**Taiwan Society of Pulmonary and Critical Care Medicine Meeting** 

# **CPAP and NIV in Japan**

Dept. of Respiratory Care and Sleep Control Medicine, Graduate School of Medicine, Kyoto University, Japan Kazuo Chin (Hwaboo JIN) (TAIWAN, Kaohsiung: Kaohsiung Exhibition Center 2019.12.8.)

### Conflict of Interest Disclosures – Authors/Presenters

The authors do not have any potential conflicts of interest to disclose,

OR

Х

The authors wish to disclose the following potential conflicts of interest related to content in this lecture:

Type of Potential Conflict	Details of Potential Conflict
Grant/Research Support	
Consultant	
Speakers' Bureaus	
Financial support	
Other	Kazuo Chin belongs to the department which are donated by 4 companies; Philips-Respironics, Resmed Japan, Fukuda Denshi, and Fukuda Lifetec Keiji.

This talk presents material that is related to one or more of these potential conflicts, and the following objective references are provided as support for this lecture:

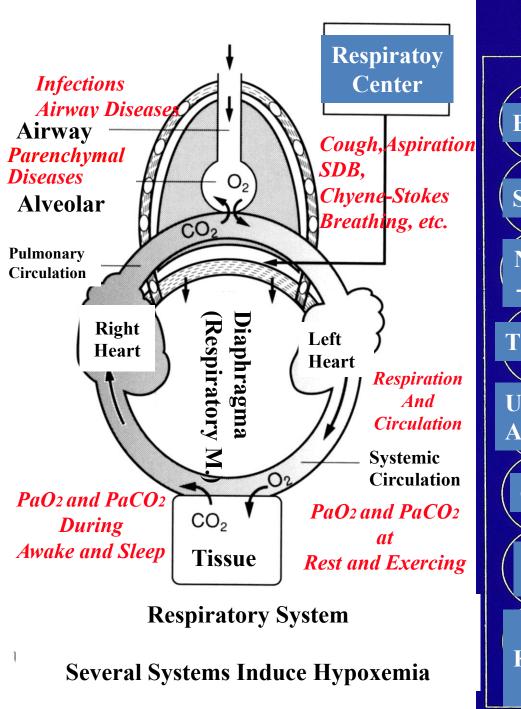
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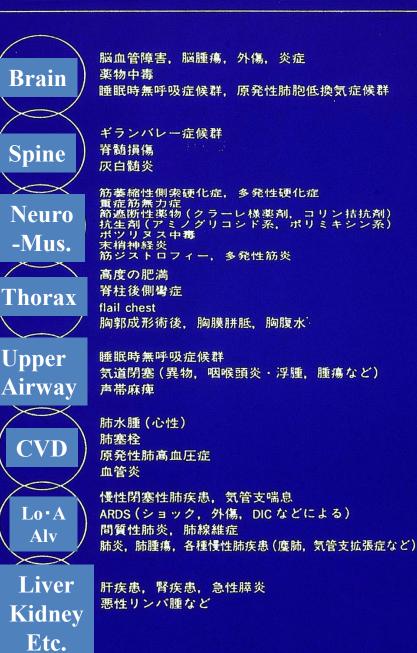
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3.

# Today's presentation

- Respiratory care and sleep disordered breathing
- The history of home respiratory care in Japan
- Telemedicine of CPAP in Japan
- Future home respiratory care





**Factors for Respiratory Failure** 

It is important to manage or control sleep disorders including sleep disordered breathings from ICU to Home.

Sleep Disorders (over 60 diseases) (International Classification of Sleep Disorders: ICSD-3, 2014)

1) Insomnia: 3+2

2) Sleep Related Breathing Disorders: 17+2

- 3) Central Disorders of Hypersomnolence: 8+1
- 4) Circadian Rhythm Sleep-Wake Disorders: 7

5) Parasomnias: 14+1

6) Sleep Related Movement Disorders: 10+3

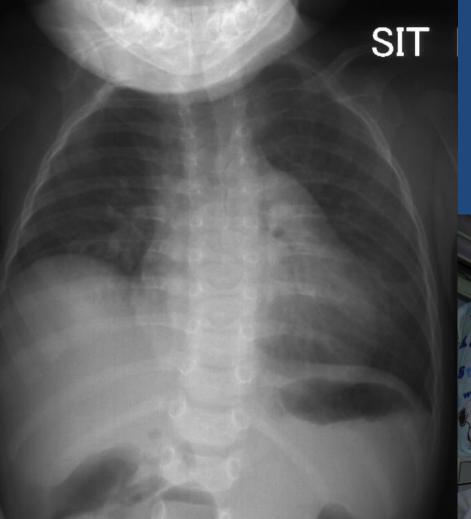
pOther Sleep Disorder

 Apendix A: Sleep Related Medical and Neurological Disorders: 6 Fatal Familial Insomina, Sleep Related Epilepsy, Sleep Related Headaches, Sleep Related Laryngospasm, Sleep Related Gastroesophageal Reflux, Sleep Related Myocardial Ischemia7)



- 7 mo. Female
- Diagnosis: Atrial Septal Defect, Pulmonary Hypertension, R-phrenic nerve palsy Cervical bone abnormality
- Therapy: Closure of ASD

# Chest X-rays

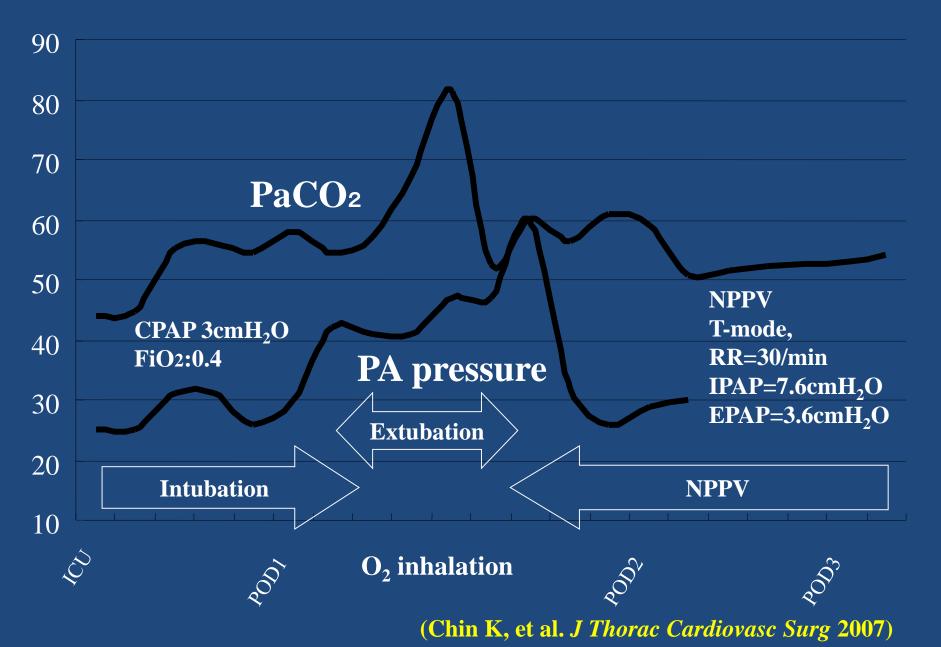


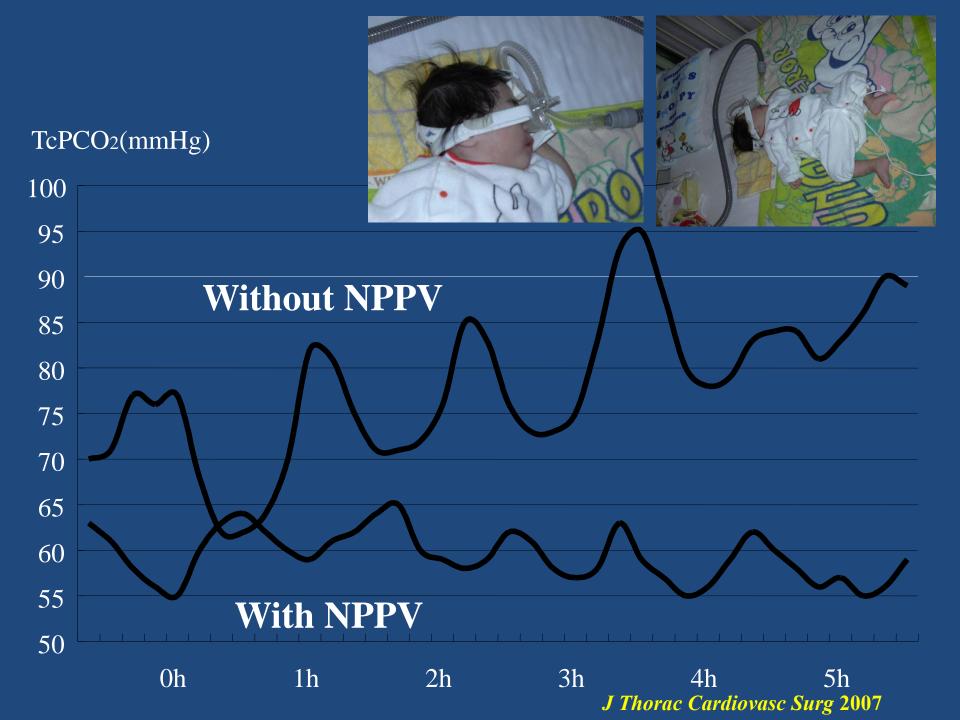


Elevation of r-diaphragm CTR: 57% Bilateral pulmonary vascular shadow increase



### PaCO<sub>2</sub> PA pressure (mmHg)







Pictures of pediatric patients receiving noninvasive ventilation during the perioperative stage of liver transplantation. And the cover of the Journal.

Murase K, Chin K et al. *Liver Trsnspl* 2012.

Predictive Factors for Reintubation following Noninvasive Ventilation in Patients with Respiratory Complications after Living Donor Liver Transplantation Chihara Y, Chin K et al. PIOS ONE 2013

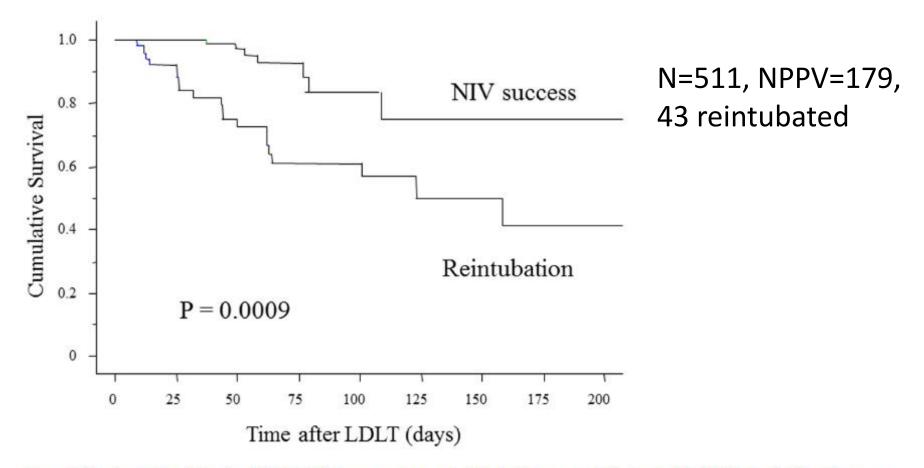


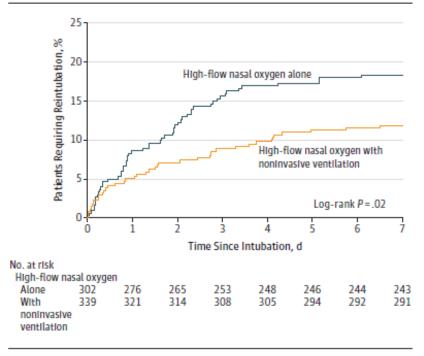
Figure 1. Survival curve following LDLT in NIV success group and reintubation group. Patients who failed NIV had a significantly poorer prognosis (p = 0.0009). Abbreviations: LDLT, living-donor liver transplantation; NIV, noninvasive ventilation. doi:10.1371/journal.pone.0081417.g001

#### JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

## Effect of Postextubation High-Flow Nasal Oxygen With Noninvasive Ventilation vs High-Flow Nasal Oxygen Alone on Reintubation Among Patients at High Risk of Extubation Failure A Randomized Clinical Trial

JAMA. 2019;322(15):1465-1475. doi:10.1001/jama.2019.14901 Published online October 2, 2019.

Figure 2. Kaplan-Meier Analysis of Time From Extubation to Reintubation for the Overall Study Population



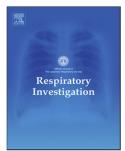
The median observation time was 7 days (interquartile range, 7-7) in both treatment groups.



Contents lists available at ScienceDirect

### **Respiratory Investigation**

journal homepage: www.elsevier.com/locate/resinv



### Guideline

### The Japanese Respiratory Society Noninvasive Positive Pressure Ventilation (NPPV) Guidelines (second revised edition)



Tsuneto Akashiba<sup>a,1</sup>, Yuka Ishikawa<sup>b,1</sup>, Hideki Ishihara<sup>c,1</sup>, Hideaki Imanaka<sup>d,1</sup>, Motoharu Ohi<sup>e,1</sup>, Ryoichi Ochiai<sup>f,1</sup>, Takatoshi Kasai<sup>g,1</sup>, Kentaro Kimura<sup>h,1</sup>, Yasuhiro Kondoh<sup>i,1</sup>, Shigeru Sakurai<sup>j,1</sup>, Nobuaki Shime<sup>k,1</sup>, Masayuki Suzukawa<sup>l,1</sup>, Misa Takegami<sup>m,1</sup>, Shinhiro Takeda<sup>n,1</sup>, Sadatomo Tasaka<sup>o,1</sup>, Hiroyuki Taniguchi<sup>i,1</sup>, Naohiko Chohnabayashi<sup>p,1</sup>, Kazuo Chin<sup>q,\*,1</sup>, Tomomasa Tsuboi<sup>r,1</sup>, Keisuke Tomii<sup>s,1</sup>, Koji Narui<sup>t,1</sup>, Nobuyuki Hasegawa<sup>u,1</sup>, Ryuichi Hasegawa<sup>v,1</sup>, Yoshihito Ujike<sup>w,2,3</sup>, Keishi Kubo<sup>x,2,4</sup>, Yoshinori Hasegawa<sup>y,2,4</sup>, Shin-ichi Momomura<sup>z,2,5</sup>, Yoshitsugu Yamada<sup>aa,2,6</sup>, Masahiro Yoshida<sup>ab,2,7</sup>, Yukie Takekawa<sup>ac,8</sup>, Ryo Tachikawa<sup>ad,8</sup>, Satoshi Hamada<sup>ad,8</sup>, Kimihiko Murase<sup>ad,8</sup>

> \*Corresponding author. Tel.: +81 75 751 3852; fax: +81 75 751 3854. E-mail address: chink@kuhp.kyoto-u.ac.jp (K. Chin).

## Sleep Related Breathing Disorders(17+2) (ICSD-3)

## OBSTRUCTIVE SLEEP DISORDERS

# Obstructive Sleep Apnea, Pediatric CENTRAL SLEEP APNEA SYNDROMES

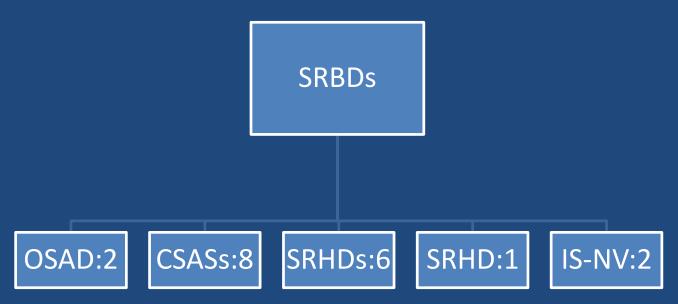
**Central Sleep Apnea with Cheyne-Stokes Breathing (CSB)** Central Apnea Due to a Medical Disorder without CSB Central Sleep Apnea Due to High Altitude Periodic Breathing Central Sleep Apnea Due to a Medication or Substance Primary Central Sleep Apnea Primary Central Sleep Apnea of Infancy Primary Central Sleep Apnea of Prematurity Treatment-Emergent Central Sleep Apnea
 SLEEP RELATED HYPOVENTILATION DISORDERS

**Obesity Hypoventilation Syndrome** Congenital Central Alveolar Hypoventilation Syndrome Late-Onset Central Hypoventilation with Hypothalamic Dysfunction Idiopathic Central Alveolar Hypoventilation Sleep Related Hypoventilation Due to a Medication or Substance

SLEEP RELATED HYPOXEMIA DISORDER

Sleep Related Hypoxemia ISOLATED SYMPTOMS AND NORMAL VARIANTS Snoring Catathrenia

### Sleep-Related Breathing Disorders (SRBDs) (2014 ICSD-3)



Body weight reduction, CPAP, Oral appliance, Surgery, Oxygen, NPPV, ASV, Artificial ventilation with tracheostomy, Nasal high flow

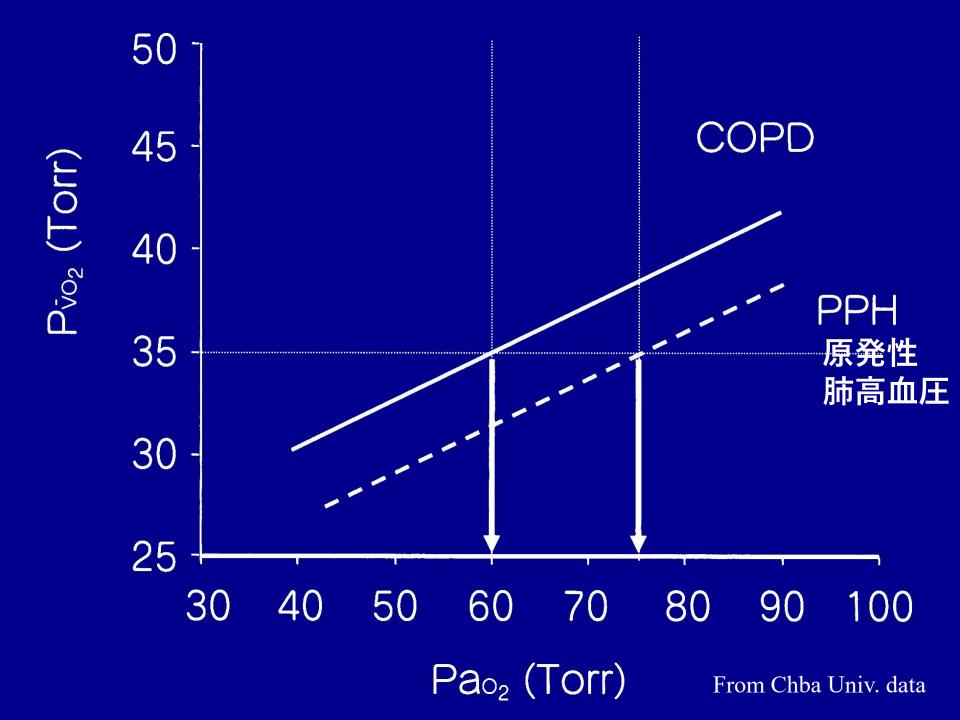
Managing respiratory care is managing respiratory events during sleep.

# Home Respiratory Care in Japan I

- LTOT (long-term oxygen therapy), HOT (home oxygen therapy) in Japan
- **TIPPV** (tracheostomy intermittent positive pressure ventilation)
- NPV (negative pressure ventilation)
- NPPV (noninvasive positive pressure ventilation)
- **CPAP** (continuous positive airway pressure)
- ASV (adaptive servo ventilation)

Home Respiratory Care in Japan II • **LTOT:** long-term oxygen therapy **1985.3:** PaO2  $\leq$  50 mmHg or  $\leq$  60 mmHg with Cor Pulmonale **1988.4:** PaO2  $\leq$  55 mmHg or  $\leq$  60 mmHg with desaturation during sleep or exercise, and portable oxygen tank was permitted. **1996.4:** Pulmonary hypertension

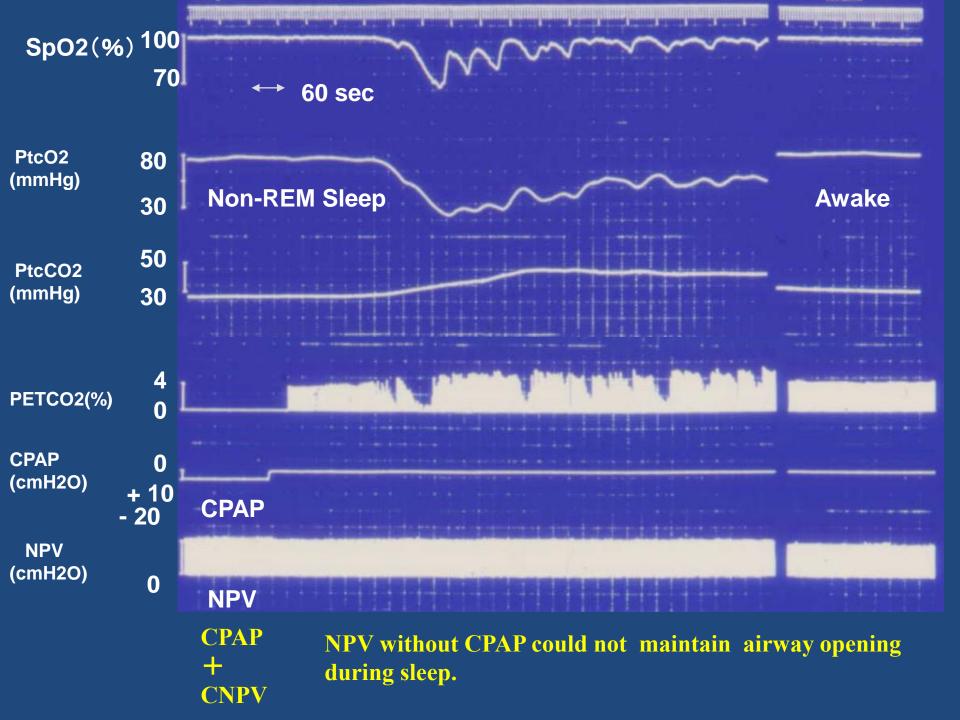
- 2004.4: Chronic heart failure with Cheyne-Stokes breathings and apnea and hypopnea index ≥ 20.
- 2008.3: Demand valve was permitted



Home Respiratory Care in Japan III

- **TIPPV:** tracheostomy intermittent positive pressure ventilation
  - **1990.4:**ALS, Muscular dystrophy, Multiple myositis, and etc. neuro-mascular disease
- NPV: negative pressure ventilation
   1992.4: ALS, Muscular dystrophy, Multiple myositis, and etc. neuro-mascular disease
   TURBY NPV
  - 1994.4: Patients who are needed home mechanical ventilation (HMV), which are diagnosed by doctors





		Pathophysiology of SDB						
			SDB	Factors				
<b>Sleep-Disordered Breathing</b>			CSA	<b>Control of Breathing</b>				
		OSA	Upper Airaway					
		Hypo (REM)	Inspiratory M.					
<b>Respiratory support during sleep</b>								
		Patency of		spiratory				
		Upper Airway	S	upport				
	CPAP	+		—				
	NPPV	+		+				
	NPV			+				

The efficacy of a custom-fabricated nasal mask on gas exchange during nasal intermittent positive pressure ventilation.

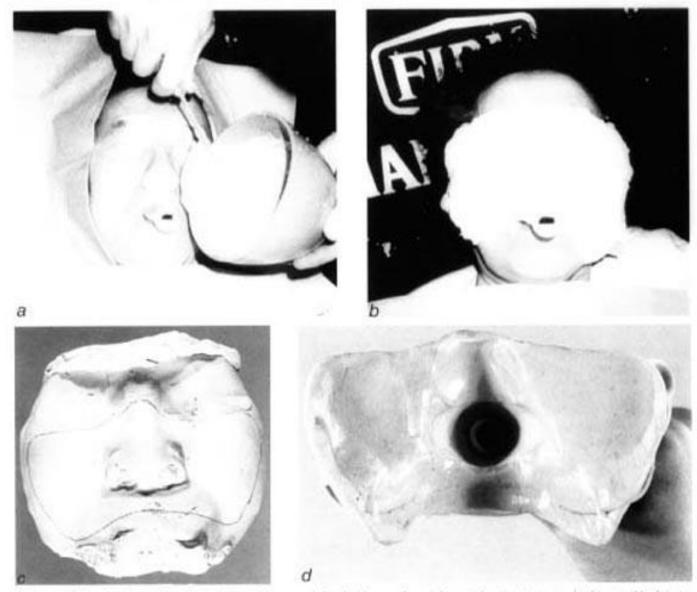
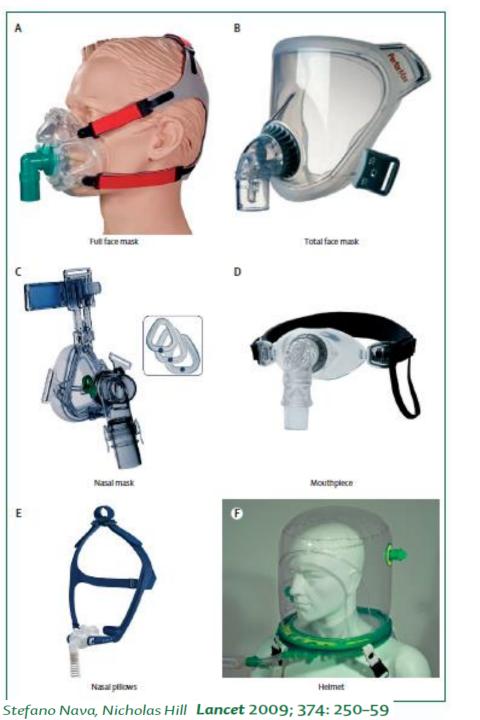


Fig. 1 — a) Parent breating through mouthpress with every socied and with now plagged, by a multiple impression made of investigated approach approach in the society of th







## **Panel 3:** Advantages and disadvantages of different types of interfaces

## Total face mask—covers mouth, nose, and eyes Advantages

- Minimum airleaks
- Little cooperation required
- Easy fitting and application

#### Disadvantages

- Vomiting (risk of aspiration)
- Claustrophobia
- Speaking difficult

### Full face (or oronasal) mask—covers mouth and nose Advantages

- Few air leaks
- Little cooperation required
- Can be adjusted for comfort

#### Disadvantages

- Vomiting
- Claustrophobia
- Possible nasal skin damage
- Speaking and coughing difficult

## Nasal mask—covers nose and not mouth Advantages

- Possibility of speaking and drinking
- Allows cough
- Reduced danger of vomitingMinimum risk of asphyxia
- Nasal

#### Disadvantages

- Air leaks if mouth opens
- Possible nasal skin damage
- Needs patent nasal passages

### **Total Face**

**Full Face** 

# Home Respiratory Care in Japan IV

• **CPAP:** continuous positive airway pressure **1998.4:** Patients who are diagnosed as sleep apnea by polysomnography and apnea and hypopnea index (AHI)  $\geq 20$  with symptoms and complications (hypertension, IHD,--). The diagnosis should be done by PSG. **2000.4:**AHI  $\geq$  20 with symptoms and complications. If AHI  $\geq$  40 with portable monitorings, CPAP can be used.

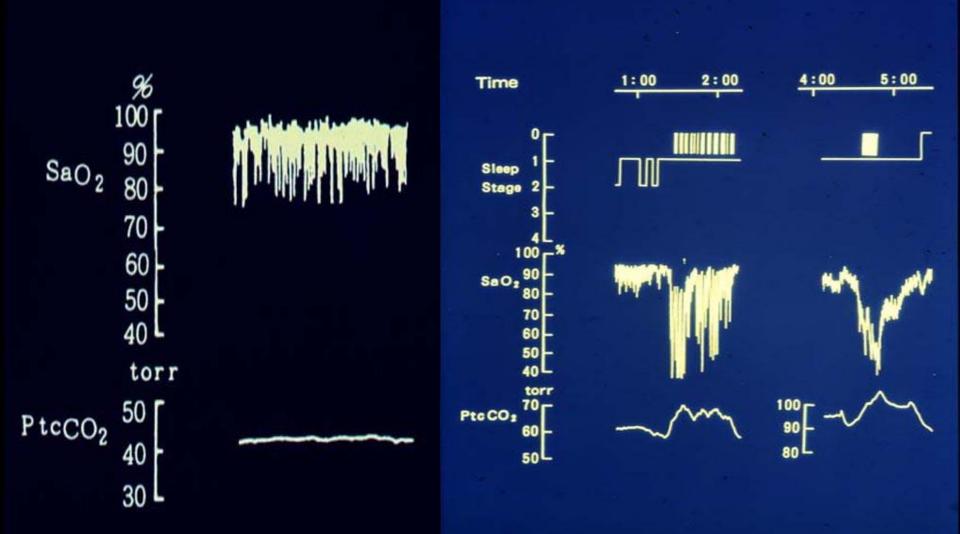
# Home Respiratory Care in Japan V

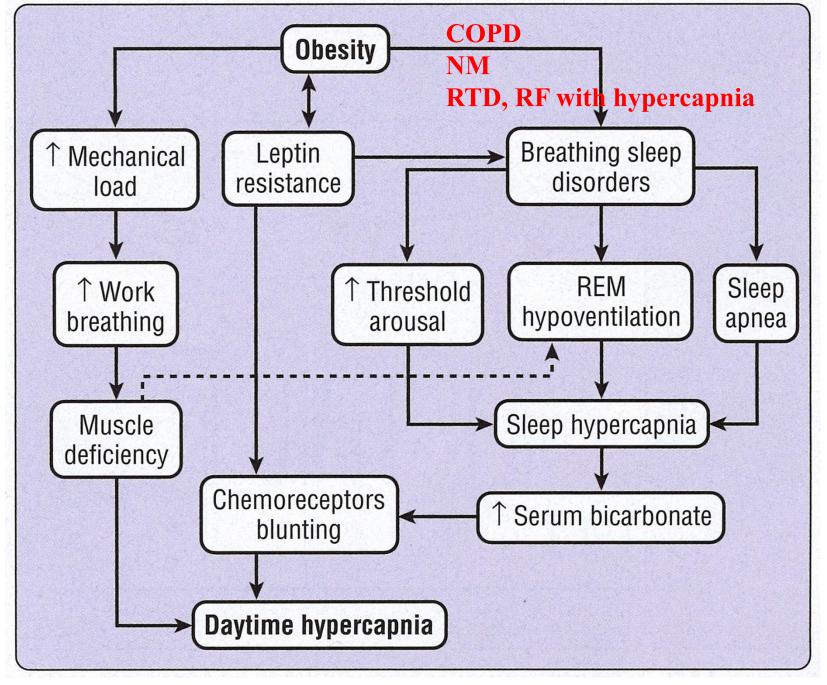
- NPPV: noninvasive positive pressure ventilation 1998.4: Patients who are needed home mechanical ventilation (HMV), which are diagnosed by doctors, but should not used for patients with sleep apnea
- ASV: adaptive servo ventilation
- Advanced ASV: ASV is firstly used as one of NPPV machines.

**2018:**In addition, it is also permitted for patients with congestive heart failure as one of CPAP categolized machine.

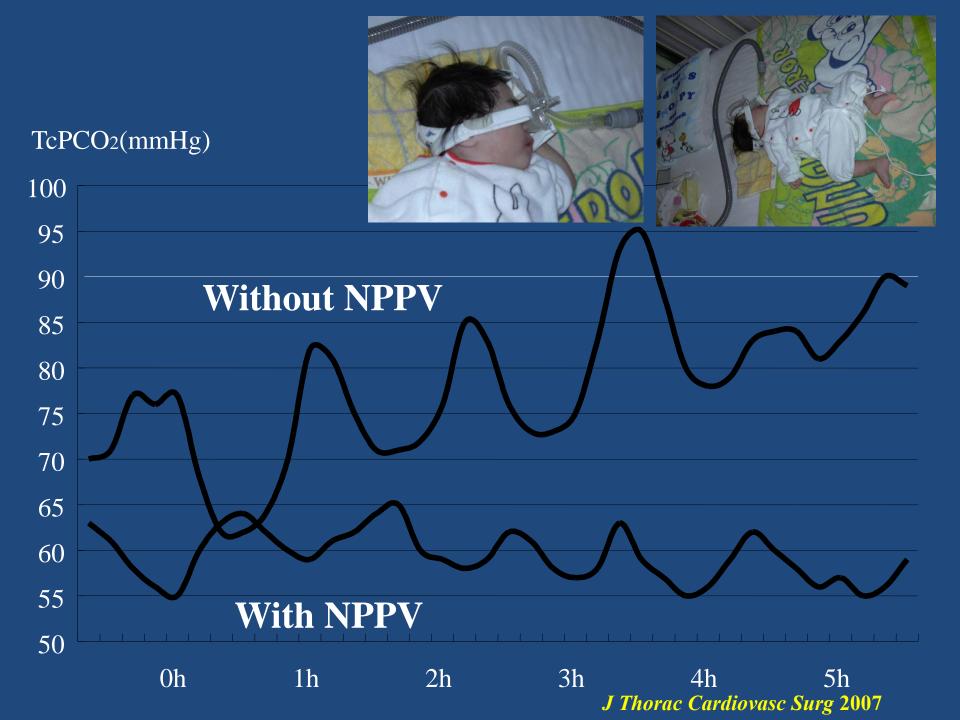
Usually, mild-moderate OSA don't show hypercapnia during sleep

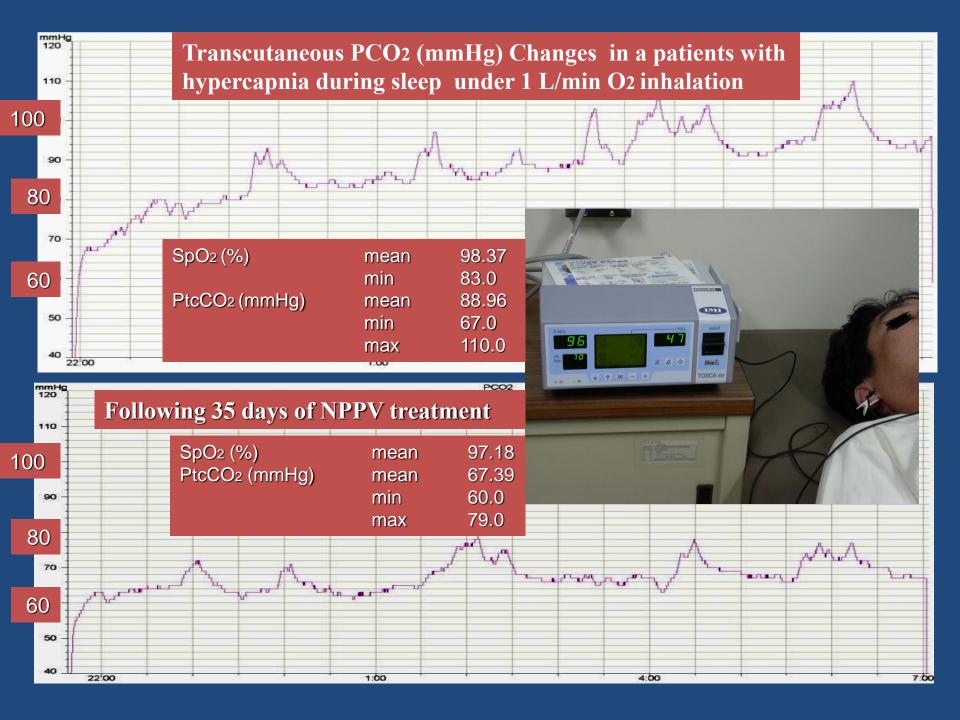
Severe OSA (OHS: Pickwickian syn.) REM stage Respiratory failure with hypercapnia REM stage



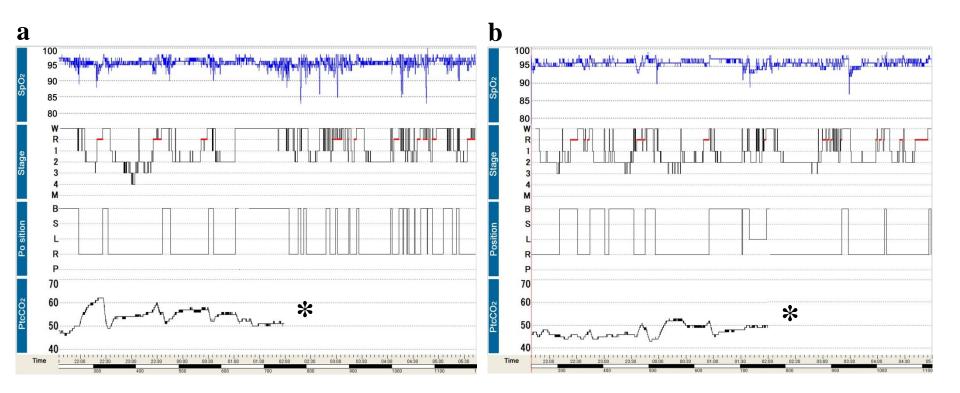


Kryger MH, et al. Sleep Medicine 5<sup>th</sup> ed. 2011

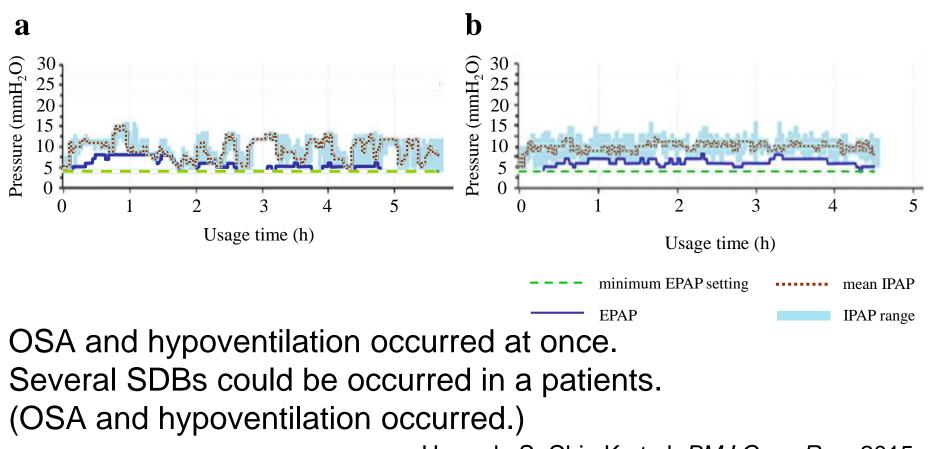




### Neurodegenerative disease: Multiple Atrophy



Several SDBs could be occurred in a patients.



Hamada S, Chin K et al. BMJ Case Rep. 2015

## **Patients with Home Respiratory Care Instruments**

	(Costs)	<b>2014</b> (84,104)	<b>2015</b> (86,529)	<b>2016</b> (87,436)	<b>2017</b> (88,349)	<b>2018</b> (88,988)	(年齢別件数)	
酸素濃縮装置 ( <mark>濃縮器のみ</mark> ) (HOT:LTOT)	40,000+ 20,000 γ	137,308	139,681	140,820	143,494	145,079	<ul> <li>00~19歳</li> <li>20~39歳</li> <li>40~59歳</li> <li>60~79歳</li> <li>80歳以上</li> </ul>	
人工呼吸器加算 陽圧式人工呼吸器 <b>(TPPV)</b>	74,800+ 28,000 y	5,277	5,485	5,749	5,991	6,285	<ul> <li>00~19歳</li> <li>20~39歳</li> <li>40~59歳</li> <li>60~79歳</li> <li>80歳以上</li> </ul>	
人工呼吸器加算 人工呼吸器 <b>(NPPV)</b> ※2016年よりASV独立	64,800+ 28,000 y	19,483	21,256	12,604	12,110	12,121	<ul> <li>00~19歳</li> <li>20~39歳</li> <li>40~59歳</li> <li>60~79歳</li> <li>80歳以上</li> </ul>	
経鼻的持続陽圧呼吸療法用治療器加算 <b>(ASV)</b> ※2016年よりASV独立	37,500+ 22,500 or 2,500 y			7,111	7,828	7,838	<ul> <li>00~19歳</li> <li>20~39歳</li> <li>40~59歳</li> <li>60~79歳</li> <li>80歳以上</li> </ul>	
経鼻的持続陽圧呼吸療法用治療器加算 <b>(CPAP)</b>	10,000+ 2,500 y	315,389	353,835	384,253	411,732	446,514	00~19歳         20~39歳         40~59歳         60~79歳         80歳以上	

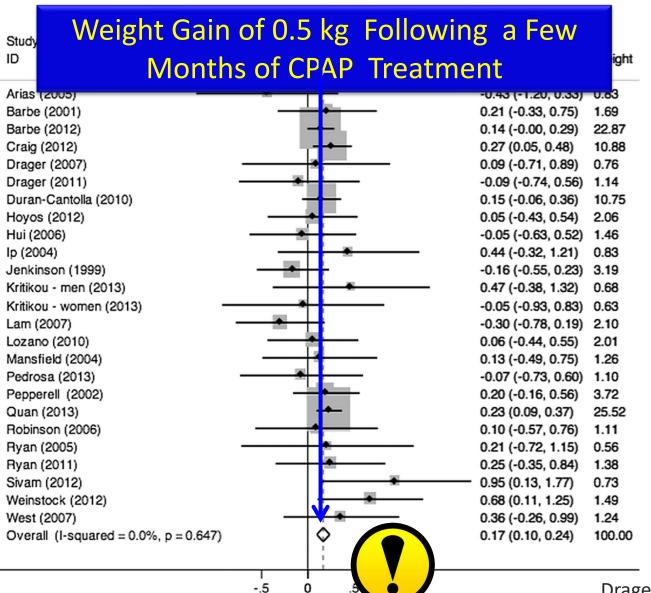
データ参照先:厚生労働省 社会医療診療行為別統計の概況

## **Patients with Home Respiratory Care Instruments**

	(Costs)	<b>2014</b> (84,104)	<b>2015</b> (86,529)	<b>2016</b> (87,436)	<b>2017</b> (88,349)	<b>2018</b> (88,988)	(年齢別件数)	
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データ参照先:厚生労働省 社会医療診療行為別統計の概況

### Body Weight Gain Following CPAP Treatment - Metanalysis From RCT Trials-



Drager LF, Thorax 2014

### Changes in Energy Metabolism after Continuous Positive Airway Pressure for Obstructive Sleep Apnea Tachikawa R, Chin K et al. *Am J Respir Crit Care Med* 194:729–738, 2016



*Rationale*: Disrupted energy homeostasis in obstructive sleep apnea (OSA) may lead to weight gain. Paradoxically, treating OSA with continuous positive airway pressure (CPAP) may also promote weight gain, although the underlying mechanism remains unclear.

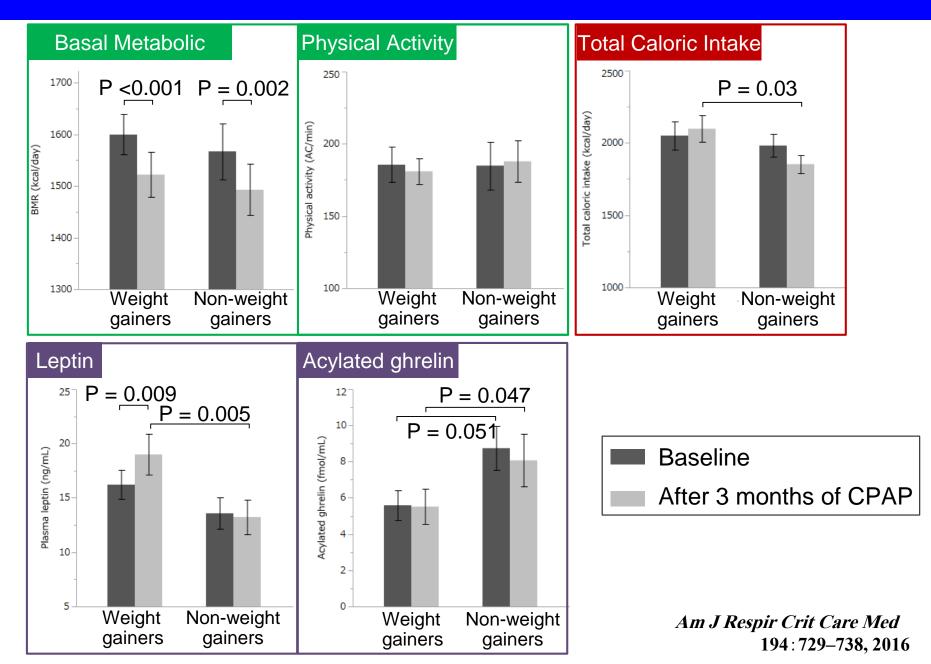


*Objectives*: To explore the underlying mechanism by which patients with OSA gain weight after CPAP.



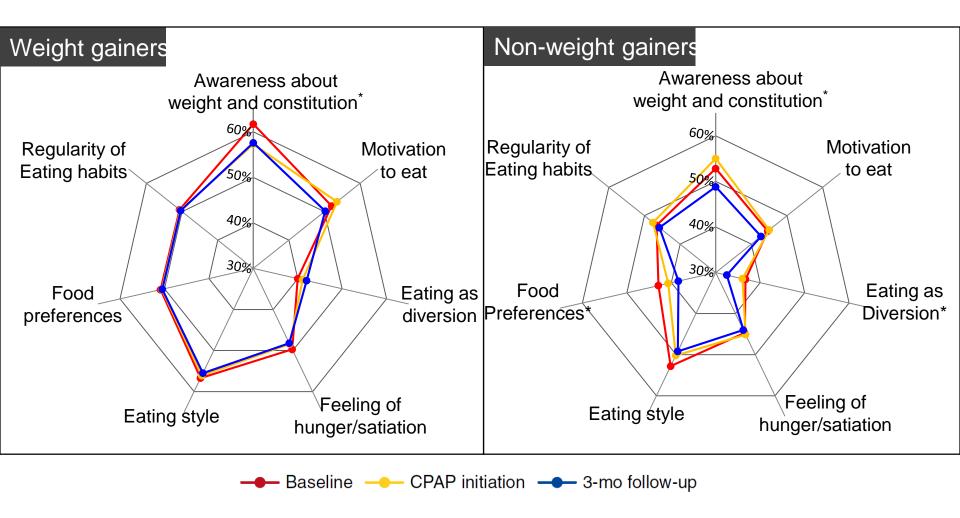
Methods: A comprehensive assessment of energy metabolism was performed in 63 newly diagnosed OSA study participants (51 men; 60.8±10.1 yr; apnea hypopnea index >20 /h) at baseline, CPAP initiation, and at a 3-month follow-up. **Measurements** included polysomnography, body weight, body composition, basal metabolic rate (BMR), hormones (norepinephrine, cortisol, leptin, ghrelin, insulin-like growth factor-1), dietary intake, eating behavior, and physical activity.

### Increased energy intake had a greater impact on weight change



### BMR reduction after CPAP may favor a positive energy balance

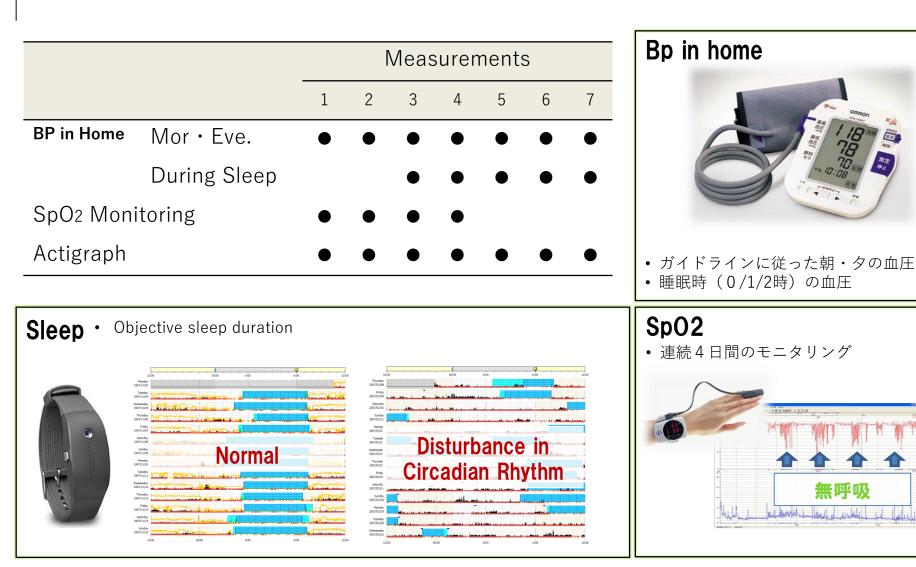
		Baseline	CPAP initiation	3-month follow-up	P value <sup>*</sup>
Basal metabolic ra	1584 ± 261	1561 ± 252	1508 ± 258	< 0.001	
Physical activity (a	185	± 80	184 ± 65	0.95	
Body weight (kg)	77.8 ± 12.6	77.6 ± 12.5	78.2 ± 12.3	0.01	
Energy Expenditure	After 3 month of CPAP				

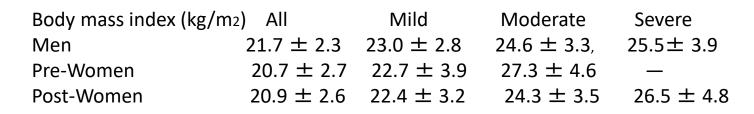


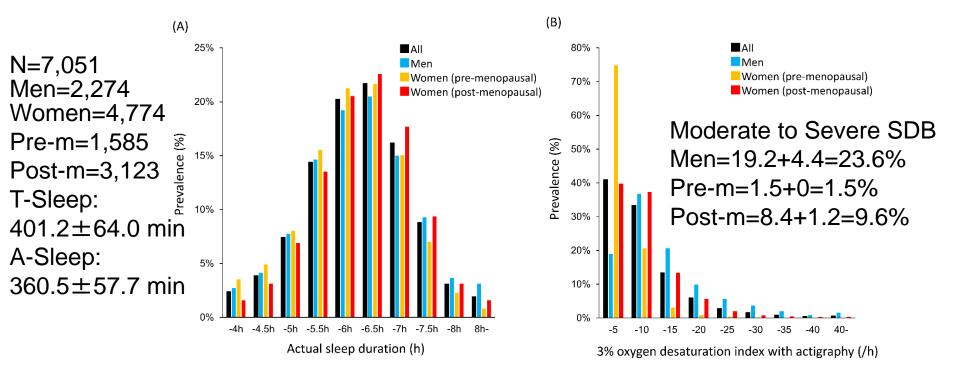
Tachikawa R, Chin K et al. Am J Respir Crit Care Med 194:729–738, 2016



#### • Measurements in Nagahama Cohort.



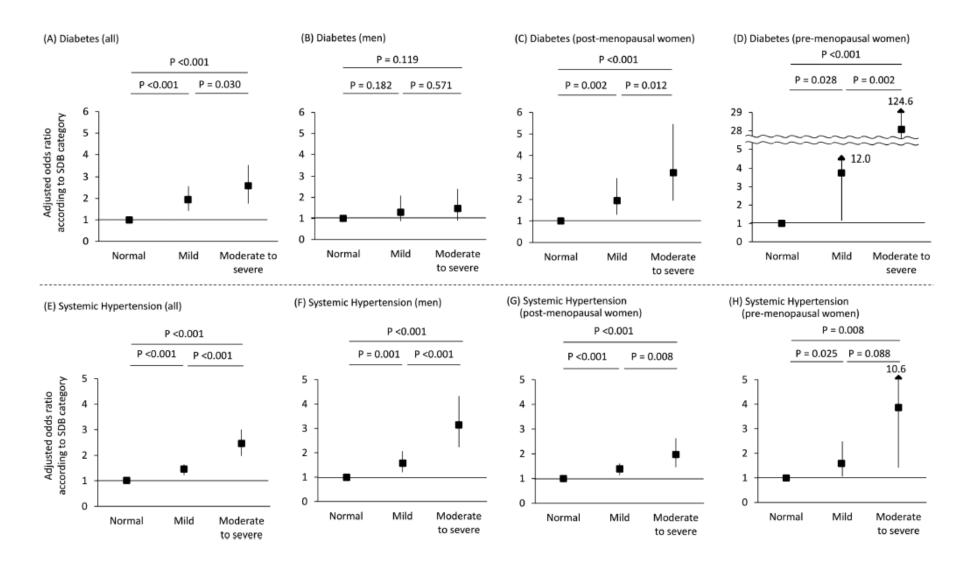


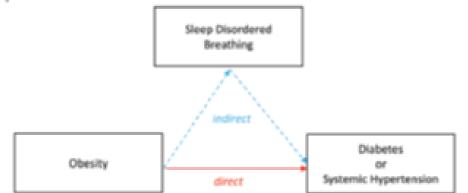


#### Sleep parameter distributions.

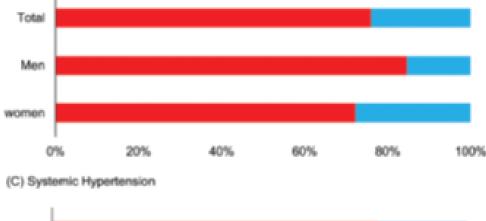
(A) Distribution according to actual sleep duration, (B) distribution according to 3% oxygen desaturation index with actigraphy.

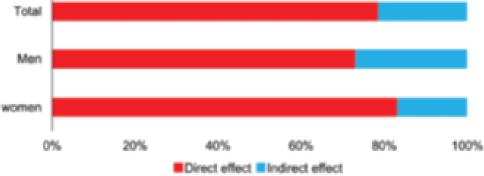
Matsumoto T, Chin K et al. Sleep 2018





(B) Diabetes



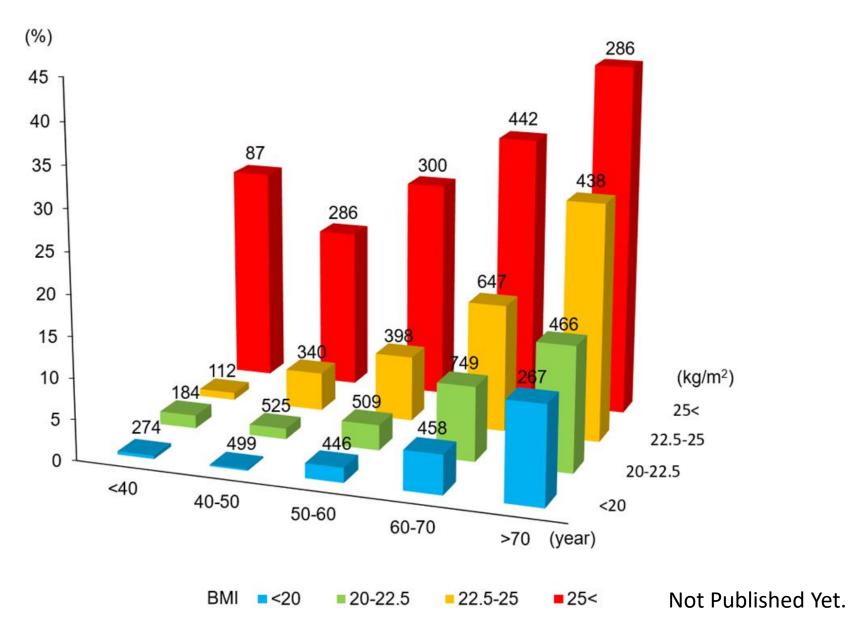


Mediation analyses for sleep-disordered breathing as a mediator of obesity and diabetes or systemic hypertension. (A) The scheme of the mediation analysis.

(B) The direct and indirect
effects of obesity to
diabetes. (C) The direct and
indirect effects of obesity
to systemic hypertension.

#### Matsumoto T, Chin K et al. Sleep 2018

### **BMI, Age, and the Prevalence of Moderate to Severe SDB**



#### **Control of Body Weight in Middle Age People is Very Important.**

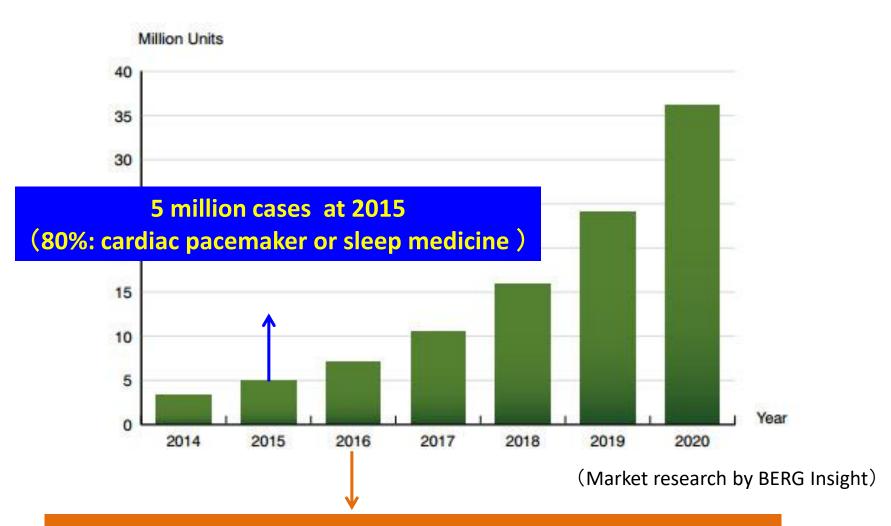
平成30年度診療報酬改定 Ⅱ-2-1)遠隔診療の評価①

### 診療報酬における遠隔診療(情報通信機器を用いた診療)への対応

		診療形態	診療報酬での対応		
医師対医師 (D to D)		器を用いて画像等の送受信を行い 専門的な知識を持っている医師と 寮を行うもの	<ul> <li>「遠隔画像診断」</li> <li>・ 画像を他医療機関の専門的な知識を持っている医師に送信し、その読影・診断結果を受信した場合</li> <li>[遠隔病理診断]</li> <li>・ 術中迅速病理検査において、標本画像等を他医療機関の専門的な知識を持っている医師に送信し、診断結果を受信した場合(その後、顕微鏡による観察を行う。)</li> <li>・ (新)生検検体等については、連携先の病理医が標本画像の観察のみによって病理診断を行った場合も病理診断料等を算定可能</li> </ul>		
<mark>医師対患者</mark> (D to P)	情報通信機 器を用いた 診察	医師が情報通信機器を用いて 患者と離れた場所から診療を 行うもの	[オンライン診療] ・(新)オンライン医学管理料 ・(新)オンライン医学管理料 ・(新)オンライン在宅管理料・精神科オンライン在宅管理料 対面診療の原則の上で、有効性や安全性等への配慮を含む一定の要件を満た すことを前提に、情報通信機器を用いた診察や、外来・在宅での医学管理を行っ た場合 ※電話等による再診 (新)患者等から電話等によって治療上の意見を求められて指示をした 場合に算定が可能であるとの取扱いがより明確になるよう要件の見直し (定期的な医学管理を前提とした遠隔での診察は、オンライン診療料に整理。)		
	情報通信機 器を用いた 遠隔 モニタリング	情報通信機能を備えた機器を 用いて患者情報の遠隔モニタリ ングを行うもの	[遠隔モニタリング] ・心臓ペースメーカー指導管理料(遠隔モニタリング加算) 体内植込式心臓ペースメーカー等を使用している患者に対して、医師が遠隔モ ニタリングを用いて療養上必要な指導を行った場合 ・(新)在宅患者酸素療法指導料(遠隔モニタリング加算) ・(新)在宅患者持続陽圧呼吸療法(遠隔モニタリング加算) 在宅酸素療法、在宅CPAP療法を行っている患者に対して、情報通信機器を備 えた機器を活用したモニタリングを行い、療養上必要な指導管理を行った場合 147		

(厚生労働省Webサイトより引用)

## The number of cases of telemedicine in the world



From 2016, the number of sleep telemedicine cases would become the largest number

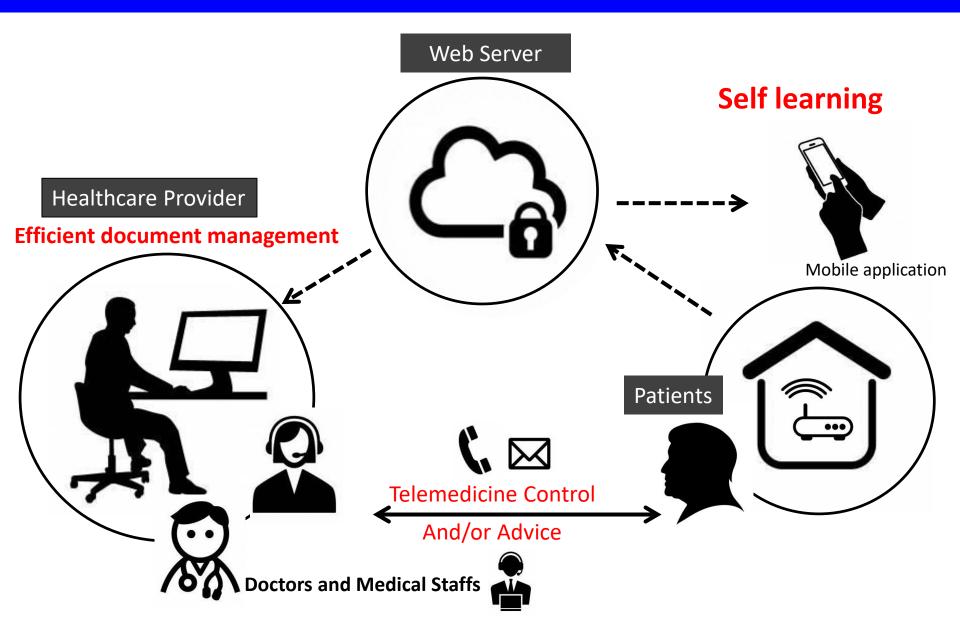
# **Sleep Apnea in the Telemedicine System**

### Telehealth/telemedicine

= Telehealth is the distribution of health-related services and information via electronic information and telecommunication technologies.

- 1. Telemedicine with real-time
  - PSG with telemedicine :
  - CPAP titration with telemedicine :
  - Medical examination with online
- 2. Telemedicine that does not require real-time
  - CPAP data monitoring and feed back to patients
  - Troubleshooting、self-learning、coaching
  - Changes for CPAP setting

# **Telemedicine in CPAP Therapy**



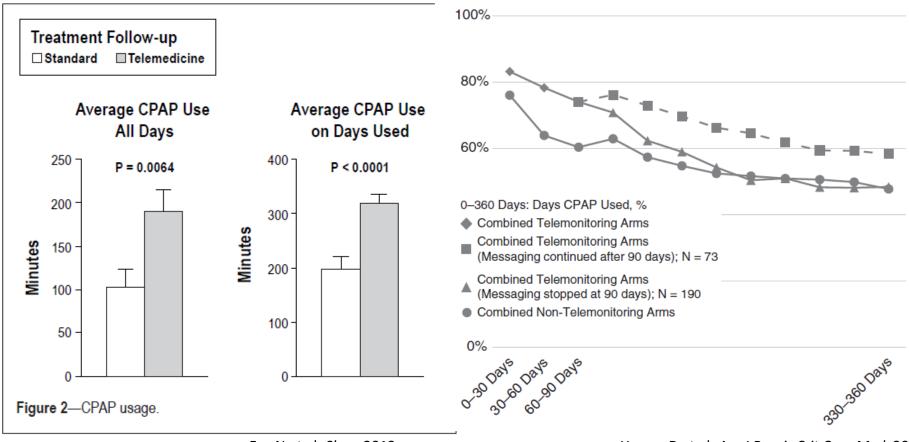
## The Results of Clinical Trials in CPAP Treatment with Telemedicine

Key 7 RCT Trials

Author		Time of intervention	介入方法	Adhe- rance	Cost	labor
Turino	2017	At Start of CPAP	遠隔モニタ+早期介入	$\rightarrow$	$\checkmark$	N.A.
Munafo	2016	At Start	遠隔モニタ+自動コーチング	$\rightarrow$	N.A.	$\checkmark$
Fields	2016	At Start	遠隔診断+モニタ+診察	$\rightarrow$	N.A.	N.A.
lsetta	2015	At Start	遠隔診察+自己管理・サポート	$\rightarrow$	$\checkmark$	N.A.
Kuna	2015	At Start	遠隔モニタ+ウェブアクセス	$\uparrow$	N.A.	N.A.
Fox	2012	At Start	遠隔モニタ+早期介入	$\uparrow$	N.A.	$\uparrow$
Sparrow	2010	At Start	自己管理・遠隔サポート	$\uparrow$	N.A.	N.A.

Overall, adherence increased and costs decreased.

### Telemedicine in CPAP treatment



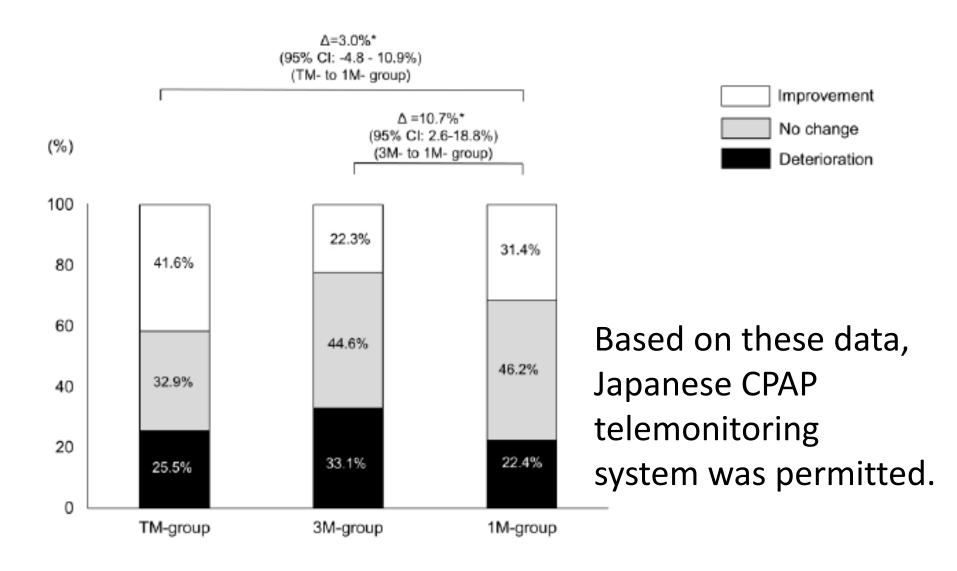
Fox N et al. Sleep 2012

Hwang D et al. Am J Respir Crit Care Med. 2018

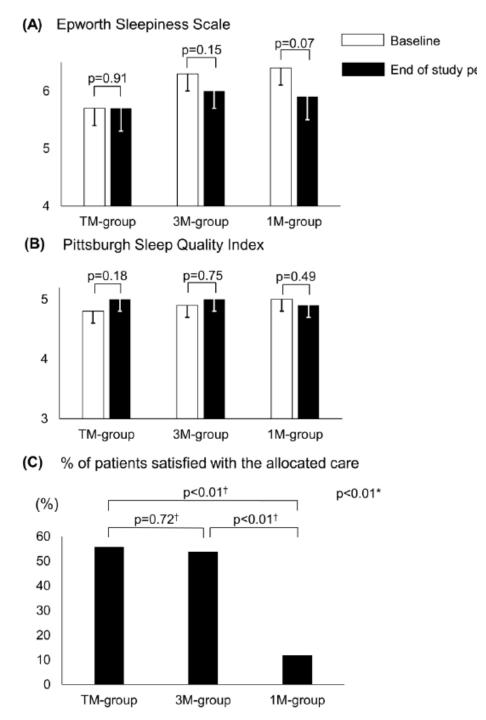
Most of reports of the telemedicine system in CPAP treatment were based on the data at the start of CPAP treatment.

A Randomized Controlled Trial of Telemedicine for Long-Term Sleep Apnea CPAP Management. . *Ann Am Thorac Soc* in press

**Results:** Analyzed were 483 patients (median duration of CPAP use, 29 (interguartile range, 12-71) months), and deterioration of adherence was found in 41/161 (25.5%), 55/166 (33.1%) and 35/156 (22.4%) patients in the TM-, 3M- and 1Mgroups, respectively. The non-inferiority of the TM-group compared with the 1M-group was verified (difference in % of patients with adherence deterioration, 3.0%, 95% confidence interval (CI) -4.8 – 10.9%, p<0.01).



Murase K, Chin K et al. Ann Am Thorac Soc in press



Does remote monitoring change OSA management and CPAP adherence? (Pepin JL, et al. *Respirology* (2017) 22, 1508–1517)

The evolution of sleep medicine care is full of incredible opportunities given its natural reliance of technology and relevance to so many medical specialties. The field has the potential to be a model to the greater healthcare community in transforming the cost-effective management of chronic disease conditions.

Physiological sensors at home



#### Compliance, leaks, residual events





Physical activity/sleep duration



Home self-measurement of blood pressure



**Oximetry (daytime and nocturnal SaO2)** 



CPAP side effects (Oneline questionnaires, mobile apps)



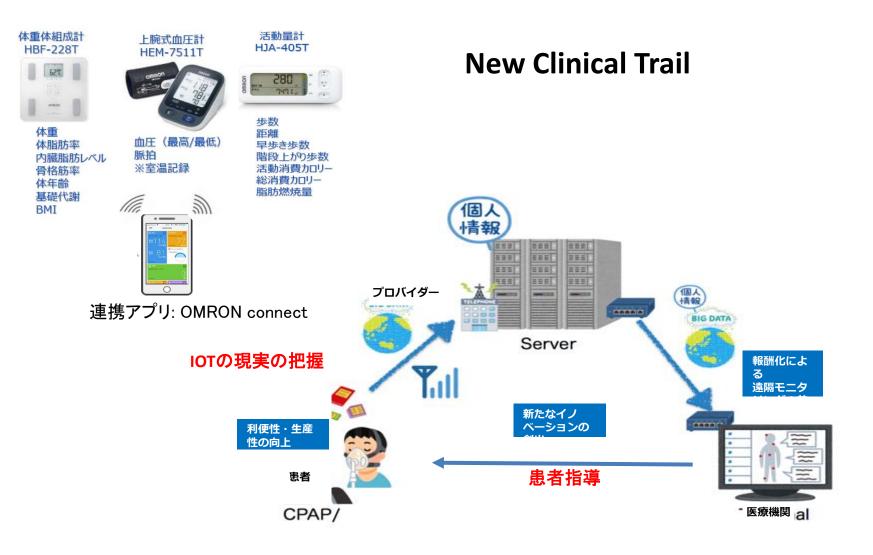
Multidisciplinary web platform medical chart



Access to home data monitoring for physicians and home care providers

(Pepin JL, et al. Respirology (2017) 22, 1508–1517 )

(1)



# Conclusions

- To understand the pathophysiology of sleepdisordered breathings is important to use the proper therapeutic instruments: oxygen, CPAP, NPPV, ASV and etc.
- Home respiratory care has developed in Japan following the health insurance system under the government
- Benefits of home respiratory care under the governmental health insurance system should be proven from the healthy (mortality) and economical points

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