**Actigraphy vs sleep diary**	**87% congruency between actigraphy & sleep diaries** **Actighray » significantly more nighttime awakenings**
Sanchez-Ortuno et.al/2010	**62 (28.4)**	**Pts with insomnia (31), control subjects (31)**	**Actigraphy vs PSG vs sleep diary**	**No significant difference in WASO, TST, or SE for either group** **Stronger correlation between actigraphy & sleep diaries than PSG & sleep diaries for SOL**

Study/Year	Population (mean age in yrs)	Subjects	Comparison Methodology	Outcome/ Comments
Sivertsen et.al/2006	**34 (60.5)**	**Chronic primary insomnia**	**Actigraphy vs PSG**	**Actigraphy » sensitivity 95.2% for detecting sleep** **Specificity 36.3% for detecting wakefulness, accuracy 83.1%** **Actigraphy underestimated total wake time, SOL & overestimated TST & SE**
Hedner et.al/2004	**228 (48.8)**	**Suspected OSA**	**Actigraphy vs PSG**	**SE, TST, SL » not different in mild, mod or severe OSA betw both groups** **In mild OSA pts actigraphy overestimated SL**

- The International Classification of Sleep Disorders, 2nd edition » Atleast 7 days of actigraphy performed with a sleep diary demonstrate consistency in pathology

Take home message

- Both type 1 and type 3 PSG perform same as regards diagnosis of OSA

- Type 3 PSG is cost-effective and easily accessible » improves adherence to treatment

- Type 3 PSG can expedite management

- Actigraphy » newer adjunct for diagnosing insomnia, circadian rhythm disturbances, and excessive somnolence