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Artículo especial

## Home Non-Invasive Ventilation for COPD: How, Who and When?

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### ABSTRACT

Patients with chronic obstructive pulmonary disease (COPD) and chronic respiratory failure have high levels of morbidity and mortality. The clinical efficacy of long term home oxygen therapy has been well documented in this patient group but despite the efficacy of non-invasive ventilation (NIV) during acute decompensated respiratory failure the addition of home NIV has been associated with equivocal results. The physiological efficacy of home NIV to improve gas exchange in chronic stable hypercapnic respiratory failure has been proven in small studies but larger clinical trials failed to translate this into clinical efficacy. Criticisms of early clinical trials include the use of marginally hypercapnic patients and failure to demonstrate effective delivery of home NIV. When considering recent trial data it is important to clearly evaluate the patient phenotype and timing and delivery of NIV. Recent data supports the delivery of home NIV in patients with chronic hypercapnia ( $\text{PaCO}_2 > 7 \text{ kPa}$  or  $50 \text{ mmHg}$ ) and the frequent or infrequent exacerbator phenotype. Importantly in the frequent exacerbator the timing of the assessment needs to be in the recovery phase, 2-4 weeks after resolution of acute acidosis, to delineate transient from persistent hypercapnia. In patient with persistent hypercapnia NIV must be titrated to achieve control of sleep disordered breathing with the aim of improving daytime respiratory failure. Furthermore there are observational data to support the use of home positive airway pressure therapy (NIV or continuous positive airway pressure; CPAP) in patients with COPD and obstructive sleep apnoea (OSA) both with and without hypercapnia.

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## Ventilación no invasiva domiciliaria para la EPOC: cómo, quién y cuándo

### RESUMEN

Los pacientes con enfermedad pulmonar obstructiva crónica (EPOC) e insuficiencia respiratoria crónica tienen morbilidad y mortalidad elevadas. La efectividad de la oxigenoterapia domiciliaria a largo plazo ha sido bien documentada en esta población pero, aunque está demostrada la eficacia de la ventilación no invasiva (VNI) durante la insuficiencia respiratoria descompensada aguda, añadir VNI domiciliaria se ha dado lugar a resultados conflictivos. La eficacia fisiológica de la VNI domiciliaria para mejorar el intercambio de gases en la insuficiencia respiratoria hiper-cápnica crónica estable se ha demostrado en estudios pequeños, pero ensayos clínicos de mayor tamaño no han logrado mostrar eficacia clínica. Las críticas a los primeros ensayos clínicos comprenden la inclusión de pacientes marginalmente hiper-cápnicos y la imposibilidad de demostrar que la VNI domiciliaria se administrara correctamente. Al considerar los datos de ensayos recientes, es importante evaluar claramente el fenotipo del paciente y el momento y administración de la VNI. Datos recientes respaldan el uso de VNI domiciliaria en pacientes con hiper-capnia crónica ( $\text{PaCO}_2 > 7 \text{ kPa}$  o  $50 \text{ mmHg}$ ) y fenotipo de exacerbador frecuente o poco frecuente. Es importante destacar que, en el exacerbador frecuente, la evaluación se debe realizar en la fase de recuperación, 2-4 semanas después de la resolución de la acidosis aguda, para diferenciar la hiper-capnia

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transitoria de la persistente. En pacientes con hipercapnia persistente, la VNI se debe ajustar para controlar el trastorno respiratorio del sueño y así mejorar la insuficiencia respiratoria diurna. Además, hay datos observacionales que apoyan el uso de ventilación mecánica domiciliaria con presión positiva (VNI o presión positiva continua en las vías respiratorias, CPAP) en pacientes con EPOC y apnea obstructiva del sueño (OSA) con y sin hipercapnia.

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## Introduction

The use of non-invasive ventilation (NIV) to support patients during acute decompensated respiratory failure secondary to an exacerbation of chronic obstructive pulmonary disease (COPD) has unequivocal evidence of benefit in terms of reduction in the need for intubation, length of hospital stay and mortality.<sup>1,2</sup> The clinical impact of the treatment effect with acute NIV, coupled with the high levels of morbidity and mortality experienced by COPD patients with chronic hypercapnic respiratory failure,<sup>3</sup> provides an appealing clinical rationale for treating such patients with home NIV.

When examining the evidence for home NIV in COPD patients with hypercapnic respiratory failure, it is important to phenotype the patients by (1) the frequency of exacerbations and stability of the clinical condition; infrequent stable exacerbators with low acute hospital admission rate vs. frequent unstable exacerbators with high acute hospital admission rate requiring acute NIV and (2) the presence of co-existent obstructive sleep apnoea, termed COPD-OSA overlap syndrome.

Patients with stable chronic hypercapnia with low exacerbation frequency may have NIV added to standard care and indeed this can be timed to augment the response to pulmonary rehabilitation.<sup>4</sup> The addition of home NIV to the high exacerbation frequency and high acute admission group is more challenging. Despite these differences, it is essential to assess and optimise NIV treatment delivery and demonstrate effective management of chronic respiratory failure during initiation and maintenance treatment with NIV.

## Delivery of NIV in COPD: How?

The optimal approach to deliver effective NIV in COPD has been debated, but there is consensus that overnight physiologically titration of NIV is required to control nocturnal hypoventilation and treat chronic respiratory failure. The use of 'high intensity' NIV in COPD has been reported, but concerns have been raised regarding tolerability and adherence as well as physiological coherence of such a strategy in patients with expiratory airflow limitation. These concerns have been addressed, in part, in a small randomised controlled crossover trial performed in a highly specialist centre [4]. Dreher and colleagues showed that high inspiratory positive airways pressure and high back up rate ('high intensity' NIV) had superior physiological efficacy, reflected as greater control of nocturnal carbon dioxide, compared with low inspiratory positive airways pressure and low back up rate ('low intensity' NIV).<sup>5</sup> Whilst greater pressure support is expected to enhance alveolar ventilation and increase carbon dioxide clearance, interestingly, far from 'high intensity' being associated with lower NIV adherence it was, in fact, associated with improved adherence compared to 'low intensity' NIV (mean difference in ventilator usage of 3.6 hours; 95%CI 0.6 to 6.7 hours,  $p=0.024$ ). In a subsequent study, the same group of investigators demonstrated that 'high intensity' NIV has a similar effect on sleep disruption as 'low intensity' NIV.<sup>6</sup> However, there remain concerns that the 'high intensity' approach may

have negative short term cardiovascular consequences<sup>7</sup> with the long-term cardiovascular consequences largely unknown.

Although the benefit of a 'high intensity' approach is clear in terms of the management of chronic respiratory failure, it remains unclear if both delivery of high pressure and high backup rate are required. Indeed, the use of 'high intensity' NIV (high inspiratory pressure support and high back up rate) has demonstrated similar benefit as 'high pressure' NIV only (high inspiratory pressure support and low back up rate) in COPD patients.<sup>8</sup> Furthermore, the use of a 'high pressure' strategy was associated with greater improvement in respiratory specific health related quality of life over the 'high intensity' approach.<sup>8</sup> Finally, a 'high intensity' ventilator strategy requires a slower acclimatisation for patients with a duration of admission of greater than 5 days.<sup>5,9</sup>

Studies that have failed to demonstrate control of nocturnal hypoventilation, and subsequent failure to improve chronic respiratory failure, have shown limited clinical benefit in COPD patients,<sup>10,11</sup> whereas those studies demonstrating improvement in chronic respiratory failure have generally shown a clinical benefit.<sup>9,12</sup> This supports the rationale that the major factor when treating chronic respiratory failure in COPD patients is to ensure the treatment is delivered to ameliorate nocturnal hypoventilation and improve daytime gas exchange. The clinical strategy of 'high intensity' or 'high pressure' that is employed to achieve the target of management of chronic respiratory failure is probably less important.

## COPD Phenotype: Who and When?

### Stable Chronic Respiratory Failure

Detailed physiological studies have previously demonstrated the mechanism of action of home NIV in stable COPD with chronic hypercapnia.<sup>13-15</sup> Until recently, the physiological science has failed to translate to a beneficial clinical outcome in randomised clinical trials. Careful consideration must always be given to the target population, intervention type and delivery, comparator group and the primary outcome when considering trial design. Indeed, a number of the earlier clinical trials investigating the effect of home NIV enrolled stable COPD patients with only borderline hypercapnic respiratory failure with, as expected, limited physiological efficacy demonstrated, which resulted in a lack of clinical benefit.<sup>10,11</sup> Furthermore, these early NIV studies failed to show a physiological effect (Table 1) because they employed a 'low intensity' (low inspiratory pressure and low back up rate) ventilator strategy as the intervention.<sup>16,17</sup>

Whilst the lack of clinical effectiveness demonstrated in earlier trials can be attributed to the inappropriate target population and suboptimal intervention delivery, the randomised clinical trial from Kohnlein and colleagues has provided evidence that a moderate inspiratory pressures and back up rate are beneficial in terms of mortality in stable COPD patients.<sup>9</sup> Kohnlein and colleagues randomised 195 patients with stable severe COPD (GOLD stage IV) and chronic respiratory failure ( $\text{PaCO}_2 > 7 \text{ kPa}$  or 53 mmHg). Patients were excluded if they had significant co-morbidity, obesity (body

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