

myAIRVO2 for the treatment of chronic obstructive pulmonary disease

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is myAIRVO2. It is designed to warm and humidify respiratory gases used for nasal high-flow therapy. This briefing focuses on its potential use in a community setting.
- The **innovative aspects** are that myAIRVO2 is designed to allow the delivery of nasal high-flow therapy in a community setting. It is also designed to allow clinicians to titrate flow and oxygen independently from one another and does not need a sealed interface.
- The **intended place in therapy** would be as well as standard management in the home or long-term care environment for people with chronic obstructive pulmonary disease (COPD) having nasal high-flow oxygen therapy.
- The **main points from the evidence** summarised in this briefing are from 5 studies, 1 randomised controlled trial and 4 randomised crossover trials including a total of 232 adults. They show that myAIRVO2 is at least as effective as non-humidified and unwarmed gases in patients with COPD and has the potential to reduce hospital admissions.
- **Key uncertainties** around the evidence relate to the lack of follow-up to show the long-term positive effects of myAIRVO2 and the generalisability to UK NHS practice. There are also uncertainties around which patient group nasal high-flow therapy would most benefit in a community setting and if it should be used with or instead of current treatments.

- The cost of myAIRVO2 is £2,475 per unit (excluding VAT). The overall resource impact is uncertain because there is no published evidence assessing the resource consequences of myAIRVO2 in a community setting. More information on this would be helpful.

The technology

The myAIRVO2 system delivers warmed and humidified respiratory gases, including at high-flow rates. It includes a humidifier with an integrated flow generator that is designed for use in patients who are breathing without help and has interfaces to suit both upper and bypassed airways (tracheostomy patients). Other features of myAIRVO2 are that it allows clinicians to titrate flow (from 10 to 60 litres/min on adult mode) and oxygen independently from one another and does not need a sealed interface. The product is marketed as AIRVO2 and myAIRVO2. myAIRVO2 is a device that is being used in the home or other domiciliary care environment. This briefing focuses on myAIRVO2 delivering nasal high-flow therapy for treating chronic obstructive pulmonary disease (COPD), including in a community setting.

Innovations

myAIRVO2 differs from standard respiratory gas devices in being designed to allow the delivery of nasal high-flow therapy in a community setting. It also uses room air, removing the need for piped medical air, and humidifies the delivered air to reduce the risk of dryness and trauma to the upper airway mucosa.

Current care pathway

The NICE guideline on [chronic obstructive pulmonary disease](#) recommends treatment options including smoking cessation, inhaled therapy, oral therapy, oxygen therapy, non-invasive ventilation, pulmonary rehabilitation and surgery.

The guideline makes detailed recommendations for patient selection and use of long-term oxygen therapy and non-invasive ventilation. The guideline does not include recommendations on nasal high-flow therapy as an alternative or adjunct to these interventions.

The British Thoracic Society guideline on [oxygen use in adults in healthcare and emergency settings](#) highlights that, as part of good clinical practice, high-flow nasal oxygen should be considered as an alternative to reservoir mask treatment in patients with acute respiratory failure without hypercapnia.

Population, setting and intended user

The place in treatment of myAIRVO2 in a community setting is uncertain because patient selection for nasal high-flow oxygen (or oxygen-enriched gases) isn't well defined. It could be used in place of, or as well as, long-term oxygen therapy or non-invasive ventilation.

myAIRVO2 would be prescribed by a healthcare professional and administered by a carer or community nursing staff or the patient themselves.

Costs

myAIRVO2 costs £2,475 (including 3 filters) and has a lifespan of 5 years with no additional servicing costs or needs. The consumable components cost £136 per patient per 2-month period and £9 per filter, which needs replacing every 3 months or 1,000 hours of use. Based on these costings, the total device costs of myAIRVO2 are £1,320 per patient in the first year and £1,347 in the remaining 4 years.

Standard of care

Nasal high-flow therapy is not routinely delivered in a community setting in the NHS so direct comparative costs are not available. Interventions that myAIRVO2 might replace or be used alongside include a domiciliary non-invasive ventilation service (£2,373 in the first year, excluding device costs, and £1,536 in subsequent years [Dretzke et al. 2015]).

Resource consequences

myAIRVO2 would represent an additional cost to standard care, which could potentially be offset if it resulted in a reduction in exacerbations, admissions to hospital, or antibiotic use. Other cost savings may be possible if myAIRVO2 helps support early discharge from hospital. myAIRVO2 is for use in the patient's home and in community care facilities. It is anticipated that introducing this technology for community-based patients would need some pathway redesign with changes in resourcing because of this.

Regulatory information

myAIRVO2 is a CE marked class IIa medical device. The following Medical Device Alert for this technology has been identified:

Risk of undetected auditory alarm (2016) – updated instructions for use to check the speaker before each use because undetected auditory alarms could result in the patient becoming hypoxic. All actions outlined for this alert have been completed and the alert has been archived.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Chronic obstructive pulmonary disease (COPD) is a chronic condition, which may mean someone is disabled if this has a substantial and long-term effect on their ability to do daily activities. Disability is a protected characteristic under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

The evidence base for myAIRVO2 includes over 20 studies identified as being potentially relevant, including more than 10 randomised trials. Seven studies were published in abstract form only. Five studies (1 randomised controlled trial and 4 randomised crossover trials) are summarised in this briefing, including 232 patients. Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence suggests that myAIRVO2 shows efficacy in treating patients with chronic obstructive pulmonary disease compared with non-humidified unheated respiratory support. One study reported a reduction in hospital admissions. However, there is little evidence of the long-term

effects of myAIRVO2. As well as the lack of long-term studies, it is uncertain how generalisable the studies are to UK NHS practice because none of the studies were done in the UK. Only 1 study assessed myAIRVO2 in a community setting.

Table 1 Summary of selected studies

<u>Storgaard et al. (2018)</u>	
Study size, design and location	Prospective RCT of 200 patients diagnosed with COPD with chronic hypoxaemic respiratory failure. Study done at 4 outpatient clinics in Denmark.
Intervention and comparator(s)	LTOT with myAIRVO2 (n=100) at home. LTOT (n=100) at home.
Key outcomes	<p>Rate of AECOPD – myAIRVO2 3.12 vs 4.95 (control) per patient/year (p<0.001).</p> <p>Hospital admissions – 0.79 vs 1.39/patient/year for 12- vs 1-month use of HFNC respectively (p<0.001).</p> <p>Dyspnoea (mMRC score) – At 3 months, myAIRVO2 group had improved mMRC scores (p<0.05), and from 3 months onward, they had lower mMRC scores vs controls (p<0.001).</p> <p>QoL – myAIRVO group had better SGRQ at both 6 (p=0.002) and 12 months (p=0.033) vs controls.</p> <p>PaCO₂ – Over 12 months, PaCO₂ decreased in myAIRVO2 group and increased for controls (p=0.005).</p> <p>All-cause mortality – myAIRVO2 15% vs control 12% (p=0.636)</p> <p>Exercise performance – significant difference at 12 months (p=0.005) in favour of myAIRVO2 group (excluding 'non-walkers').</p>
Strengths and limitations	Treatment allocation was fully described. The baseline dyspnoea score was significantly different between groups (p=0.008). Neither the participants nor the assessors could be blinded because it was obvious if they were being treated using the myAIRVO2 device.
<u>McKinstry et al. (2018)</u>	

Study size, design and location	Single-centre randomised crossover trial in New Zealand, including 48 patients with stable COPD.
Intervention and comparator(s)	Participants had all 4 interventions in a randomised order; NHF using myAIRVO2 at 15 litres/min, 30 litres/min, 45 litres/min and room air in a hospital clinical setting.
Key outcomes	<p>Mean (95% CI) change in PtCO₂ at 20 minutes compared with room air:</p> <ul style="list-style-type: none"> • 15 litres/min: -0.6 mmHg (-1.1 to 0.0), p=0.06 • 30 litres/min: -1.3 mmHg (-1.9 to 0.8), p<0.001 • 45 litres/min: -2.4 mmHg (-2.9 to -1.8), p<0.001. <p>Mean (95% CI) change in respiratory rate at 20 minutes compared with room air:</p> <ul style="list-style-type: none"> • 15 litres/min: -1.5 (-2.7 to -0.3), p=0.02 • 30 litres/min: -4.1 (-5.3 to -2.9), p<0.001 • 45 litres/min: -4.3 (-5.5 to -3.1), p<0.001.
Strengths and limitations	Treatment allocation was fully described. Crossover design, therefore participants served as their own control, reducing the influence of selection bias. Patients said to be blinded, however it is feasible they could have differentiated between the 4 treatments.
<u>Pisani et al. (2017)</u>	
Study size, design and location	Single-centre randomised crossover trial in Italy, including 14 COPD patients with stable CHRF.
Intervention and comparator(s)	Participants completed in 5 randomised order, 30-minute trials (HFOT was delivered at 2 flow rates, 20 and 30 litres/min with the participants' mouth open and closed, and the fifth trial was NIV) in a hospital clinic setting.

Key outcomes	<p>The data were analysed by assessing differences between baseline and the 5 trials.</p> <p>TI,p (seconds) – no difference between trials.</p> <p>TE,p (seconds) breathing frequency (breaths/min) – was significantly prolonged compared with baseline for all the settings.</p> <p>Tidal volume (ml) – significantly higher compared with baseline for all settings.</p> <p>Pdi swing (cmH₂O) – reduced compared with baseline in all trials.</p> <p>PTPdi/min (cmH₂Oxs/min) – reduced compared with baseline in all trials.</p> <p>PEEPi,dyn (cmH₂O) – significantly reduced compared with baseline in all trials.</p> <p>PaCO₂ (mm Hg) – decreased but not significantly. HFOT at 30 litres/min and NIV compared with standard oxygen.</p> <p>PaO₂ (mm Hg) – no difference in HFOT 20 closed group, lower in the HFOT 30 group and significantly higher in NIV group compared baseline.</p> <p>Comfort score – did not vary among the different trials.</p>
Strengths and limitations	<p>Blinding and dropout rates were not reported. Crossover design, therefore participants served as their own control, reducing the influence of selection bias. Small numbers of participants and only short-term effects reported.</p>
<u>Cirio et al. (2016)</u>	
Study size, design and location	<p>Single-centre pilot randomised crossover trial in Italy, including 12 patients with severe COPD.</p>
Intervention and comparator(s)	<p>Participants completed in a randomised order 2 constant-load, symptom-limited exercise tests at 75% of maximum workload achieved with the incremental test, with (HFNC-test) and without (control-test) HFNC using myAIRVO2 in a hospital clinic setting.</p>
Key outcomes	<p>Exercise duration – mean difference 109±104, p<0.015, resulting in a mean increase of 41±36%.</p> <p>Dyspnoea – p=0.002</p> <p>Leg fatigue – p=0.002</p> <p>SaO₂ – p<0.005.</p>

Strengths and limitations	Treatment allocation was not described fully. Crossover design, therefore participants served as their own control, reducing the influence of selection bias. The washout period was 24 hours. Unclear if this exercise test would be generalisable to rehabilitation.
<u>Fraser et al. (2016)</u>	
Study size, design and location	Single-centre pilot randomised crossover trial in New Zealand, including 30 patients with COPD.
Intervention and comparator(s)	Intervention: NHF using air supplemented with the equivalent FiO_2 to a total flow of 30 litres/min from an AIRVO2 through an Optiflow nasal interface in a hospital clinic setting. Comparator: current LTOT in a hospital clinic setting.
Key outcomes	RR – $p=0.001$ SaO ₂ – $p=0.06$ Dyspnoea – $p<0.001$ Tidal volume – $p=0.003$ End-expiratory lung impedance – $p<0.001$.
Strengths and limitations	Treatment allocation fully described in supplementary document. Crossover design, therefore participants served as their own control, reducing the influence of selection bias. Male-only participants, therefore difficult to generalise results to female participants. This is a short-term study, therefore it is unclear if these benefits can be realised long term.
<p>Abbreviations:</p> <p>AECOPD, acute exacerbation of COPD; CHRF, chronic hypercapnic respiratory failure; CI, confidence interval; COPD, chronic obstructive pulmonary disease; FiO_2, fraction of inspired oxygen; HFNC, high-flow nasal cannula; HFOT, high-flow oxygen therapy; LTOT, long-term oxygen therapy; mMRC, modified Medical Research Council; NHF, nasal high-flow; NIV, non-invasive ventilation; PaCO₂, partial pressure carbon dioxide; PaO₂, partial pressure oxygen; Pdi swing, transdiaphragmatic pressure; PEEPi,dyn, dynamic intrinsic positive end-expiratory pressure; PTPdi, diaphragm pressure time product; QoL, quality of life; RCT, randomised controlled trial; RR, respiratory rate; SaO₂, oxygen saturation; SGRQ, St George's Respiratory Questionnaire; TE,p, patient's own expiratory time; TI,p, patient's own inspiratory time; vs, versus.</p>	

Recent and ongoing studies

- [Feasibility of using daily home HNHF-O2 during sleep and/or daytime in hypercapnic COPD patients following recent hospitalization for AECOPD for 90 days](#). ClinicalTrials.gov identifier: NCT03221387. Estimated completion date: September 2018. Indication: COPD. Devices: myAIRVO2. USA.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 5 of the specialist commentators were familiar with or had used this technology before.

Level of innovation

One commentator felt this technology was a variation to current therapy. Three experts think myAIRVO2 is a novel and developing concept. One commentator added that nasal high-flow therapy is innovative but not new; however, the application of nasal high-flow therapy using this technology to support early discharge from hospital or as an alternative to long-term oxygen therapy or domiciliary continuous positive airway pressure (CPAP)/non-invasive ventilation in the community setting is novel. One commentator stated that the myAIRVO2 is not a new technology.

Potential patient impact

One specialist commentator stated the myAIRVO2 can improve stability of the disease. Two specialist commentators stated humidified air benefits patients by helping mucus clearance and helping to wash out CO₂ from the airway dead space. One commentator concluded the main benefit of the myAIRVO2 is that humidified therapy with a high percentage of oxygen can be offered through nasal interfaces. This improves a patient's quality of life because they are able to communicate, eat and drink easily, which are limited with a face mask or with non-invasive ventilation. The high-flow aspect makes the device suitable for those patients who are extremely breathless. One specialist noted possible patient benefits such as the potential to avoid long-term supplemental oxygen therapy, domiciliary CPAP or non-invasive ventilation, the ability to relieve breathlessness at rest or during physical activity, and a reduction in complications related to non-invasive ventilation interfaces. The myAIRVO2 provides greater flexibility to titrate respiratory therapy in comparison to long-term oxygen therapy and has the potential to reduce exacerbations

of chronic obstructive pulmonary disease (COPD) and prevent admission to hospital. Three commentators feel that the myAIRVO2 would be of benefit for patients having end-of-life care.

Potential system impact

Two commentators feel there is potential for myAIRVO2 to reduce the number of COPD exacerbations and hospital admissions and the associated costs. One specialist highlighted a recent publication (Storgaard et al. 2018), citing improved admission-free survival in COPD patients treated with home nasal high-flow therapy. One commentator stated that this technology provides another treatment option. One specialist commentator stated that there is potential for myAIRVO2 to support early discharge from hospital after exacerbation of COPD, reducing the amount of time in hospital. The same commentator also highlighted the potential to reduce costs compared with alternative domiciliary respiratory support therapies such as long-term oxygen therapy and non-invasive ventilation. One specialist outlined that it is expected that the community staff and service needs will be similar to home oxygen or non-invasive ventilation. There is also potential that there would be a little more pressure on the outpatient services that would support the equipment – such as home ventilation services.

General comments

Specialist commentators identified a diverse range of patient groups for whom myAIRVO2 could be suitable, some of which are outside the scope of this briefing. In the community, this device may be considered for some patients with bronchiectasis or cystic fibrosis and in patients with a tracheostomy with thick tenacious secretions needing humidification. One expert concluded that myAIRVO2 and nasal high-flow therapy is a developing field, which appears to be having a real impact on patient care. One expert advised that to address some of the uncertainty in this promising technology, UK-based research exploring clinical outcomes (for example, length of stay, hospital admissions, rates of exacerbations, antibiotic and steroid use, arterial blood gas measurements, patient-reported outcomes) as well as an economic evaluation should be done. This could include a more detailed cost comparison for a patient cohort. Studies should also address the following:

- Directly comparing the use of AIRVO2 in comparison to each of long-term oxygen therapy and non-invasive ventilation across a range of specific clinical states.
- Exploring the role of AIRVO2 specifically for early supported discharge following exacerbation of COPD.

- Exploring the role of AIRVO2 specifically when long-term oxygen therapy is not tolerated/ adhered to or non-invasive ventilation is not tolerated/adhered to.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Iain Wheatley, Nurse Consultant acute and respiratory care, Association of Respiratory Nurse Specialists (ARNS), did not declare any interests.
- Mr Matthew Quint, Respiratory Clinical Specialist, Member of the Chartered Society of Physiotherapy, received financial support for travel and accommodation at 2 UK conferences by the company producing the technology.
- Dr Christopher Carlin, Consultant Respiratory Physician and Honorary Senior Lecturer, received financial support for travel, accommodation and catering for attendance at 2 UK conferences by the company producing the technology.
- Ms Ema Swingwood, Respiratory Pathway Lead/Physiotherapist, Member of Association for Chartered Physiotherapists in Respiratory Care (ACPRC), consultancy fee received from the company producing the technology.
- Mr Gareth Cornell, Clinical Specialist Physiotherapist Critical Care, member of Association of Chartered Physiotherapists in Respiratory Care, did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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