CURSO DE VMNI

NIPPON 2026

VNI na DPOC estável

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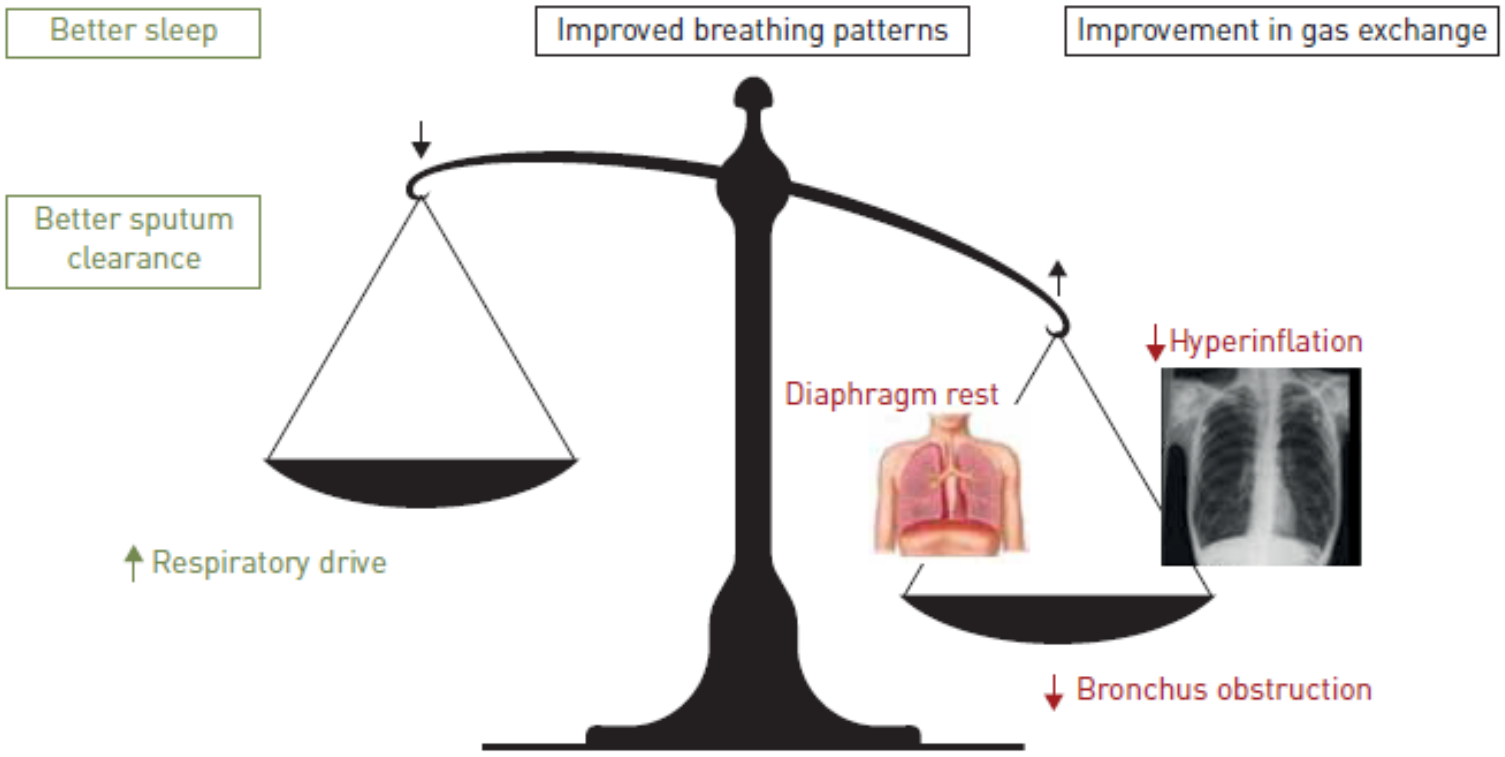
FMUP

NIPPON GASES
Healthcare

Agenda

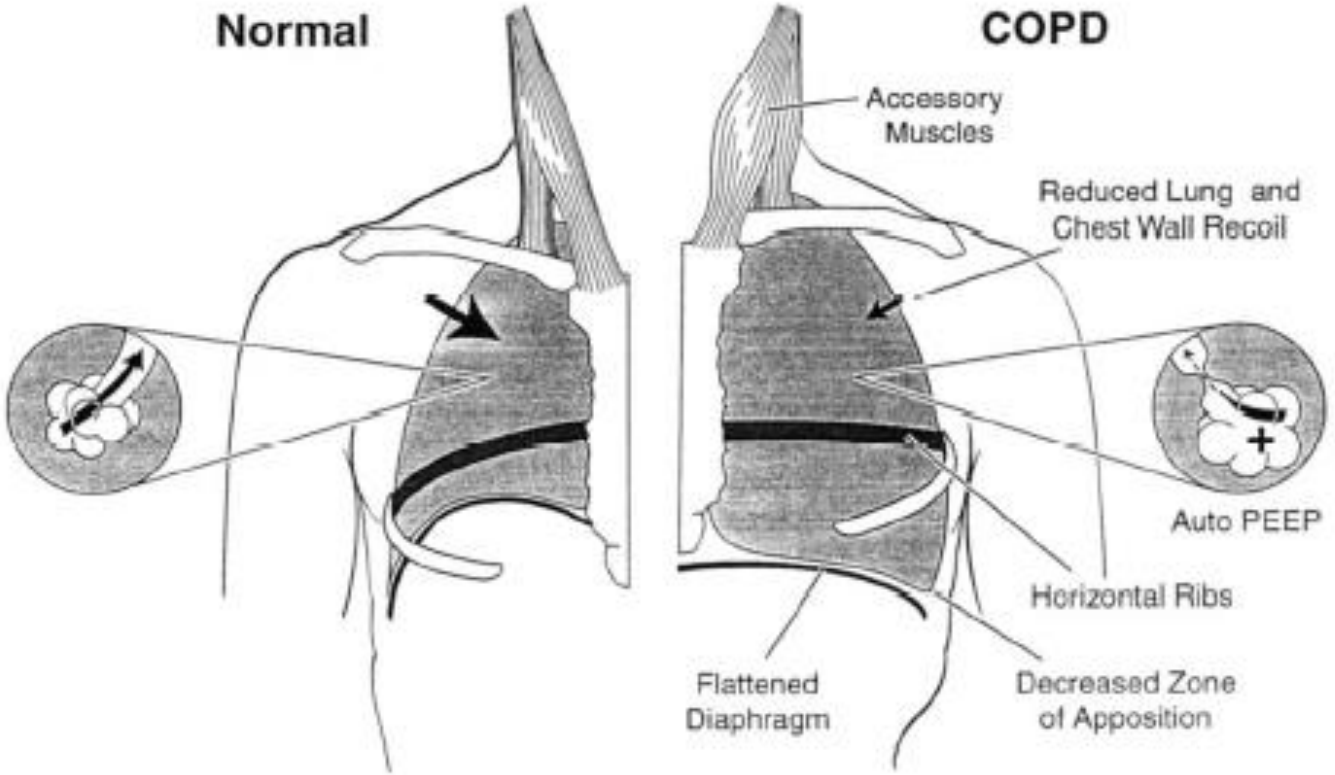
Rationale
Early evidence (metanalysis)
High-intensity NIV
Recent evidence
Ongoing studies
Future
What GOLD says
Conclusions

NIV and the balance between increased load and decreased capacity of the respiratory system



Duiverman ML. ERJ Open Res 2018

Physiologic rationale for NIV in stable COPD



NIV improves

Hyperinflation

Gas exchange

Sleep quality

Budweiser S, Respir Med 2005

Krachman S, Chest 1997

Meecham-Jones, Am J Respir Crit Care Med 1995

Early Evidence

A Meta-analysis of Nocturnal Noninvasive Positive Pressure Ventilation in Patients With Stable COPD*

Studies 3 months of NIPPV : Gay, Strumpf, Meecham-Jones and Casanova

Outcomes	Reference No. of Contributing Trials	Sample Size (NIPPV/Control), No.	Treatment Effect	
			Mean	95% Confidence Interval
FEV_1, L	13,14,29,30	33/33	0.02	−0.04,0.09
FVC, L	13,14,29,30	33/33	−0.01	−0.14,0.13
Pimax, cm H_2O	13,14,30	24/24	6.2	0.2,12.2
Pemax, cm H_2O	13,14,30	24/24	18.4	−11.8,48.6
Pao_2, mm Hg	13,14,29,30	33/33	0.0	−3.8, 3.9
$Paco_2$, mm Hg	13,14,29,30	34/33	−1.5	−4.5,1.5
6MWT, m	13,29	12/11	27.5	−26.8,81.8
Sleep efficiency, %	13,14,29	13/11	−4.0	−14.7,6.7

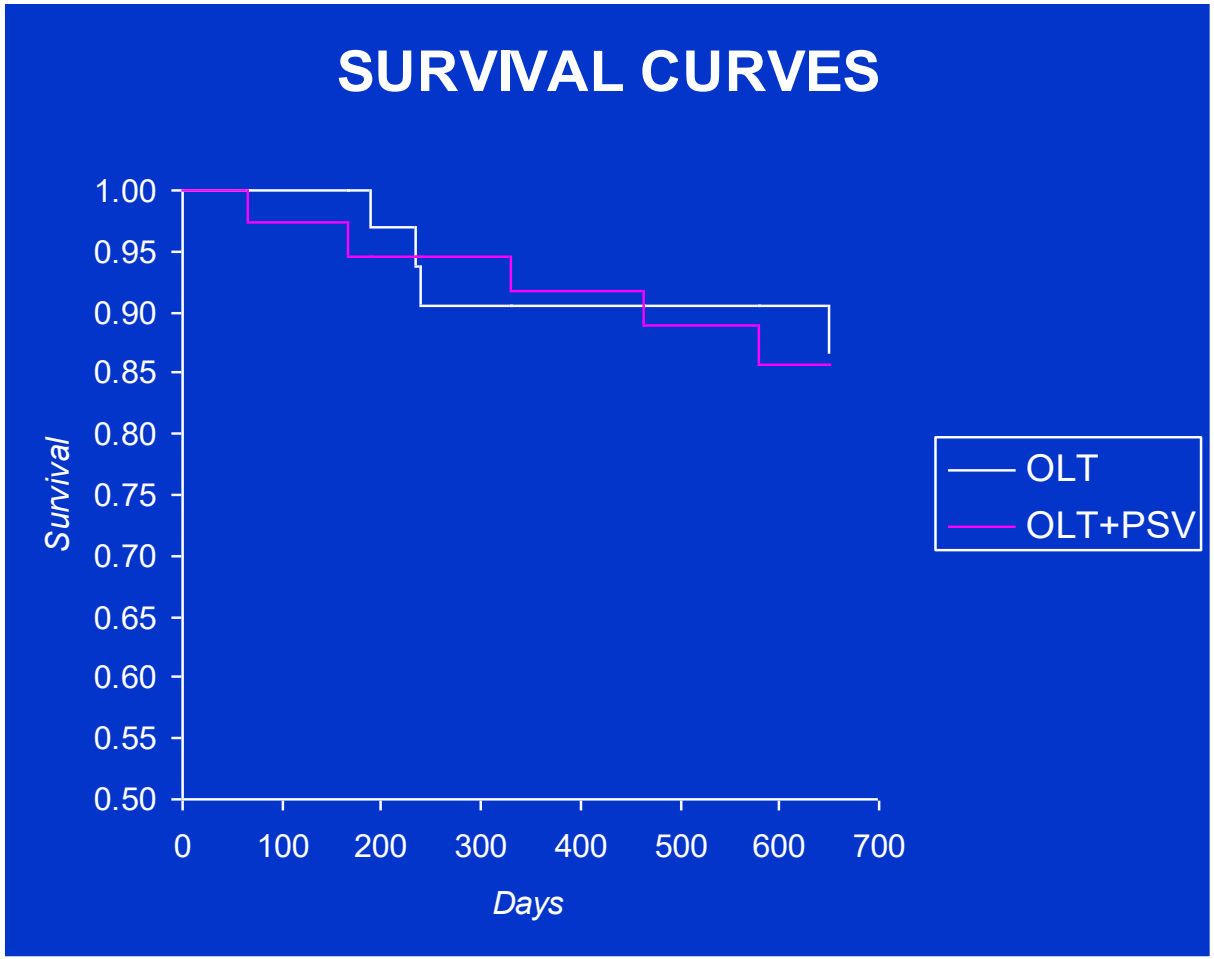
Some patients do improve their walking distance

Wijkstra P, Chest 2003

VMNI na DPOC estável
Estudos RCT a longo prazo

- **European Multicentre study** – *ventilação volumétrica* -122 doentes (60 LTOT+NPPV/62 LTOT), PaO2 51, PaCO2 56- Report April 1999: melhoria da sobrevida em pacientes > 65 anos, taxa de internamentos reduzida- *Am J Respir Crit Care Med 2000 (Abstract)*
- **Italian Multicentre study** – *pressão assistida-90* doentes (43 LTOT+NPPV/47 LTOT), PaO2 51, PaCO2 56- sem melhoria da sobrevida , redução da PaCO2, dispneia e melhor HRQL- Clini E, Eur Respir J 2002

VMNI na DPOC estável
Italian Multicenter Trial



Clini E, Eur Respir J 2002

Eur Respir J 2007; 30: 293–306
DOI: 10.1183/09031936.00145106

Systematic review of noninvasive positive pressure ventilation in severe stable COPD

M.A. Kolodziej*, L. Jensen#, B. Rowe¶ and D. Sin+

TABLE 10 Dyspnoea ratings with bilevel noninvasive positive pressure ventilation use in chronic obstructive pulmonary disease

First author [Ref.]	Scale used	Trial length	Before/after Rx/CL	Outcome data	Comments
RCTs					
CASANOVA [11]	BORG/MRCD	1 yr	Rx	5±1.63*/2*	
			CL	4±1.63/2	
CLINI [23]	MRCD at 0 months/	2 yrs	Rx	3.3±0.3/2.7±0.8#/	
GARROD					e
			CL	15.1 to 16.8	CRDQ instrument
RENSTON [22]	BORG	5 days	Rx	2.0±1.2 to 0.7±0.9**	
			CL	1.8±1.13 to 1.3±1.13	
Non-RCTs					
STRUMPF [30]	Dyspnoea scale of Mahler	6 months	Before	0.6±1.7	Functional impairment dyspnoea rating
			After	0.3±1.3	

All RCT show significant improvement in dyspnoea in the NIV group

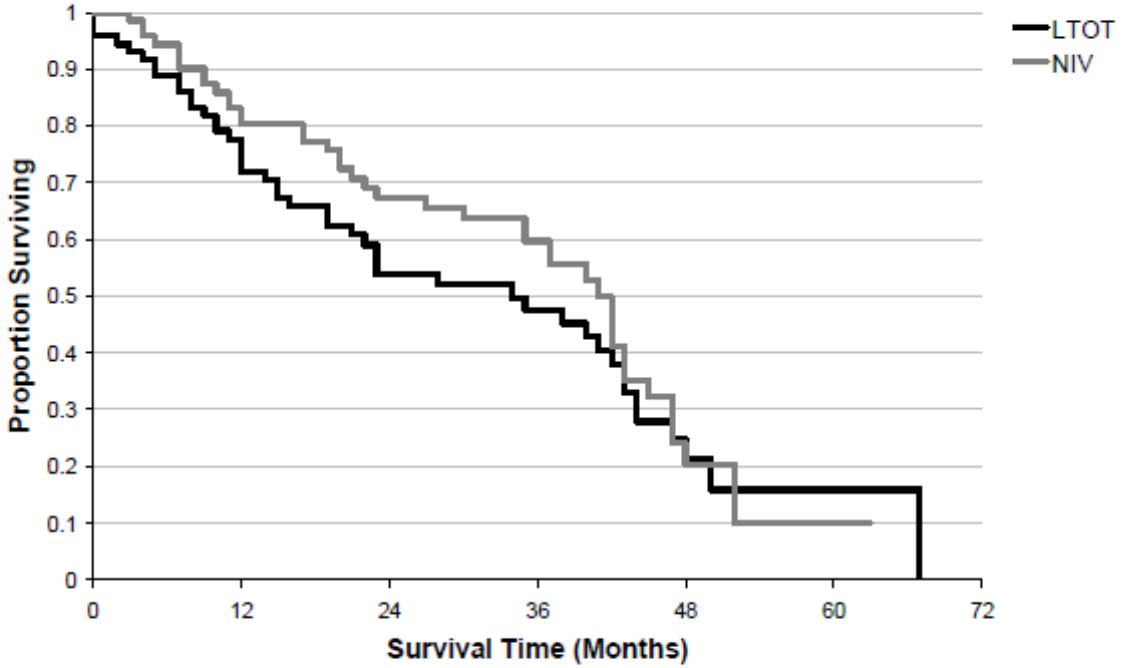
Data are presented as mean±SD. Rx: treatment; CL: control; BORG: Borg dyspnoea scale; MRCD: Medical Research Council dyspnoea scale; CRDQ: Chronic Respiratory Disease Questionnaire. #: p=0.048 at 12 months; ¶: p=0.013 at 24 months. *p<0.05; **: p<0.01; ***: p<0.001.

Nocturnal Non-Invasive Nasal Ventilation in Stable Hypercapnic COPD: A Randomised Controlled Trial

R Douglas McEvoy, Robert J Pierce, David Hillman, Adrian Esterman, E E Ellis, Peter G Catcheside, Fergal J O'Donoghue, David J Barnes and Ronald R Grunstein

Thorax published online 12 Feb 2009;
doi:10.1136/thx.2008.108274

Figure 2. Survival curves in the two treatment groups



Number at risk							
LTOT	72	50	31	21	3	1	0
NIV	72	56	37	28	4	1	0

High-intensity NIV

Outcome of Patients With Stable COPD Receiving Controlled Noninvasive Positive Pressure Ventilation Aimed at a Maximal Reduction of $Paco_2$*

Wolfram Windisch, MD; Sergej Kostić, MD; Michael Dreher, MD; Johann Christian Virchow, Jr, MD, FCCP; and Stephan Sorichter, MD

Conclusions: **Controlled NPPV using a mean inspiratory pressure of 28 cm H_2O is well tolerated over longer periods and can improve blood gas levels and lung function. Prospective, randomized controlled trials of high-intensity NPPV are required to evaluate its role in patients with stable hypercapnic COPD.** ***(CHEST 2005; 128:657–662)***

Table 3 Physiological and clinical effects of high-intensity noninvasive positive pressure ventilation (NPPV) [11, 17, 24–33]

Physiological effects
• Improvement in blood gases during NPPV
• Improvement in daytime blood gases during subsequent spontaneous breathing following periods of nocturnal NPPV
• Improvement in breathing pattern with increased tidal volume during spontaneous breathing following periods of nocturnal NPPV
• Improvement in lung function
• Improvement in global inspiratory muscle strength
• Increments in haematocrit in anaemic patients
• Reduction of haematocrit in patients with polyglobulia
• Superior to conventional (low-intensity) NPPV using assisted ventilation with low IPAP regarding the improvement of blood gases

Windisch W, Breathe 2011

Clinical effects

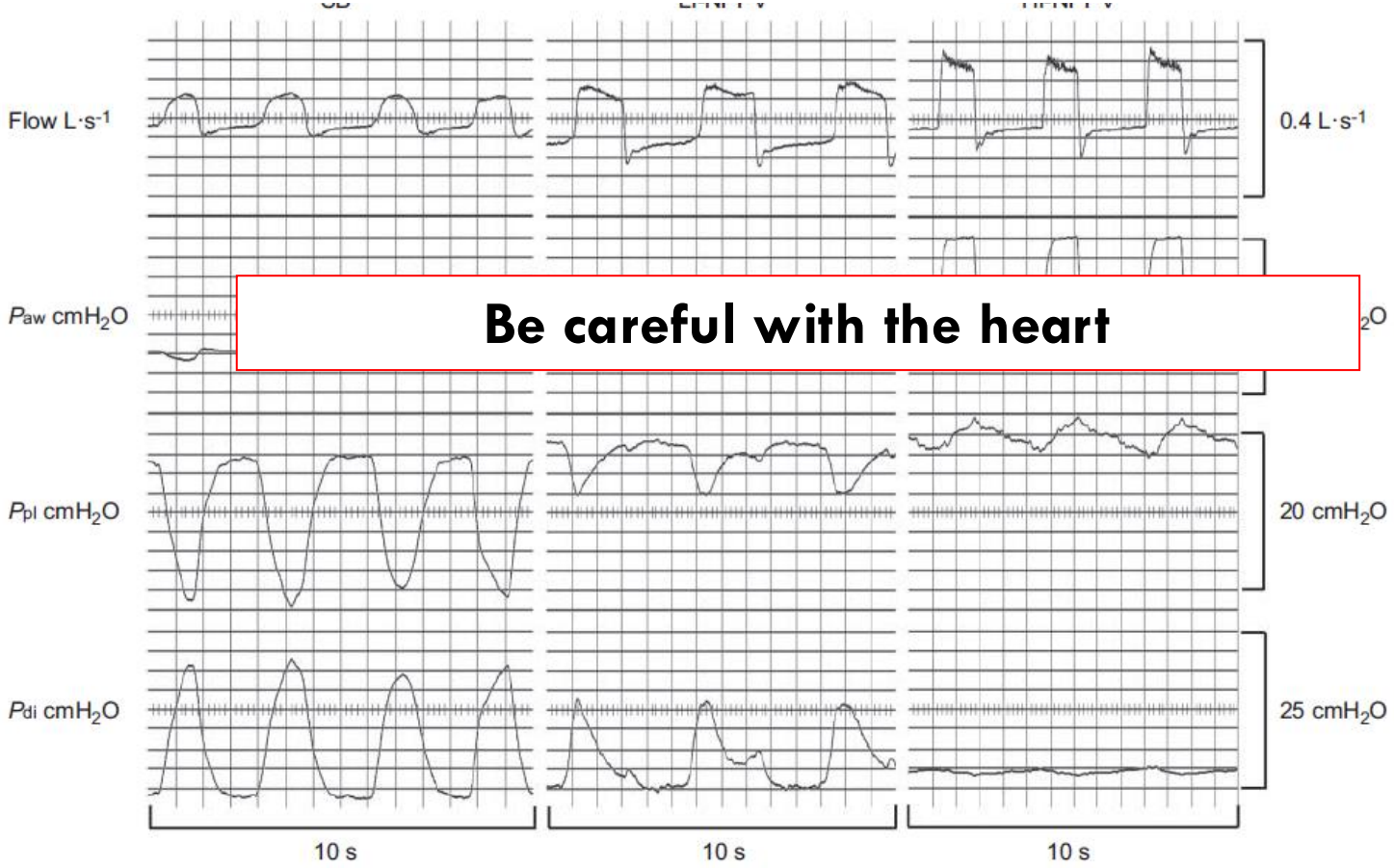
- Improvement in HRQoL assessed by questionnaires specific to CRF
- Improvement in dyspnoea during walking while breathing spontaneously
- Improvement in dyspnoea and walking distance during NPPV-aided walking compared with walking unaided by NPPV
- Acceptable sleep quality
- Superior adherence to therapy *versus* conventional (low-intensity) NPPV using assisted ventilation with low IPAP

Windisch W, Breathe 2011

Eur Respir J 2012; 39: 869–875
DOI: 10.1183/09031936.00056111

Physiological changes during low- and high-intensity noninvasive ventilation

J. Lukácsovits*, A. Carlucci#, N. Hill¶, P. Ceriana#, L. Pisani+, A. Schreiber#, P. Pierucci#, G. Losonczy* and S. Nava§



Be careful with the heart

Respiratory Medicine (2013) xx, 1–9

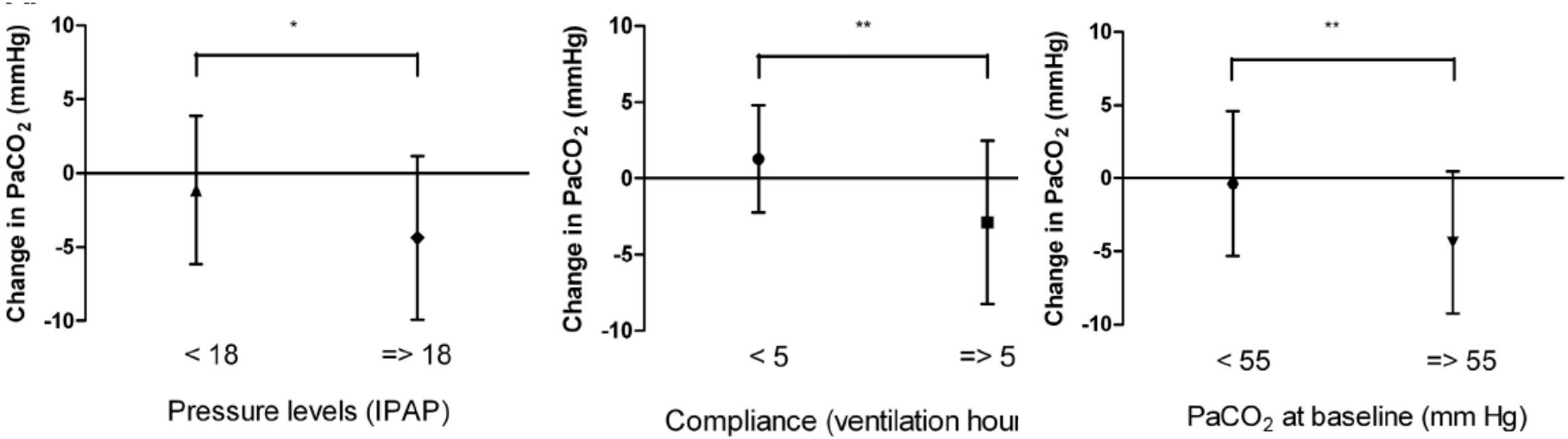
Available online at www.sciencedirect.com

ScienceDirect

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

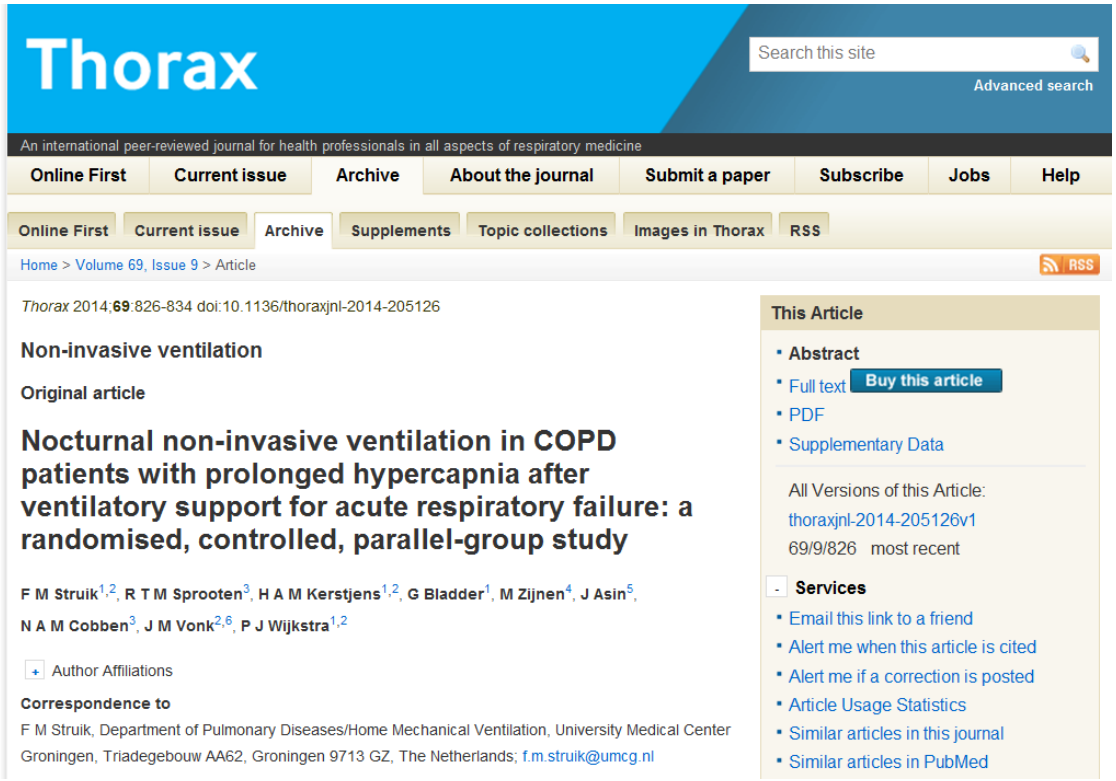
Nocturnal noninvasive positive pressure ventilation in stable COPD: A systematic review and individual patient data meta-analysis

F.M. Struik [a,b,*], Y. Lacasse [c], R.S. Goldstein [d], H.A.M. Kerstjens [a,b], P.J. Wijkstra [a,b]



Recent evidence

2014



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RSS

Thorax 2014;**69**:826-834 doi:10.1136/thoraxjnl-2014-205126

Non-invasive ventilation

Original article

Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study

F M Struik[1,2], R T M Sprooten[3], H A M Kerstjens[1,2], G Bladder[1], M Zijnen[4], J Asin[5], N A M Cobben[3], J M Vonk[2,6], P J Wijkstra[1,2]

+ Author Affiliations

Correspondence to

F M Struik, Department of Pulmonary Diseases/Home Mechanical Ventilation, University Medical Center Groningen, Triadegebouw AA62, Groningen 9713 GZ, The Netherlands; f.m.struik@umcg.nl

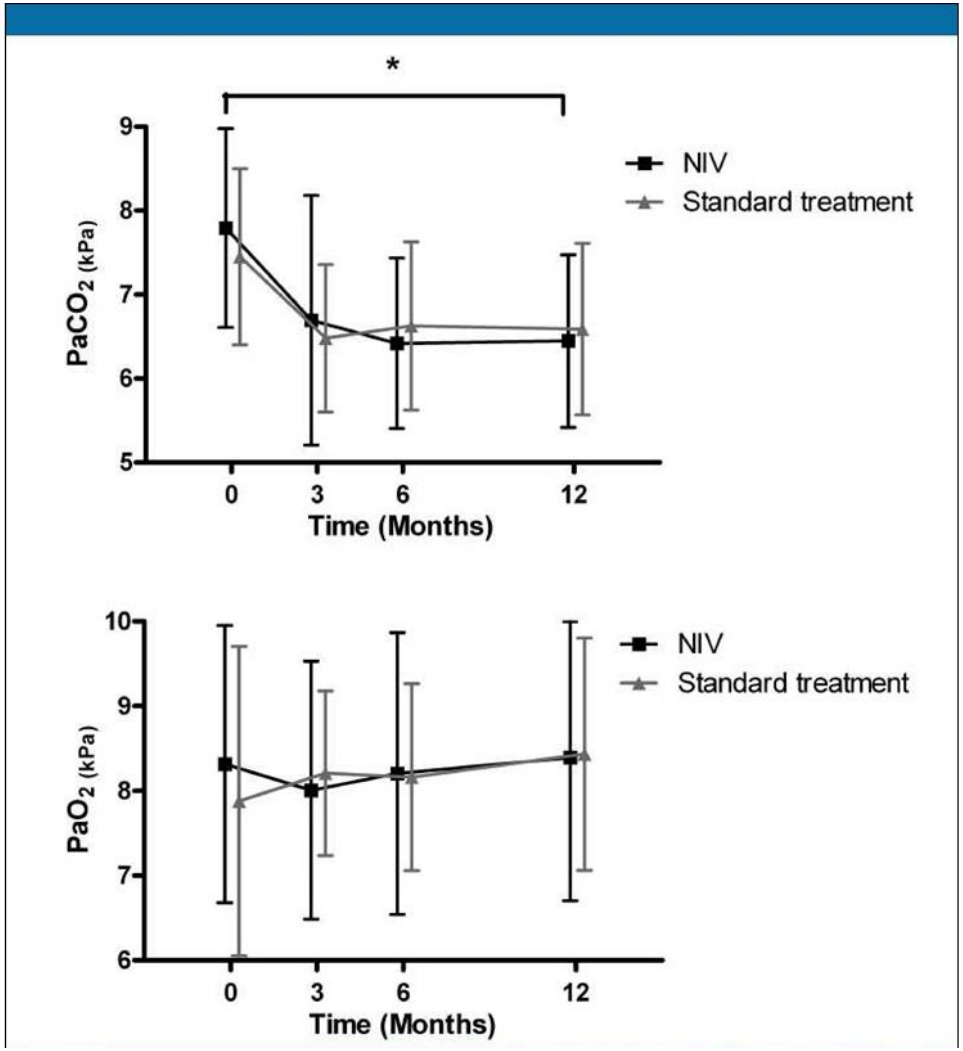
Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial

Thomas Köhnlein, Wolfram Windisch, Dieter Köhler, Anna Drabik, Jens Geiseler, Sylvia Hartl, Ortrud Karg, Gerhard Laier-Groeneveld, Stefano Nava, Bernd Schönhofer, Bernd Schucher, Karl Wegscheider, Carl P Criée, Tobias Welte

Lancet Respir Med 2014

Published Online
July 25, 2014

Struik: Daytime PaCO2 and PaO2



Event free survival curves of patients randomised to non-invasive positive pressure ventilation (NIV) and standard treatment.

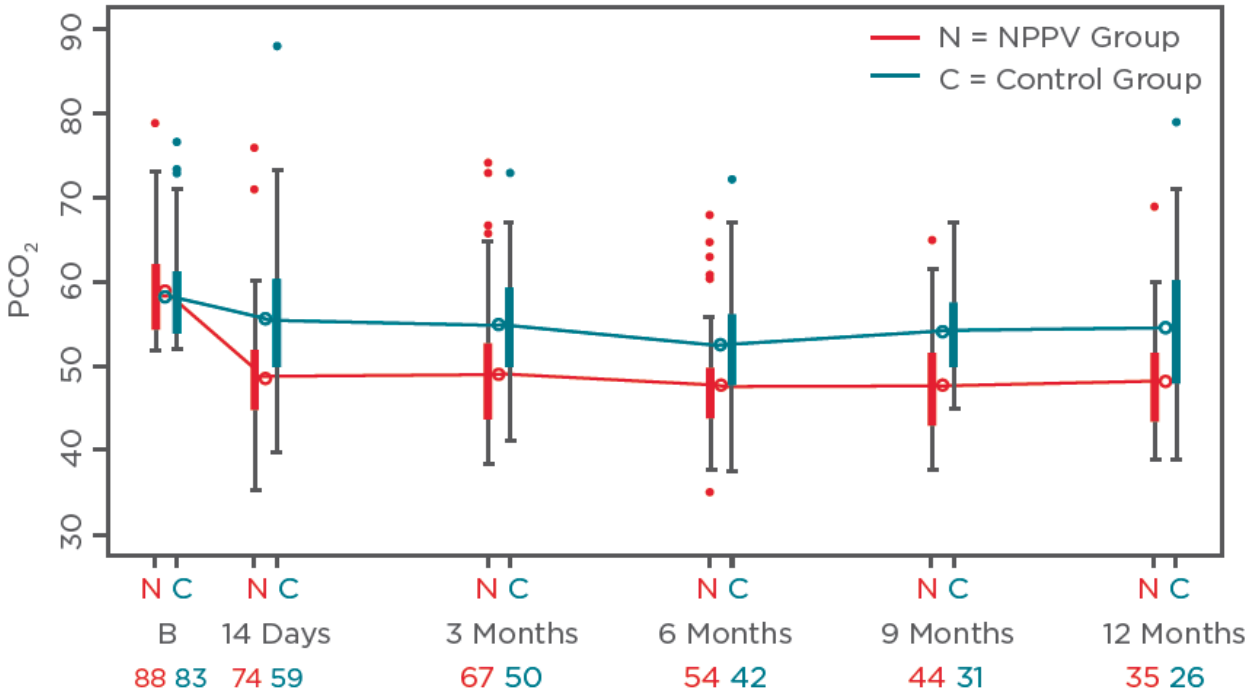
After one year 65% (NIV) vs 64% (ST) were either readmitted or died

Struik F M et al. Thorax doi:10.1136/thoraxjnl-2014-205126

THORAX

Kohnlein's study: main difference form previous studies

- VNI with the aim at deduction of ≥ 20% in PaCO2 during spontaneous breathing or a return to the normal values



NIPPV for stable hypercapnic COPD: the new evidence

Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial

Lancet Respir Med 2014
Published Online
July 25, 2014

Thomas Köhnlein, Wolfram Windisch, Dieter Köhler, Anna Drabik, Jens Geiseler, Sylvia Hartl, Ortrud Karg, Gerhard Laier-Groeneveld, Stefano Nava, Bernd Schönhofer, Bernd Schucher, Karl Wegscheider, Carl P Criée, Tobias Welte

362 assessed for eligibility

6 years

36 respiratory units GER & AUSTRIA

195 randomized : 93 control & 102 NIV

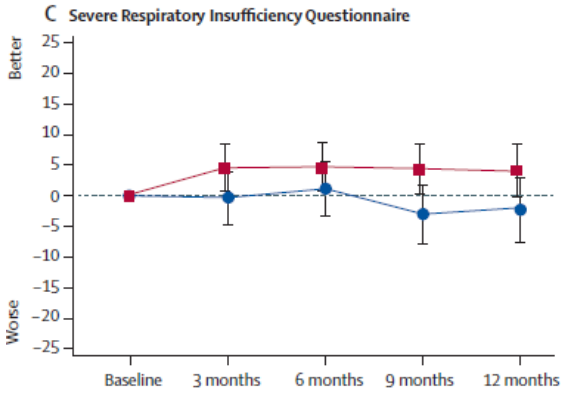
66% under LTOT

PaCO2 58.5±6 mmHg, FEV1 26%, BMI 24.8

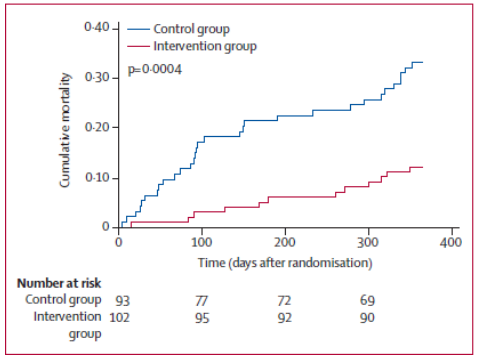
NIV targeted to reduce 20% of PaCO2

Improvement in Quality of Life

Improve of 5,6 points



Improvement in Survival



33.3% controls
11.8% NIV

NIPPV for stable hypercapnic COPD: the new evidence

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Compliance

5.9h+- 3.1/day

mIPAP 21.6+-4.7

mEPAP4.8+-1.6 BR 16.1+-3.6

Hospital LOS: Study entry 5.6+-1.1 days

F-up: 3.1+-0.9 days

(x 4: 2wk, 3M, 6M, 9M)

FEV1 improvement at 1 year: 2%

Emergency Hospital Admissions at 1 year 2.2+-10.2

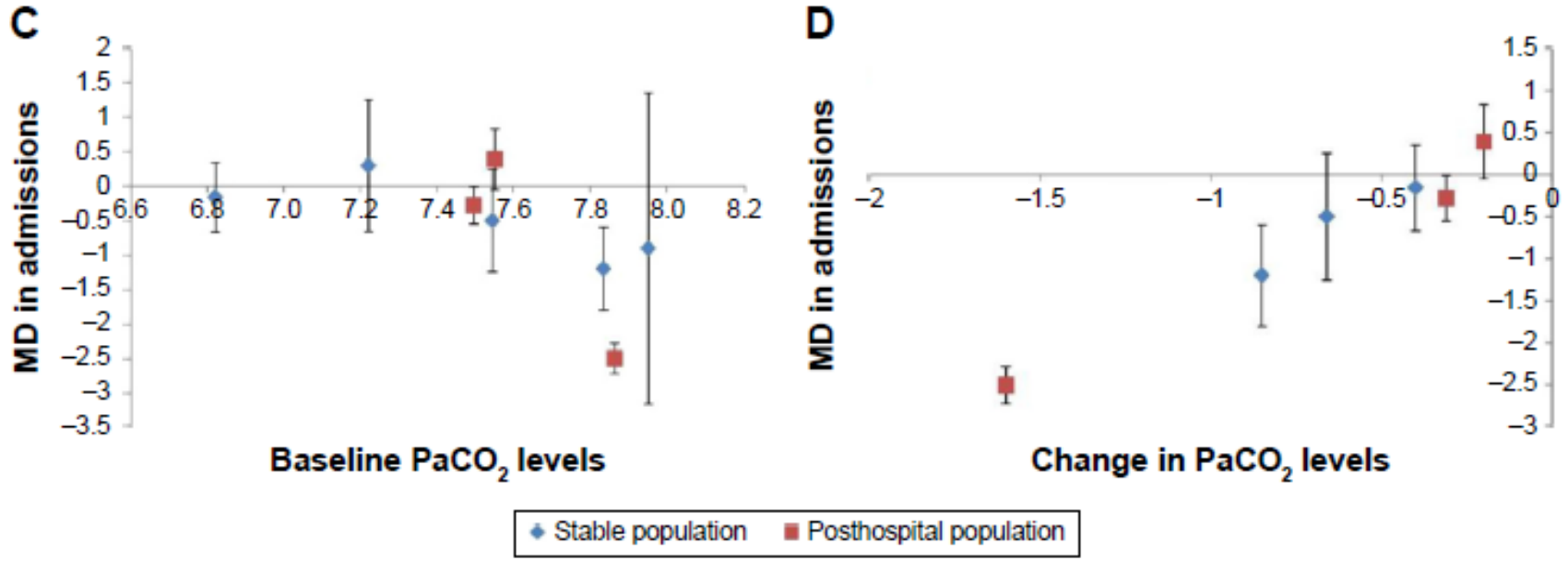
Blood gas analysis:

Arterialised capillary ear lobe blood during SB

HRQoL: SF-36, SGRQ, SRI

Ventilators: VPAP II ST QuickNav

The effect of domiciliary noninvasive ventilation on clinical outcomes in stable and recently hospitalized patients with COPD: a systematic review and meta-analysis



International Journal of COPD 2016:11 2269–2286

Ongoing studies

Murphy *et al.*, Guy's and St Thomas' NHS Foundation Trust, London, UK. [ClinicalTrials.gov identifier: NCT00990132]	Recruitment is finished, waiting for follow-up results	Acute COPD exacerbation with AHRF ⩾2 weeks previously (at least 2 weeks following resolution of the respiratory acidosis) At enrollment in the study, $PaCO_2$ > 7 kPa
NIVOLD study, University Hospital Rouen, France [ClinicalTrials.gov identifier: NCT01526642]	Terminated, not published yet	Patients weaned from ventilation for acute COPD exacerbation ⩾7 days with stable arterial blood gas for at least 2 days: $PaCO_2$ > 7.3 kPa and pH > 7.35
Ankjærgaard *et al.*, Gentofte Hospital Copenhagen, Denmark [ClinicalTrials.gov identifier: NCT01513655]	Running, still recruiting	The home NIV treatment is a direct continuation of the acute treatment, patients are not weaned. So, persistent hypercapnia is not an inclusion criterion

NIV, noninvasive ventilation; AHRF, acute hypercapnic respiratory failure; $PaCO_2$, arterial carbon dioxide tension. Status of the trials not published yet retrieved from ClinicalTrials.gov, and through contact with study coordinators.

JAMA | Original Investigation

Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation

A Randomized Clinical Trial

JAMA. doi:10.1001/jama.2017.4451
Published online May 21, 2017.

Patrick B. Murphy, PhD; Sunita Rehal, MSc; Gill Arbane, BSc (Hons); Stephen Bourke, PhD; Peter M. A. Calverley, PhD; Angela M. Crook, PhD; Lee Dowson, MD; Nicholas Duffy, MD; G. John Gibson, MD; Philip D. Hughes, MD; John R. Hurst, PhD; Keir E. Lewis, MD; Rahul Mukherjee, MD; Annabel Nickol, PhD; Nicholas Oscroft, MD; Maxime Patout, MD; Justin Pepperell, MD; Ian Smith, MD; John R. Stradling, PhD; Jadwiga A. Wedzicha, PhD; Michael I. Polkey, PhD; Mark W. Elliott, MD; Nicholas Hart, PhD

JAMA | Original Investigation

Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation

A Randomized Clinical Trial

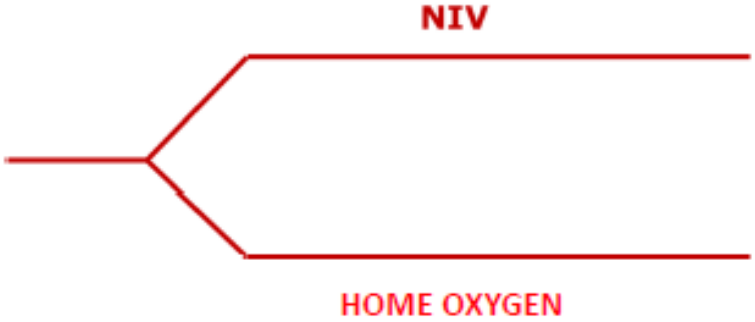
FEV1 0.6 (0.2) L/ 24 (8.6) %
BMI 21.5 Female 51%
13 centres

HoT-HMV UK Trial

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial of patients with persistent hypercapnia ($Paco_2$ >53 mm Hg) 2 weeks to 4 weeks after resolution of respiratory acidemia, who were recruited from 13 UK centers between 2010 and 2015. Exclusion criteria included

- patients after acute exacerbation
- pCO2 > 7 kPa after 2-3 w
- randomisation HOT/HOT-HMV
- 116 pts.
- **primary endpoint:** admission free survival

IPAP	26±3
EPAP	4±1

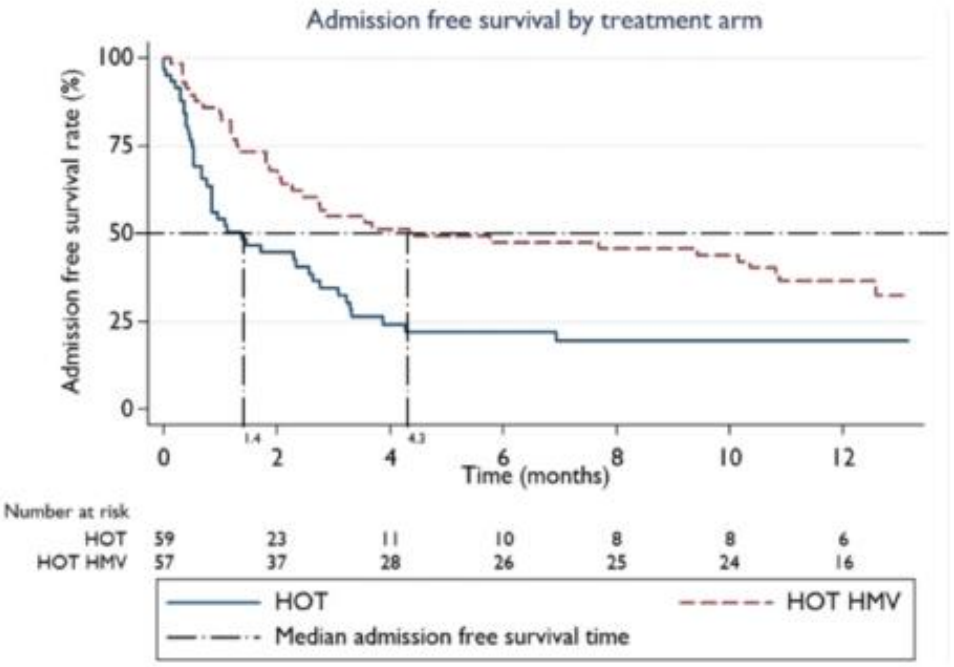


Murphy P et al, JAMA 2017

HOT HMV trial: main results

NIV compliance at 6 weeks (hours:minutes)	4:01±1:48
NIV compliance at 3 months (hours:minutes)	4:17±1:48

	HOT HMV	HOT
Median admission free survival	4.3	1.4
Adjusted HR (95% CI)	0.49 (0.31 -0.77), p=0.002	

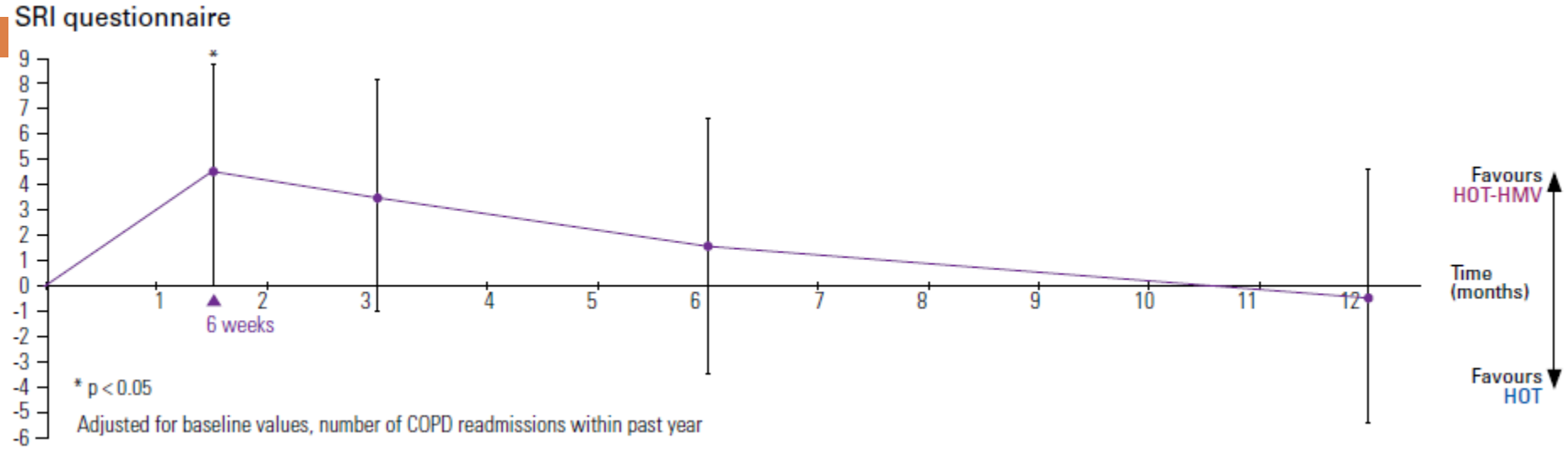


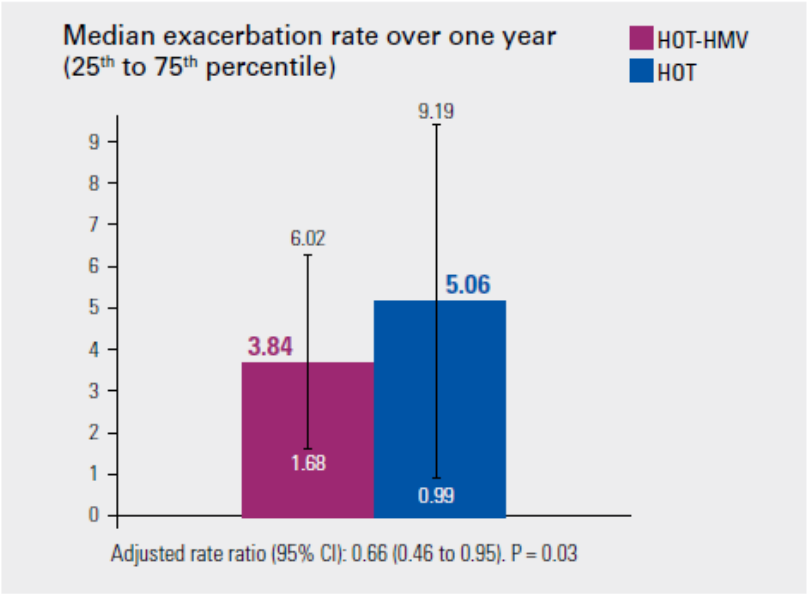
Conclusion: Although prognosis is poor in patients with persistent hypercapnia post exacerbation of COPD, the addition of HMV to HOT improved admission free survival.

Need to treat 6 patients to avoid one hospital readmission or death in 12 months

Murphy P et al, JAMA 2017

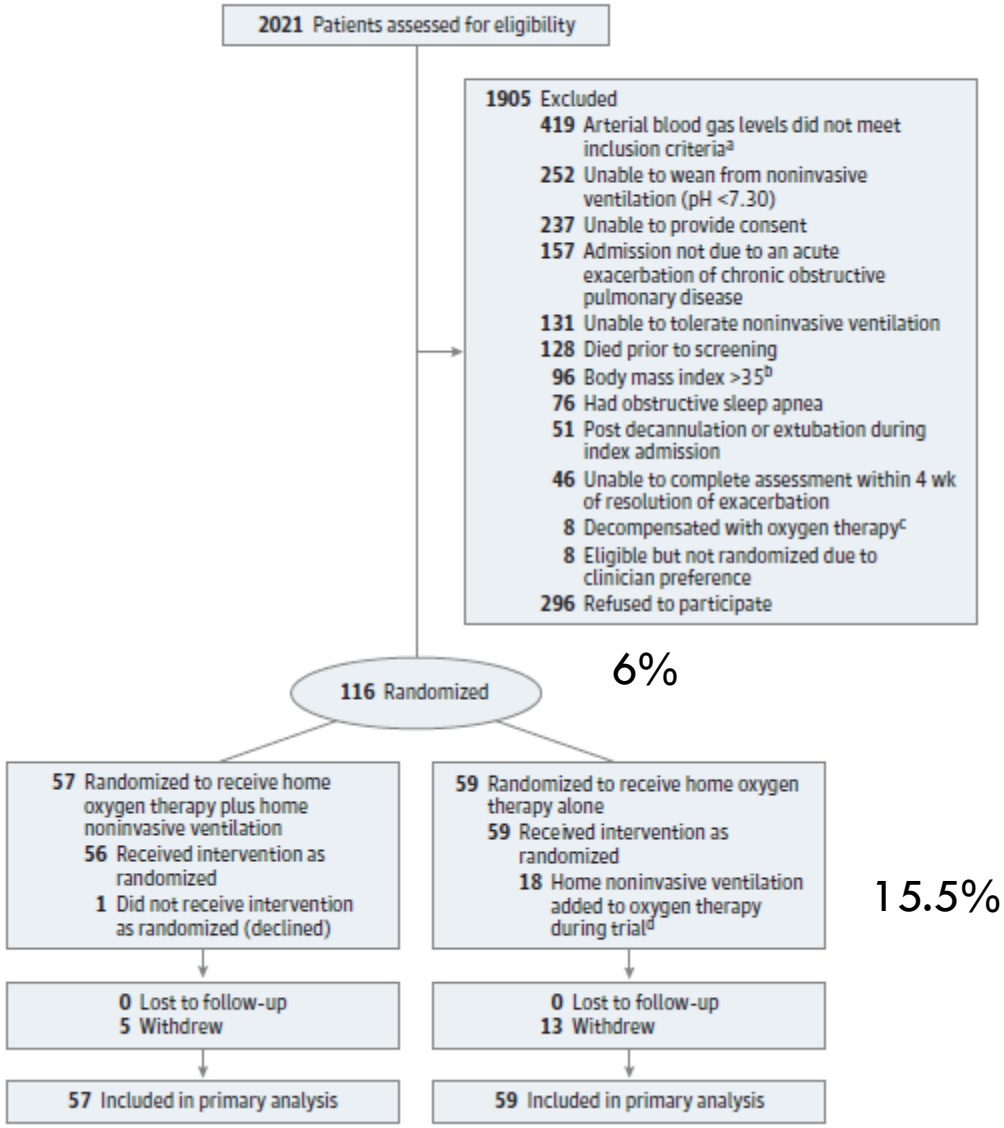
HOT-HMV trial: secondary outcomes





JAMA 2017

Figure 1. Participant Flow Diagram



20.7%

12.4%

6,5%

6%

15.5%

[a] Defined as absence of hypercapnia ($PaCO_2$ <53 mm Hg), hypoxemia (PaO_2 >60 mm Hg), or both.

[b] Calculated as weight in kilograms divided by height in meters squared.

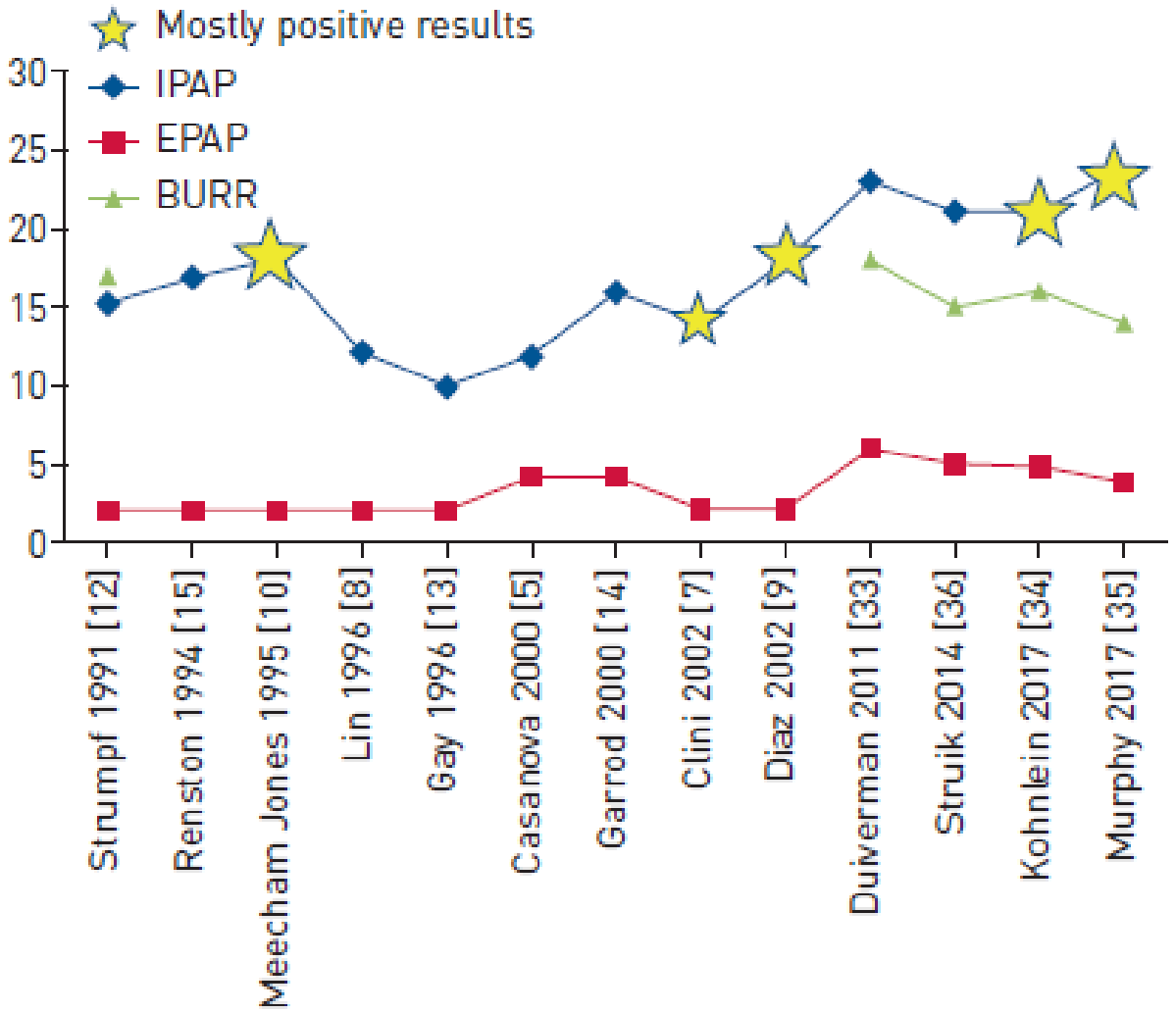
[c] Defined as an arterial pH of less than 7.30 when morning arterial blood gas measured after use of oxygen therapy alone.

[d] Seventeen patients received home noninvasive ventilation after hospital readmission (consistent with trial protocol) and, at the discretion of the treating clinician, 1 patient received home noninvasive ventilation prior to reaching the primary outcome.

Other comments: Murphy's study

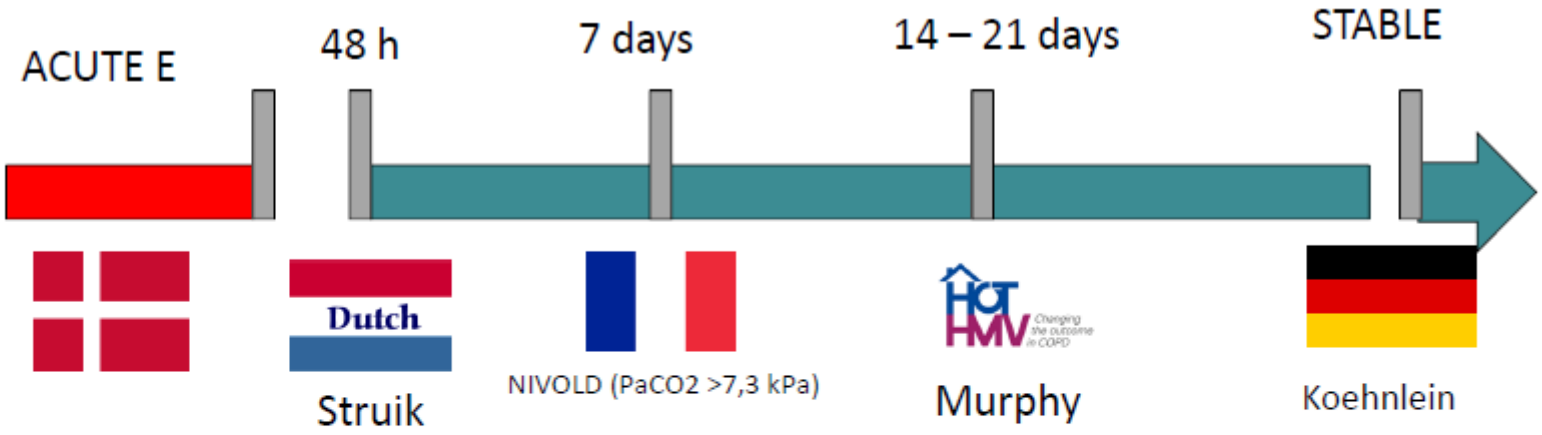
- No Pulmonary Rehabilitation
- Only one centre: respiratory poligraphy (n=47)
- Crude mortality rate in these 116 patients over 1 year is around 30%: no mention of EOL plans

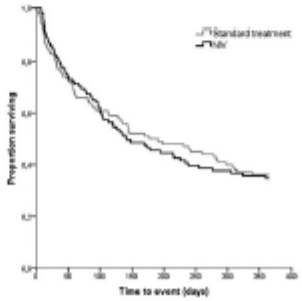
Evolution of ventilatory settings in RCT

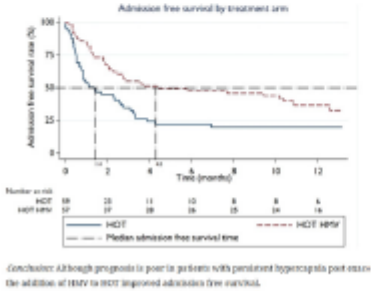


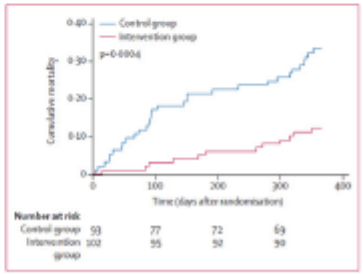
Duiverman ML. ERJ Open Res 2018

HMV timing


ACUTE E
48 h
7 days
14 – 21 days
STABLE
Dutch
Struik
NIVOLD (PaCO2 >7,3 kPa)
Murphy
Koehnlein





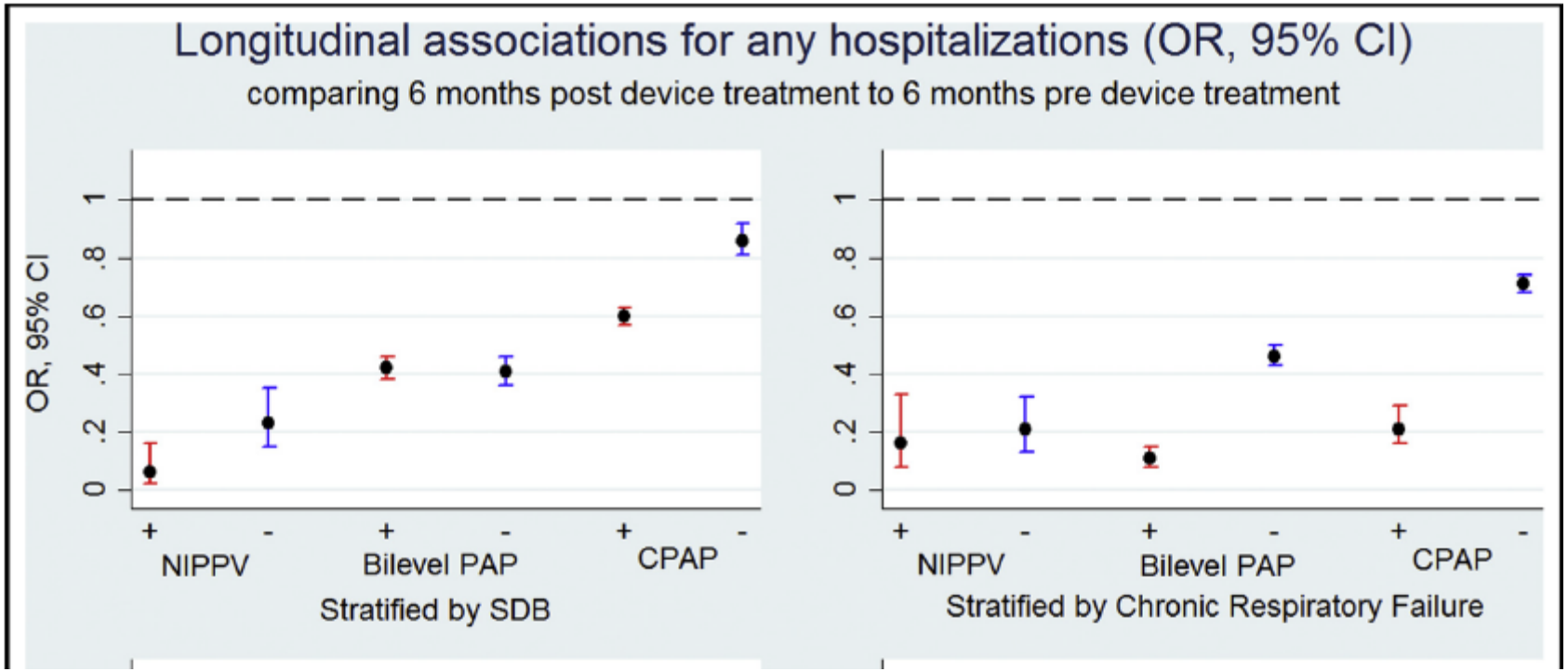


BIG DATA

CLINICAL RESEARCH STUDY

THE AMERICAN JOURNAL of MEDICINE®

Positive Airway Pressure Therapies and Hospitalization in Chronic Obstructive Pulmonary Disease



Outcomes and COPD phenotype

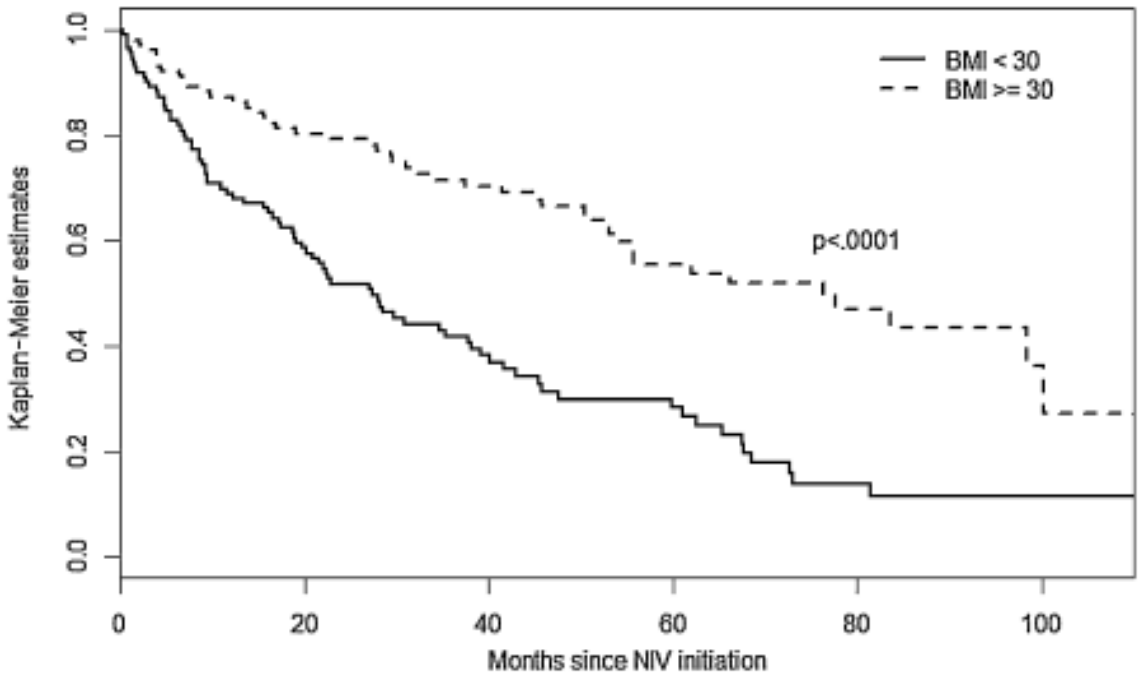
Official Journal of the Asian Pacific Society of Respirology
Respirology

ORIGINAL ARTICLE

Long-term adherence with non-invasive ventilation improves prognosis in obese COPD patients

JEAN-CHRISTIAN BOREL,[1,2] JEAN-LOUIS PEPIN,[1,2] CHRISTOPHE PISON,[3,4,5] AURÉLIEN VESIN,[6] JESUS GONZALEZ-BERMEJO,[7] ISABELLE COURT-FORTUNE[8] AND JEAN-FRANÇOIS TIMSIT[6,9]

N=213



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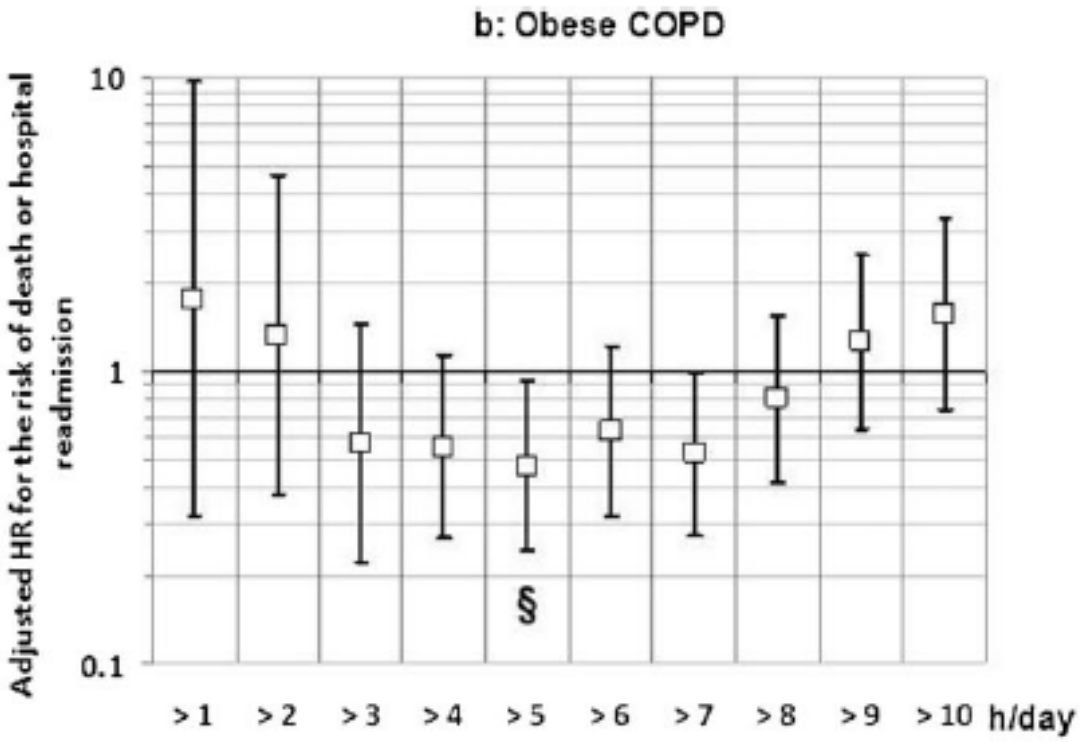
Long-term adherence with non-invasive ventilation improves prognosis in obese COPD patients

JEAN-CHRISTIAN BOREL,[1,2] JEAN-LOUIS PEPIN,[1,2] CHRISTOPHE PISON,[3,4,5] AURÉLIEN VESIN,[6] JESUS GONZALEZ-BERMEJO,[7] ISABELLE COURT-FORTUNE[8] AND JEAN-FRANÇOIS TIMSIT[6,9]



N=102
BMI 34.5
PaCO2 47
IPAP 20
EPAP 8
BUR 14

The future

Physiologic Effects of an Ambulatory Ventilation System in Chronic Obstructive Pulmonary Disease

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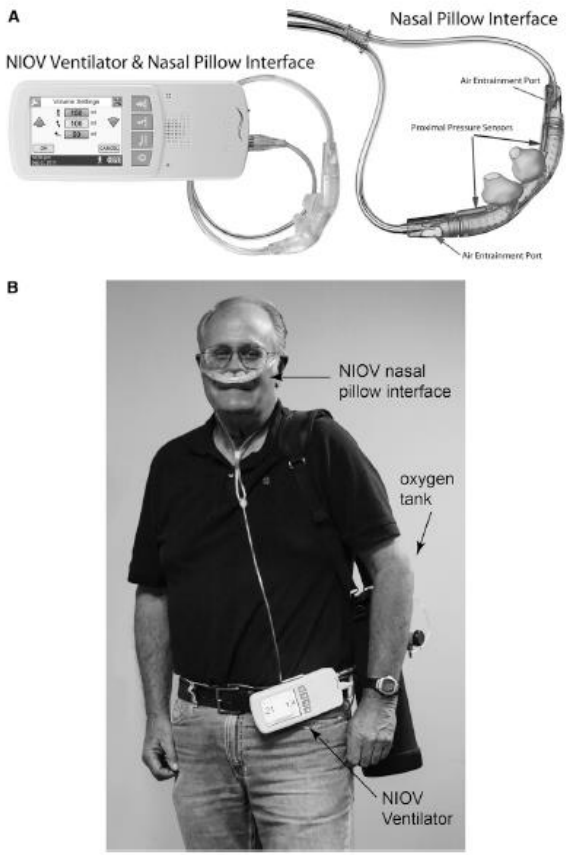

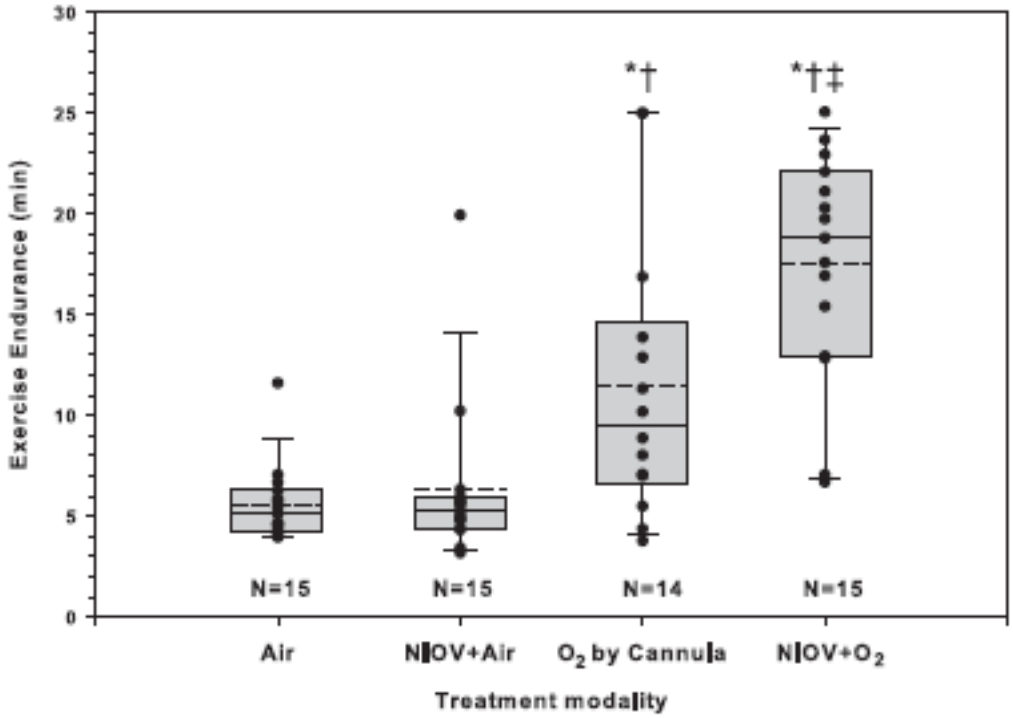

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Open Access Protocol

BMJ Open

Medium-term cost-effectiveness of an automated non-invasive ventilation outpatient set-up versus a standard fixed level non-invasive ventilation inpatient set-up in obese patients with chronic respiratory failure: a protocol description

P Mur
M Polkey

Lane Fox Unit Ventilator Set Up
Outpatient Set up

Pre screen patient for Sleep Disorder Breathing (SDB) with home oximetry

Evidence for SBD → Screen for OPIP Trial at site

Take ABG
If fits criteria – RANDOMISE
Returns to site within 2 weeks as outpatient
CONTINUE IF OUTPATIENT SET UP

TOSCA to be left on for 120 minutes
Repeat ABG

Trial with AE AVAPS
- Titrate volume 8-10mls/kg ideal body weight *
- Aim to reduce TcCO2 by 0.5kPa
- MAXIMUM IPAP = 30cm H20
- MAXIMUM EPAP = 14cm H20
- Back up Rate = Resting Respiratory Rate-2
- Digital Auto Trak Algorithm
- If SpO_2<88% titrate O_2 to maintain >88%

ALARMS:
Can be set according to site preference

Humidification:
Offer to patients – record date of starting

* Ideal body weight should be calculated using the assumption that the BMI is 23kg/m². E.g. if some one is 176cm:
Weight (Kg)=BMI x height (m)²
Weight = 23 x (1.76x1.76)
=23 x 3.1
=71.2Kg

- Train patient/relative how to use
- Assess patient/relative competency
- Send patient home with 2 night oximetry (return to site)

- IF inadequate control of ventilation of difficulties with NIV use → patient to return to Outpatients for review

Research Follow up:
- 6 weeks
- 3 months

OPIP Trial: Nurse-Led Protocolised Ventilator Set-up

TOSCA Monitoring
- Capnography
- Oximetry
EMBLETTA monitoring
All baseline studies on room air

OBESITY RELATED RESPIRATORY FAILURE
OSA
OSA-OHS
Lone OHS

Ventilators to use
A40
Starting Ti Settings
1.2s
Starting Backup rate
14bpm

START HERE

MODE
PRESSURE SUPPORT

STARTING PRESSURES
OSA-OHS - IPAP 18cmH2O EPAP 8cmH2O
Lone OHS - IPAP 18cmH2O EPAP 4cmH2O
Max Settings IPAP 32 cmH2O EPAP 14 cmH2O

Is there persistent snoring, chest wall paradox with oxygen desaturations?

Yes

No

Is $TcCO_2$ falling? Or Is the TcCO2 <7.0kPa?

Aim for fall of 0.5kPa to 1kPa overnight

No

Check for leak and mask fit before changing settings

Check for leak and mask fit before changing settings

Is SpO_2 > 88%?

Increase EPAP by 2cmH_2O
Review over 30 minutes
Do not increase EPAP above 14 cmH_2O unless specified by the consultant

No

Yes

Increase IPAP by 2cmH_2O
Review over 1 hour

Entrain O_2 @ 1-4L/min
Aim SpO_2 > 88%

Titration achieved
Continue to monitor

Telemedicine and Ventilator Titration in Chronic Respiratory Patients Initiating Non-invasive Ventilation (TeleMotiNIV)

This study is currently recruiting participants.

Verified October 2012 by Hospital Sao Joao

Sponsor:
Hospital Sao Joao

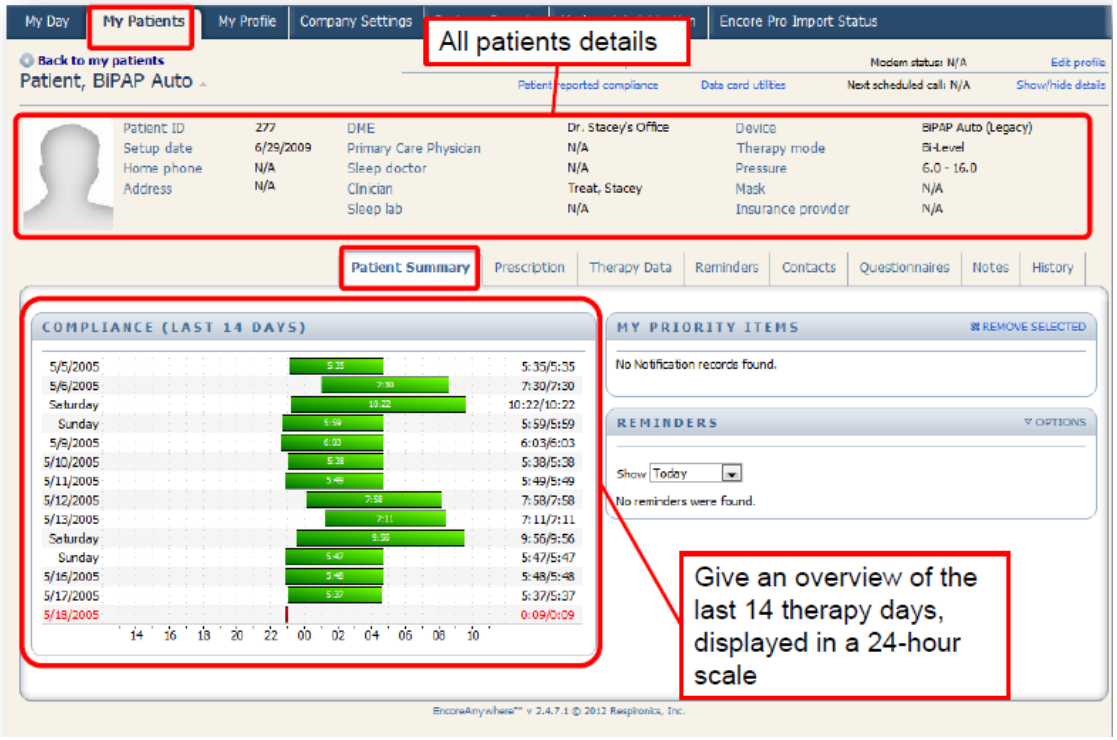
ClinicalTrials.gov Identifier:
NCT01560741

First received: March 20, 2012
Last updated: October 3, 2012
Last verified: October 2012

PHILIPS

Introducing EncoreAnywhere

4 Patient record

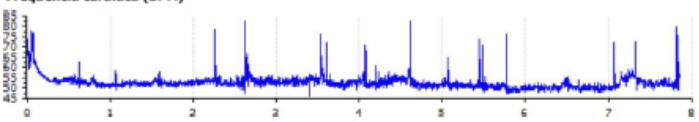


Detalhes diários do ventilador

10/10/2012 1:31

SpO2 (%)

Frequência cardíaca (BPM)



Índice de dessaturação de oxigênio
0,1
Média de SPO2
93,5%
Média de frequência cardíaca
52,7

Tempo passado na faixa de oximetria

	Alto	Média	Baixo
SpO2	98,0%	93,5%	89,0%
Frequência cardíaca (batimentos por minuto)	83,0	52,7	46,0

	>95%	90-95%	85-89%	80-84%	<80%
% do tempo	5,8%	94,2%	0,0%	0,0%	0,0%
Tempo real (hh:mm:ss)	00:27:10	07:23:40	00:00:10	00:00:00	00:00:00

Nível de saturação baixa (SB)	90%
% do tempo < SB(90%)	0,0%
Tempo real < SB(90%) (hh:mm:ss)	00:00:10
Número de eventos de dessaturação	1
Índice de dessaturação de oxigênio	0,1
Tempo real <= 88% (hh:mm:ss)	00:00:00

Patient Summary | Prescription

DEVICE PRESCRIPTION

› Sleep

⌄ Vent Therapy

Mode *	S/T
Device *	BiPAP A30
Mode Attribute *	Nenhum
Serial Number	N04924518DA44
Issued On *	24/10/2013

Configurações do dispositivo

Pressão IPAP	27,0
Pressão EPAP	
Taxa respiratória	
Inspiração cronometrada	
Configuração do umidificador	
Humidificação do System One do desvio	
Definição do tempo de elevação	
Bloqueio da definição do tempo de elevação	
Rampa	
Tempo de rampa	
Pressão inicial de rampa	

24,0
24,5
25,0
25,5
26,0
26,5
27,0
27,5
28,0
28,5
29,0
29,5
30,0

* Required Fields

Cancel

Global Initiative for Chronic Obstructive Lung Disease

2026 REPORT

Ventilatory Support

- NPPV may improve hospitalization-free survival in selected patients after recent hospitalization, particularly in those with pronounced daytime persistent hypercapnia ($PaCO_2$ > 53 mmHg) **(Evidence B)**
- In patients with severe chronic hypercapnia and a history of hospitalization for acute respiratory failure, long-term noninvasive ventilation may be considered **(Evidence B)**

Conclusions

- Evidence of NIV in stable COPD has grown, and now we have a strong survival benefit…
- Favorable Phenotypes: higher hypercapnia
- Usage of high-intensity NIV recommended
- Control of compliance (>5h) is mandatory
- Portable ventilators, Automatic set-up and Home titration (Telemedicine) a good alternative?