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Annals of the American Thoracic Society

Domiciliary High-Flow Nasal Cannula Oxygen Therapy for Stable Hypercapnic COPD Patients: A Multicenter, Randomized Crossover Trial

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Key point of the paper

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- Six weeks of therapy with nasal high flow (NHF) plus long-term oxygen therapy (LTOT) improved quality of life (QoL) and reduced hypercapnia compared with LTOT alone in stable hypercapnic chronic obstructive pulmonary disease (COPD) patients.

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Study background

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There is increasing evidence for the use of NHF in the acute setting but more information is required about its application in the home. The use of domiciliary NHF in stable COPD patients with chronic hypercapnic respiratory failure was evaluated in this study.

Aim

To compare the efficacy and safety of domiciliary NHF and LTOT vs. LTOT alone in stable hypercapnic COPD patients

Study design

A multicenter, prospective, randomized cross-over trial was conducted over 12 weeks (6 weeks for each therapy).

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Background

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Setting

Patients were recruited from nine hospitals in Japan and received therapy at home during 2015 and 2016.

Population

N = 30

- COPD patients with hypercapnia and Global Initiative for Obstructive Lung Disease (GOLD) stages 2 to 4
- Prescribed LTOT for at least 16 hours per day for at least 1 month prior to enrollment

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Methods

PRIMARY OUTCOME	SECONDARY OUTCOMES
Change in the mean total score of St. George's Respiratory Questionnaire for COPD (SGRQ-C)	Changes in: • Each component of the SGRQ-C • EuroQol five-dimensional questionnaire (EQ-5D-5L) • Dyspnea severity measured using the modified Medical Research Council (mMRC) scale • Arterial blood gas analysis • Nocturnal $PtcCO_2$, SpO_2 • Pulmonary function tests (PFTs) • 6-minute walk test (6MWT) • Physical activity • Number of exacerbations • Medication
	Adverse events were also analyzed

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Methods

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INCLUSIONS	EXCLUSIONS
20 years or older	Severe and unstable comorbidities or active malignancy
COPD patients, GOLD stages 2 to 4	History of obstructive sleep apnea
Prescribed LTOT for at least 16 hours per day for at least 1 month	Exacerbation of COPD within 6 weeks
Hypercapnic respiratory failure ($PaCO_2$ 45 — 60 mmHg)	Use of nocturnal noninvasive ventilation within 6 weeks
	Cognitive impairment, psychiatric disorder

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Methods

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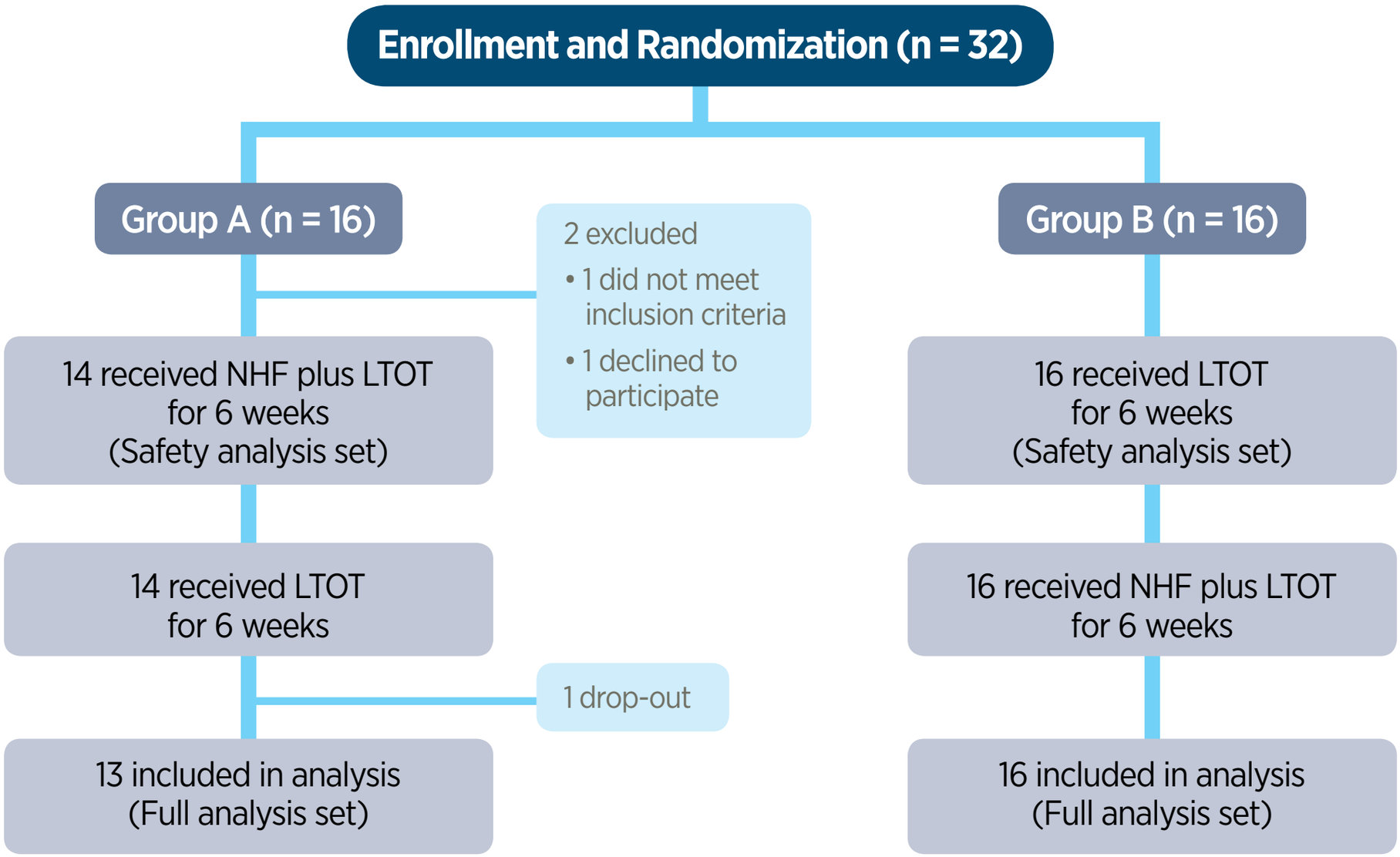

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Methods

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- NHF was administered using myAIRVO™ 2 via an Optiflow™ nasal cannula interface.
- Patients were instructed to use NHF for at least four hours per night during sleep, at flow rates of 30 to 40 L/min.

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Results

Baseline characteristics

CHARACTERISTIC	GROUP A (n = 13)	GROUP B (n = 16)
Age (years)	73.8 ± 6.9	76.2 ± 9.3
Male (%)	92.3	88.0
GOLD stage 2/3/4 (%)	7.7/23.1/69.2	6.3/37.5/56.3
Arterial blood gas		
• pH	7.39 ± 0.03	7.39 ± 0.03
• $PaCO_2$ (mmHg)	51.5 ± 8.2	52.3 ± 6.7
• PaO_2 (mmHg)	89.2 ± 27.3	87.8 ± 38.0
SpO_2 (%)	95.9 ± 1.9	95.0 ± 3.1

Data are presented as mean ± SD where applicable.

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Results

Actual NHF usage during the study

	GROUP A (n = 13)	GROUP B (n = 16)
Duration (hours/night)	7.1 ± 1.5	8.6 ± 2.9
Flow rate (L/min)	29.2 ± 1.9	30.3 ± 4.6

Data are presented as mean ± SD.

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Results

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Primary outcome

- NHF/LTOT significantly improved the mean SGRQ-C total score compared with LTOT alone.

SGRQ-C	ADJUSTED TREATMENT EFFECT (95% CONFIDENCE INTERVAL)	P VALUE
Total score*	**-7.8 (-11.9, -3.7)**	**< 0.01**
• Symptom score	-10.8 (-15.3, -6.3)	< 0.01
• Activity score	-4.7 (-8.7, -0.6)	0.03
• Impact score	-8.7 (-15, -2.5)	0.01

* The change in mean total score was the primary outcome for this study. Changes in individual components were secondary outcomes.

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Results

Secondary outcomes

- NHF/LTOT improved the following significantly compared with LTOT alone:
  - Each component of the SGRQ-C
  - Arterial blood gas: pH, $PaCO_2$
  - Nocturnal $PtcCO_2$ (95^{th} percentile and median)

	ADJUSTED TREATMENT EFFECT (95% CONFIDENCE INTERVAL)	P VALUE
Arterial blood gas		
• pH	0.02 (0.01, 0.02)	0.01
• $PaCO_2$ (mmHg)	-4.1 (-6.5, -1.7)	< 0.01
Nocturnal $PtcCO_2$ (mmHg)		
• 95^{th} percentile	-4.8 (-8.1, -1.5)	< 0.01
• Median	-5.1 (-8.4, -1.8)	< 0.01

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Results

Secondary outcomes

- No exacerbations occurred during NHF/LTOT.
  Three patients experienced an exacerbation during LTOT.

- Two severe adverse events unrelated to therapy occurred per group during the study.

- Six mild adverse events (night sweating, nasal discharge, insomnia) related to therapy occurred during NHF/LTOT compared to one during LTOT; however none of these resulted in discontinuation of treatment.

- SpO_2, PFTs, 6MWT, physical activity, dyspnea, EQ-5D-5L: no significant treatment effects seen.

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Conclusions

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- NHF improves QoL and reduces hypercapnia in COPD patients with chronic hypercapnic respiratory failure.
- NHF is well tolerated and no related severe adverse events occurred during therapy.

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Additional information

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- PubMed Link
  www.ncbi.nlm.nih.gov/pubmed/29283682
- Clinical Trial Register: NCT02545855
- No financial contribution was made by Fisher & Paykel Healthcare for this study.

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