NICE advice

SuperNO2VA for the relief of upper airway obstruction in people with obstructive sleep apnoea

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is SuperNO2VA. It is used for preventing and relieving upper airway obstruction in patients with obstructive sleep apnoea. The device can be used during intubation and postoperatively in the post-anaesthesia care unit for patients having general anaesthesia, or during the entire procedure for patients having deep sedation. The company states that SuperNO2VA can be used in other patients at risk for respiratory compromise, including those with a high body mass index, severe congestive heart failure and moderate to severe chronic obstructive pulmonary disease. This medtech innovation briefing reviews its use only in patients with obstructive sleep apnoea.
- The **innovative aspects** are that it can deliver both oxygen and ventilation and is portable, allowing use from preoperative through to postoperative care.

- The intended **place in therapy** would be as an alternative to current oxygen delivery devices for perioperative use in patients with obstructive sleep apnoea.
- The **main points from the evidence** summarised in this briefing are from 5 studies (2 observational studies, 2 case reports and 1 case series) including a total of 98 adult patients in a secondary care setting. They show that SuperNO2VA could potentially maintain oxygenation in obstructive sleep apnoea patients perioperatively.
- **Key uncertainties** around the evidence are that there is no UK evidence, and existing evidence is limited in both quality and quantity.
- The **cost** of SuperNO2VA ranges from £23.25 to £37.75 per unit (exclusive of VAT). The **resource impact** is uncertain. The company claim that SuperNO2VA could be resource-releasing if greater benefits, such as reduced hospital stay or reduced adverse events, are achieved. There is currently no published evidence to support these claims.

The technology

SuperNO2VA (Vyaire Medical) is a nasal positive airway pressure device designed to prevent and relieve upper airway obstruction. It is for use in patients with obstructive sleep apnoea throughout deep sedation, or during intubation and postoperatively in the post-anaesthesia care unit for those patients having general anaesthesia. Patients with obstructive sleep apnoea are at higher risk of upper airway obstruction, which could lead to hypoxaemia and other pulmonary complications. It is recommended by the company in the following circumstances:

- Preoxygenation, intraoperative airway maintenance and postoperative support for patients having procedures needing deep sedation (such as endoscopy, cardiac ablations, pacemaker insertions, joint replacements, bronchoscopy, transoesophageal echocardiography, interventional radiology, magnetic resonance imaging and cystoscopy).
- Preoxygenation and postoperative support for procedures needing tracheal intubation in patients with potentially and known difficult airways.
- Postoperative support for patients in the post-anaesthesia care unit after operations needing general anaesthesia, such as bariatric, abdominal, thoracic and head and neck surgeries.

The device consists of a mask and head strap which can be connected to an anaesthesia breathing circuit in the operating theatre. A kitted option (containing the SuperNO2VA device, head strap and 2 litre hyperinflation system) allows the device to be used with an oxygen flow meter or cylinder outside of the operating theatre. It is available in medium and large sizes. It is designed to create a tight seal, deliver gas and provide positive pressure when placed over a patient's nose, aiming to maintain an open upper airway. It is intended for short-term use (less than 24 hours) on adult patients (who weigh more than 30 kg). The company claims that SuperNO2VA is able to:

- preoxygenate
- relieve upper airway obstruction because of a decreased level of consciousness (after general anaesthesia or deep sedation)
- maintain ventilation or rescue ventilate
- ease access for intraoral procedures
- be used perioperatively without needing additional equipment.

The company state that SuperNO2VA should not be used for long-term ventilation or for treating obstructive sleep apnoea. It should also not be used if the patient has an allergy to any parts of the device, if the patient has a full stomach and is at high risk for aspiration, if the patient has complete nasal obstruction, if the patient is having nasal surgery, or if the patient has skin breakdown.

Innovations

The company states that SuperNO2VA aims to deliver both oxygen and ventilation, aiming to maintain a patent airway, which current standard facemasks, nasal cannulae and high flow nasal cannulae cannot achieve. It is portable and the company claims that it can also be used outside of the operating theatre. It may be used as an oxygen transport system in the postoperative care phase, without needing additional equipment.

Current care pathway

NICE's guideline on routine preoperative tests for elective surgery recommends that further research is needed about preoperative assessment and diagnosis of obstructive sleep apnoea, and whether this leads to preoperative intervention or improved

postoperative outcomes.

The Association of Anaesthetists of Great Britain and Ireland's guidance on perioperative management of the obese surgical patient (2015) recommend that patients who may be at risk of obstructive sleep apnoea should be screened preoperatively. They recommend screening with the STOP-BANG questionnaire. The Society of Anaesthesia and Sleep Medicine guidelines (2016) state that in patients with obstructive sleep apnoea, perioperative positive airway pressure (PAP) should be used if resources allow, and consideration should be given to obtaining sleep study results and a recommended PAP setting before surgery. Further evaluation for preoperative cardiopulmonary optimisation may be needed for people with obstructive sleep apnoea who have uncontrolled comorbidities. In patients with obstructive sleep apnoea and controlled comorbidities, surgery can proceed providing that strategies to mitigate postoperative complications are implemented. The use of PAP therapy in previously undiagnosed but suspected obstructive sleep apnoea should be considered on a case-by-case basis.

The American Society of Anaesthesiologists's practice guidelines on perioperative management of patients with obstructive sleep apnoea recommend preoperative use of continuous positive airway pressure (CPAP) if obstructive sleep apnoea is severe. Postoperatively, CPAP with or without supplemental oxygen should be offered if it was needed preoperatively. Nasal CPAP should be considered in cases of frequent or severe airway obstruction or hypoxaemia during postoperative monitoring.

Postoperatively, The Royal College of Anaesthetists' Guidelines for the Provision of Postoperative Care 2019 state that patients with obstructive sleep apnoea should be monitored in a high-dependency unit because of a higher risk of postoperative complications such as hypoxia. They also state that the safety of obese patients postoperatively can be improved by including supplemental oxygen and CPAP in their care.

Population, setting and intended user

SuperNO2VA is aimed to maintain upper airway patency and reduce the risk of hypoxaemia in patients with obstructive sleep apnoea having general anaesthesia or deep sedation. According to the perioperative management of the obese surgical patient guidelines from the Association of Anaesthetists of Great Britain and Ireland, severe obstructive sleep apnoea happens in 10% to 20% of patients with a body mass index of more than 35 kg/m^2 and is often undiagnosed. They also state that a diagnosis of obstructive sleep apnoea more than doubles a patient's risk of postoperative

complications such as oxygen desaturation and respiratory failure.

Expert advice states that patients are identified as having obstructive sleep apnoea at a nurse-led preoperative assessment using screening questionnaire tools (such as the STOP-BANG questionnaire), with further referral for formal sleep polysomnography and optimisation on CPAP for patients having non-urgent elective surgery.

The device is intended to be used in secondary care by anaesthetists and operating theatre staff. Training is included in the cost of the device and is done by the company.

Costs

Technology costs

The costs of the SuperNO2VA device are outlined in table 1. All costs are presented excluding VAT. The unit cost for each SuperNO2VA device ranges from £23.25 to £37.75.

Table 1 SuperNO2VA Costs

Description	Quantity	Cost	Additional information
SuperNO2VA Nasal Interface (large)	20	£465.00	Consists of large sized SuperNO2VA device and head strap.
SuperNO2VA Nasal Interface (medium)	20	£465.00	Consists of medium sized SuperNO2VA device and head strap.
SuperNO2VA Satellite Kit (large)	20	£755.00	Consists of large sized SuperNO2VA device, head strap and 2 litre hyperinflation system.
SuperNO2VA Satellite Kit (medium)	20	£755.00	Consists of medium sized SuperNO2VA device, head strap and 2 litre hyperinflation system.

Costs of standard care

The cost of standard oxygen delivery devices are listed in table 2 and are estimates

sourced from the company. According to clinical experts, patients who need home CPAP can use their own machine for use perioperatively.

Table 2 Costs of standard care

Description	Cost	Additional information
Facemask	£0.50	–
Nasal Cannula	£0.40	–
High Flow Nasal Cannula	£12.50	Additional costs include: £17.50 for the circuit. Service costs for additional capital equipment. This is factored into the consumable cost if equipment loaned free of charge.

Resource consequences

The company do not state any current NHS use of SuperNO2VA. The company states that SuperNO2VA costs more compared with current standard practice, however they claim greater benefits such as reduced need for further treatment, fewer adverse events and shorter hospital stay, that may be resource-releasing overall. There is no published evidence to support these claims.

According to a clinical expert, issues in adopting the device may be related to comfort and fit of the mask. CPAP is not tolerable for many patients, and the mask interface must be comfortable and able to create an adequate seal despite varying facial anatomy.

Regulatory information

SuperNO2VA is a CE marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and

others.

Obstructive sleep apnoea is a common condition. Risk factors include increasing age, obesity and being male. Certain specific craniofacial characteristics, for example Pierre Robin syndrome or Treacher-Collins syndrome, and patients with Down's syndrome are more likely to have obstructive sleep apnoea. There are certain genetic disorders that predispose to obesity, for example Prader-Willi syndrome. Patients with certain congenital conditions may be considered to have a disability.

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

Five studies are summarised in this briefing: 2 observational studies, 2 case reports and 1 case series. The 5 studies included 98 adult patients, 68 of whom used the SuperNO2VA device. All included studies were done in the USA. Clinically relevant outcomes reported include: oxygen saturation, procedural interruptions and length of post-anaesthesia care unit stay. Included studies used SuperNO2VA intraoperatively for patients having deep sedation, and during intubation and postoperatively in cases needing general anaesthesia. Table 3 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

There is limited published evidence on SuperNO2VA. Only 1 of the included studies involved a comparator (conventional nasal cannula), making it difficult to draw conclusions about the efficacy of SuperNO2VA compared with standard therapy. Furthermore, only 35 out of a total of 98 patients in the included studies had a confirmed diagnosis of obstructive sleep apnoea, making it difficult to generalise all study findings to this patient population. Sample sizes are also small.

Evidence is limited to the USA and there is no UK-based study evaluating SuperNO2VA.

There is also a lack of statistical analysis, with only Dimou et al. (2019) reporting p values. A comparative study of SuperNO2VA compared with standard NHS perioperative care would be useful, involving a larger patient population with diagnosed obstructive sleep apnoea, to better establish its efficacy.

Table 3 Summary of selected studies

Ghebremichael et al. (2017)	
Study size, design and location	A pilot observational study involving 30 adult patients with ASA status I to III having elective surgery needing general anaesthesia and tracheal intubation. Location: USA.
Intervention and comparator(s)	Intervention: SuperNO2VA (n=30). Comparator: none.
Key outcomes	SuperNO2VA provided adequate oxygenation and successful ventilation in 29 out of 30 patients (97% success rate, 95% confidence interval 83 to 100). Out of these 29 patients, 6 patients needed a nasal airway adjuvant and 1 patient needed 2 staff to successfully ventilate with SuperNO2VA. The mean duration of laryngoscopy was 50.7±23.3 seconds. During this time, the average oxygen saturation was 99.6±0.8%. The average of the lowest values of oxygen saturation seen throughout the airway procedure was 98.1±7.0%. The average peak airway pressure for the 29 patients was 17.97±3.95 mmHg with mean tidal volume of 573.7±40.7 ml.

Strengths and limitations	A good range of outcomes are considered. This is a single-arm observational study involving a small number of patients and so is considered to be low-quality evidence. Only 7 patients had OSA so limited generalisability to this population. The study was done in the USA therefore is not generalisable to a UK NHS setting. The study was supported by the company, increasing the potential for bias. Only the adult large mask size was evaluated. Use of the SuperNO2VA device was stopped after successful intubation, so it is not possible to generalise results to the intraoperative or postoperative settings. Intubation was successful on the first attempt and within 2.5 minutes for all cases, so the results are not generalisable to prolonged or difficult intubation.
Dimou et al. (2019)	
Study size, design and location	A prospective observational study involving 56 consecutive patients presenting for EGD before bariatric surgery between June 2016 and August 2017. Location: USA.
Intervention and comparator(s)	Intervention: SuperNO2VA (n=26). Comparator: conventional nasal cannula (n=30).
Key outcomes	There were fewer episodes of desaturation in the SuperNO2VA group compared with nasal cannula (11.5% compared with 46.7%, p=0.004). The median lowest oxygen saturation was higher in the SuperNO2VA group (100% compared with 90.5%, p<0.0001). There were no interruptions in the SuperNO2VA group for bag-valve-mask ventilation, compared with 3 cases in the nasal cannula group (0 compared with 3, p=0.24). There was no significant difference in mean postoperative oxygenation (97.4±1.9% compared with 98±1.9%, p=0.36), PACU stay (49.9±10.1 minutes compared with 61.7±30.5 minutes, p=0.35) or procedure length (9.2±4.8 minutes compared with 7.8±2.9 minutes, p=0.18) in SuperNO2VA compared with nasal cannula groups. There were no complications in SuperNO2VA group but 1 complication in the control group.

Strengths and limitations	Statistically significant differences in baseline characteristics between the 2 groups limit comparability. The sample size was small. Only 22 patients overall had OSA (14 in SuperNO2VA group) limiting generalisability of study findings specifically to this patient group. Patients were allocated to either group by the anaesthetist with no randomisation, which may have introduced bias. Oxygen was delivered at the discretion of the anaesthetic team for the nasal cannula group, compared with 10 litres/minute in the SuperNO2VA group, limiting comparability of findings.
Cataldo et al. (2019)	
Study size, design and location	A case report involving a 46-year old patient with OSA having a cardiac ablation needing tracheal intubation. Location: USA.
Intervention and comparator(s)	Intervention: SuperNO2VA (n=1). Comparator: none.
Key outcomes	Oxygen saturation was kept at 100% during intubation while the SuperNO2VA device was in situ. Postoperatively in the PACU with SuperNO2VA connected to wall oxygen, oxygen saturations were 99%.
Strengths and limitations	Patient had OSA which helps generalisability in this patient population. Author is a medical director of Vyaire Medical. A case report is low-quality evidence, with sample size of 1 and no comparator group. There was no statistical analysis of the results and limited reported outcomes. Study done in the USA which limits generalisability to NHS.
Kozinn et al. (2018a)	
Study size, design and location	A case report involving a 50-year old patient using SuperNO2VA having transoesophageal echocardiography and electrical cardioversion under deep sedation. Location: USA.
Intervention and comparator(s)	SuperNO2VA (n=1). Comparator: none.

Key outcomes	SuperNO2VA device attached to a hyperinflation bag, maintained oxygen saturation of 99%, after unsuccessful nasal cannula use with oxygen desaturation to 85%. SuperNO2VA maintained oxygenation during the 45-minute procedure. During a repeat procedure the next day, SuperNO2VA maintained oxygen saturation ≥96% without the need for manual airway support or manipulation.
Strengths and limitations	Patient had severe OSA so findings are generalisable to this patient population. A case report is low-quality evidence. No comparator so unable to compare with standard care. Study done in the USA so not generalisable to NHS.
Kozinn et al. (2018b)	
Study size, design and location	A multicentre case series involving 10 patients having deep sedation procedures using the SuperNO2VA mask. Location: USA.
Intervention and comparator(s)	Intervention: SuperNO2VA (n=10). Comparator: none.
Key outcomes	Oxygen saturation was maintained at >97% (range 98% to 100%, average 99%) in all cases. There were no cases of hypoxaemia, procedural interruption or termination or tracheal intubation.
Strengths and limitations	All patients were high risk or diagnosed with OSA so are generalisable to this population. A range of procedures (1 TEE, 1 OGD, 1 SVT ablation, 2 AV fistula procedures). Good range of clinically relevant outcomes. Multicentre study is higher quality evidence. Similar baseline characteristics of patients, however no statistical analysis of results or p values reported. No comparator so unable to compare with standard care. Only assessed use of SuperNO2VA in deep sedation procedures. Authors are on the medical advisory board of the company. One of the patients included in the study is the same patient reported on in the other study Kozinn et al. (2018a).
Abbreviations: ASA, American Society of Anaesthesiologists; AV, arteriovenous; EGD, esophagogastroduodenoscopy; OGD, oesophagogastroduodenoscopy; OSA, obstructive sleep apnoea; PACU, post-anaesthesia care unit, SVT, supraventricular tachycardia; TEE, transoesophageal echocardiogram.	

Recent and ongoing studies

- SuperNO2VA™ and General Anesthesia Postoperative Care: Comparing the Incidence, Severity, and Duration of Postoperative Oxygen Desaturation Between SuperNO2VA™ and Standard of Care, a RCT. ClinicalTrials.gov identifier: NCT03969615. Status: Recruiting. Indication: hypoxaemia, acute respiratory failure. Devices: SuperNO2VA, supplemental oxygen.
- Comparison of Oxygenation and Ventilation With a Novel Nasal Mask Versus Standard of Care During Colonoscopy: a Prospective Randomized Trial. ClinicalTrials.gov identifier: NCT03139448. Status: Completed. Indication: colonoscopy, oxygenation, ventilation. Devices: oxygen via nasal cannula, oxygen via SuperNO2VA.

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.

No commentators had used SuperNO2VA before, however all commentators were familiar with the principles of the technology.

Level of innovation

All commentators thought that SuperNO2VA was innovative. One commentator noted that it is a new development of an established treatment modality, with the novel aspect being its ability to deliver positive-pressure ventilation through a nasal continuous positive airway pressure (CPAP) mask which up until now has been able to offer CPAP only. Another commentator highlighted that it allows oral cavity access for procedures such as oesophagoscopy and oral intubation, it can be used with an anaesthesia machine or oxygen cylinder (without the need for additional equipment or CPAP machine), it can be used to give CPAP perioperatively to any patient needing CPAP or when sedation has been administered, and that it could be specifically useful when patients are identified at preoperative assessment to have obstructive sleep apnoea, but that there is no additional time available for further evaluation or for starting CPAP treatment. A different commentator suggested it was innovative in offering a cost-effective way of delivering CPAP for those patients who are not already on CPAP. Current alternatives identified by

commentators were nasal oxygen delivery devices, however these devices need additional equipment. A different commentator highlighted that patients with their own CPAP machine are encouraged to bring this in for use in the perioperative setting.

Potential patient impact

Potential patient benefits identified by commentators included providing oxygen during the entire perioperative period, delivering CPAP when patients forget to bring their own CPAP machine, and preventing airway collapse. Particular patients who may benefit from this technology include patients with obstructive sleep apnoea, morbid obesity and patients having deep sedation. Another commentator identified benefits for patients in high dependency and intensive care units having close monitoring, in the operating theatre as part of general anaesthesia equipment (for use in supervised operative procedures by trained anaesthetists), and also in the recovery room for patients with obstructive sleep apnoea or those with neuromuscular diseases recovering from sedation or anaesthesia.

However, risks if used by non-experts were also highlighted. Patients may be over-sedated into the territory of needing general anaesthesia, leading to a risk of gastric aspiration, hypoventilation and desaturation. Other concerns related to the risk of gastric insufflation and aspiration if oxygen was applied at too high a pressure. The same commentator identified that effectiveness would be reduced if the mouth was left open, for example, during a dental or ear, nose and throat procedure, because of entrained gas leaking out of the mouth, resulting in hypoventilation and hypoxaemia.

Potential system impact

One commentator stated that SuperNO2VA may result in shorter stays for outpatient procedures (such as endoscopy or transoesophageal echocardiography) in patients who would normally need intubation under general anaesthesia. It may also allow patients with obstructive sleep apnoea to have procedures under sedation without intubation. However, this places these patients at risk of airway aspiration, which they would not be exposed to with intubation. The commentator concluded that the device must be used in carefully selected patients and by expert anaesthetists only. Two other commentators did not think that SuperNO2VA would result in substantial changes in the patient pathway, outcomes, or length of hospital stay. One of the commentators cited lack of evidence to back up outcomes. Another commentator thought that the most important affect is from clinicians being aware of the potential for airway obstruction. The same commentator thought that it

was a cheap and accessible way to deliver CPAP in the perioperative period and patients most able to benefit could be those in the post-anaesthesia care unit who may be able to be discharged back to the ward earlier.

Commentators estimated that costs would likely be similar to current options, with a measurable cost benefit unlikely. However, 1 commentator identified that current practice for patients who do not have their own CPAP device needs sophisticated apparatus with much more expensive masks. The need for a full cost analysis was emphasised. Two commentators agreed that SuperNO2VA would be in addition to standard care and not a replacement, whereas another commentator was unable to state this because of the lack of evidence.

General comments

Commentators identified that training for anaesthetists, operating department practitioners and recovery nurses would be needed to use the device and to troubleshoot problems with the interface or seal. One commentator thought that the training would be rapidly achieved, but that the same level of monitoring as for general anaesthesia would be needed. Safety concerns highlighted were that the device must only be used in appropriate patients, is not a replacement for invasive ventilation, and is not appropriate when endotracheal intubation and ventilation is needed. A different commentator highlighted that there may be pressure exerted on clinicians to do procedures currently done on an inpatient basis in outpatient settings. For this reason, very specific patient pathways must be developed including case selection, procedure selection, minimal standards for recovery and access to high dependency units to ensure that SuperNO2VA is used safely. A further concern related to resource burden in the outpatient setting. More expert trained theatre staff and access to a postoperative recovery room would be needed because of patients known to be higher risk having outpatient rather than inpatient procedures.

The eligible population was estimated by 1 commentator as 10% of the target population. Other commentators estimated that 5% of women, 10% of men and 20% to 40% of patients with morbid obesity also have obstructive sleep apnoea and could benefit from nasal CPAP.

Highlighted practical issues with SuperNO2VA included the need to ensure the mask is well-fitted to make sure that there is no leak. Adoption issues were identified by 2 commentators, naming cost, lack of staffing in outpatients and lack of patient pathways as

barriers. All commentators stated that further research is needed. Suggested research included a sham study, a comparative study comparing SuperNO2VA with standard techniques (nasal oxygenation and non-invasive ventilation) in patients who are morbidly obese or have obstructive sleep apnoea, and more clinical trials to show safety around aspiration risk and showing improved oxygenation.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr A David G Dawson, consultant anaesthetist, specialist in sleep medicine, Bradford Teaching Hospitals NHS Foundation Trust. Stated conflicts of interests: private patient work with Philips Respironics, independent practice (98% NHS) with obstructive sleep apnoea Risk Management Ltd, work with Sleep Doctor Ltd to provide affordable self-pay diagnosis and treatment of obstructive sleep apnoea and through this, work with Bradford University and iBridge International to develop healthcare technologies in China.
- Dr Aamer Ahmed, consultant in cardiothoracic anaesthesia and critical care, honorary associate professor, University Hospitals of Leicester NHS Trust. Did not declare any interests.
- Dr Anjum Ahmed-Nusrath, consultant anaesthetist and airway lead, University Hospitals of Derby and Burton NHS Trust. 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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