NICE advice

PulmoVista 500 for monitoring ventilation in critical care

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is PulmoVista 500. It is for monitoring lung ventilation for people having intubation and ventilation in critical care.
- The **innovative aspects** are that the PulmoVista 500 allows non-invasive and continuous monitoring of lung ventilation at the bedside, by measuring regional gas distribution.
- The intended **place in therapy** would be in addition to standard care in people having intubation and ventilation in critical care.
- The **main points from the evidence** summarised in this briefing are from 5 studies using PulmoVista 500. These include 1 cohort study with a historic control and 3 observational studies, with a total of 210 adults having ventilatory support in a critical care unit. The studies show that it is feasible to use electrical impedance tomography to measure clinically relevant regional lung ventilation distributions in people who are intubated and ventilated in critical care.

- **Key uncertainties** around the evidence or technology are that the studies do not compare standard care with the combination of standard care and PulmoVista 500.
- The **cost** of PulmoVista 500 is approximately £79 per examination. The **resource impact** would be greater than standard of care.

The technology

PulmoVista 500 (Drager UK Ltd) is a non-invasive imaging device for monitoring lung ventilation. Pulmonary function needs to be regularly assessed during ventilation therapy. The technology uses electrical impedance tomography to measure regional gas distribution in real time. The company claims the technology can assess continuous regional ventilation distribution and changes in end-expiration lung volumes (the volume of gas left in the lungs after exhaling). These are indicators of pulmonary function.

A silicone belt with 16 integrated electrodes is put around a person's chest and is connected to the PulmoVista 500. An alternating current is applied to a pair of electrodes and the resulting surface potential is recorded. The process is repeated in the adjacent electrode pair and continues around the belt creating a voltage profile. The resistance, or impedance, experienced by the current is affected by the ventilation of the lungs. The voltage profile is reconstructed using an algorithm to display regional impedance as a 2-dimensional cross-sectional image of the lungs. The impedance represents variations in lung ventilation and end-expiratory lung volume. The device can monitor for up to 24 hours at a time. To use the PulmoVista 500 additional consumables are needed, including an electrode belt and patient cable (both available in sizes S to XXL), a reference electrode, a trunk cable and electrocardiogram (ECG) electrodes.

The PulmoVista 500 is for people having ventilation therapy in critical care. The technology should not be used in people with pacemakers, implantable cardioverter-defibrillators, implantable pumps, people with uncontrolled body movements or pregnant women. The technology should also not be used in people with damaged skin, fractures or lesions in the region where either the patient interface or electrodes will be placed.

Innovations

The PulmoVista 500 is a non-invasive imaging device to monitor regional gas distribution continuously in real time at the bedside. Investigations in standard care include arterial

blood gas analysis, chest X-ray, lung ultrasound and CT scans. This technology aims to be less invasive than current care, using no ionising radiation or invasive tests, and be more convenient because it is used at the bedside, and report real-time monitoring. The company claims the technology could result in fewer scans.

Current care pathway

NICE's guideline on acutely ill adults in hospital recommends that people should be routinely monitored using track and trigger systems in line with their monitoring plan. Physiological parameters used by track and trigger systems include, heart rate, respiratory rate, blood pressure, consciousness, oxygen saturation and temperature. People in critical care needing intubation and ventilation are reviewed by a clinician. The ventilation therapy will be prescribed based on the person's medical history, blood gas measure and imaging results such as chest X-rays, CT scans and lung ultrasound. The patient's clinical status and cardiorespiratory measures are continuously monitored and reviewed by clinicians. The ventilation therapy is adjusted accordingly. Blood gas analyses and track and trigger parameters are used to manage ventilation therapy. In cases when imaging is needed, people may be transported from critical care to imaging departments for chest X-rays, CT or MRI scans. Some imaging techniques give patients ionising radiation. Ultrasound machines are also commonly used in critical care to monitor fluid in the lungs. Many are portable and can be used at the person's bedside. Some people need prolonged periods of mechanical ventilation, when this is suitable this can be given less invasively. NICE's guideline on chronic obstructive pulmonary disease in over 16s recommends clinicians also consider non-invasive ventilation for people that come off invasive ventilation slowly. Physiotherapy should also be considered to support the rehabilitation of people that have had ventilation therapy.

Population, setting and intended user

PulmoVista 500 is for people with impaired respiratory function having mechanical ventilation therapy in critical care. The technology is used by healthcare professionals and is for use on critical care wards at the person's bedside for continuous monitoring and real-time interpretation.

The company will provide training to staff using the technology. This is included in the technology cost.

Costs

Technology costs

The price of the device ranges from £20,000 to £30,000 depending on patient numbers and usage and has a lifespan of 7 years. Annual replacement of consumables is recommended and will cost between £2,500 and £5,000 per year.

The technology is estimated to cost approximately £79 per examination. This cost is based on a 10-bed critical care unit admitting approximately 1,500 people per year, with an estimated use of PulmoVista 500 in 10% of admissions. This includes the cost of consumables and maintenance.

Costs of standard care

The costs of routine care procedures in the NHS for people having ventilatory support are summarised in table 1. Costs are from the 2019/20 national tariff payment system.

Table 1 UK NHS procedure costs

Description	National tariff	Additional information
Non-invasive ventilatory support assessment	£712	Cost for ordinary elective spell of up to 5 days.
MRI	£108	Per scan of 1 area, without contrast.
CT scan	£69	Per scan of 1 area, without contrast.
Ultrasound	£39	Per scan of less than 20 minutes, without contrast.
X-ray	£26	Per scan.

Resource consequences

The resource impact of the technology would be greater than NHS standard care. However, the company claims the technology could result in savings from fewer CT or MRI

scans and blood gas analyses. The company also claims the technology results in reduced incidence of ventilator-induced lung injury, which could reduce the length of hospital stay.

Healthcare professionals will need training to use the technology. Training is included in the cost of the device.

Regulatory information

PulmoVista 500 has a CE mark as a class IIb 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.

The technology cannot be used in pregnant women. Pregnancy and sex are protected characteristics under the 2010 Equality Act. The device can also not be used in people with uncontrolled body movements. Some people with uncontrolled body movements will be classed as disabled. Disability is a protected characteristic under the 2010 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

There are a large number of studies on electrical impedance tomography (EIT) and many include data from PulmoVista 500. This briefing summarises 6 recent studies to evaluate PulmoVista 500 in patients having mechanical ventilation.

The studies are 1 cohort study with a historical control group, 1 cross-over study and

4 observational studies. There were 238 people included in these studies. A systematic review (Kobylianskii et al. 2016) investigated the validation and application of EIT in people having mechanical ventilation. Data from multiple EIT devices, including PulmoVista 500, were included in the review. The studies of PulmoVista were not analysed independently from the studies of other EIT devices.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence base addresses the safety and feasibility of using the technology during ventilatory support. The studies report the relationship between weaning off ventilation support or short breathing test outcome and surrogate measures of pulmonary function, measured by PulmoVista 500. These include end-expiratory lung impedance, tidal volume and inhomogeneity index. The evidence base would benefit from randomised controlled trials comparing the clinical outcomes of the technology with current NHS standard care. Blinding is not possible in this evidence base because of the visual differences between this technology and any comparator. The sample sizes are small and because of the lack of power calculations it is unclear if the studies are powered for analyses, including subgroup analyses. There are limited data relating to systematic benefits such as incidence of ventilatory-induced lung injury and length of hospital admission.

Table 2 Summary of selected studies

Longhini et al. (2019)	
Study size, design and location	Multicentre observational study of 78 patients having invasive ventilation. PulmoVista 500 recordings were taken at various time points during SBT. To establish clinical relevance the population was divided into subgroups determined by successful and failed SBT and successful and failed extubation. Italy.
Intervention and comparator(s)	PulmoVista 500. No comparator.

Key outcomes	Compared with SBT successes (n=61), SBT failure (n=17) showed greater reduction in change from baseline in end-expiratory lung impedance immediately after the test (p=0.003) and at the end of the test (p=0.005). SBT failure also had significantly higher inhomogeneity at all 3 time points (baseline: p=0.002; start of test, p=0.003; end of test, p=0.005) Respiratory rate to tidal volume ratio is significantly higher in the SBT failure group at the start of the test and the end of the test (both p<0.001) but not at baseline. Across all outcome measures there were no significant differences between extubation successes (n=39) and failures (n=22).
Strengths and limitations	The study is a multicentre study and analyses were completed at a single site by an investigator blinded to SBT outcomes. The study shows the potential to use the technology clinically but does not evaluate its clinical effectiveness. Outcome measures are clinically relevant. The sample size is relatively large but the subgroups analysed are inconsistent sizes. No power analyses were done. A co-author of the study has received grants and lab equipment from the company.
Zhao et al. (2019)	
Study size, design and location	Study of 55 people with severe ARDS comparing the prospective use of PulmoVista 500 to guide PEEP titration with a historical cohort of routine methods. Taiwan.
Intervention and comparator(s)	PulmoVista 500-guided PEEP titration. Ventilator embedded pressure loop-guided PEEP.
Key outcomes	Compared with the control group, the PulmoVista 500 group had significantly higher PEEP values (13.6±3.6 cmH_2O and 17.6±3.6 cmH_2O, respectively; p=0.01), respiratory system compliance (20.4±5.3 ml/cmH_2O and 25.9±5.9 ml/cmH_2O, respectively; p=0.01) and lower driving pressure (19.1±3.7 cmH_2O and 15.1±3.1 cmH_2O, respectively; p=0.01). There were no statistically significant differences in hospital survival rate or weaning success between the 2 groups (p=0.18 for both).

Strengths and limitations	The study compares the technology with routine measures and reports clinically and systematically relevant outcome measures. The study was not randomised and demographics between groups different significantly. The experimental group was significantly younger (p=0.05) with a higher plateau pressure (p=0.01). First author receives a consultancy fee from the company.
Bickenbach et al. (2017)	
Study size, design and location	An observational study using PulmoVista 500 to predict failure of spontaneous breathing test in 31 people with prolonged weaning. Germany.
Intervention and comparator(s)	PulmoVista 500. No comparator.
Key outcomes	The global inhomogeneity index calculated using PulmoVista 500 was significantly higher during the SBT (t1) compared with early measures during pressure support ventilation (t0; 81.5±62.5 and 59.3±46.1, respectively; p=0.001). Statistically decreased measures in tidal impedance variation (72%; p=0.001) and changes in end-expiratory lung impedance (−65%; p=0.002) were recorded at t1 compared with t0. Assuming a PulmoVista 500 global inhomogeneity cut off value of higher than 40, ROC analyses reported sensitivity of 85% and specificity of 50% for predicting increased future tidal volume.
Strengths and limitations	The study shows the potential clinical application of the technology. The study is limited because of the lack of comparator arm. Differences in patient demographics were not tested statistically. This study looks specifically at people with prolonged weaning, limiting its generalisability to all people having ventilatory support. The study does not report power calculations.
Eronia et al. (2017)	
Study size, design and location	An observational study investigating PulmoVista 500 for PEEP selection in 16 hypoxemic people. Italy.

Intervention and comparator(s)	PulmoVista 500. No comparator.
Key outcomes	The procedure was feasible in 87% of people. The PEEP selection guided by PulmoVista 500 was higher than the ARDS network proposition (13±3 cmH_20 and 9±2 cmH_20, respectively; p=0.001). During the PulmoVista 500 phase driving pressure reduced and PaO_2/FiO_2 ratio improved. However, these findings were not statistically significant (p=0.035 and p=0.121, respectively). Recruited volume correlated with the decrease in driving pressure (R=0.26; p=0.36).
Strengths and limitations	The study reports relevant clinical measures and compares the PEEP guided by PulmoVista 500 with the measures recorded whilst PEEP was set using ARDS network. The selection of PEEP using ARDS network is consistent with UK methods of PEEP selection. The sample size was small, and no power calculations were reported. There was a higher percentage of male subjects. Only descriptive statistics were used to report differences in the population demographics. A co-author receives fees from the company for lecturing and consulting, this author was not involved in data collection or analyses.
Zhao et al. (2017)	
Study size, design and location	An observational study to investigate the correlation between regional ventilation measured using PulmoVista 500 and weaning outcomes in 30 people with prolonged mechanical ventilation. Taiwan.
Intervention and comparator(s)	PulmoVista 500. No comparator.

Key outcomes	Tidal volume correlated significantly with tidal variation of impedance, measured using PulmoVista 500 (r^2=0.80±0.18; p<0.001). Higher ventilatory support levels resulted in higher end-expiratory lung impedance (p<0.05). Patients that exhibited redistributed ventilation to dorsal regions with lower support rates (n=13) had a higher weaning success rate (p<0.05) compared with those that didn't (n=17). They also needed significantly fewer days of SBT for weaning (13.1±4 days and 20.9±11.2 days respectively; p=0.05).
Strengths and limitations	The study repeated the measures across varying support levels to establish any relationship. However, the population was divided into 2 groups; people having automatic tube compensation ventilatory support (n=15) and another group having external continuous positive airway pressure (n=15), limiting the power of the statistical analyses. These groups may also confound findings reported on the whole population. The study does not report power calculations. Demographic data is reported using only descriptive statistics. The first author receives a consultancy fee from the company.
Mauri et al. (2014)	
Study size, design and location	Randomised crossover study investigating PulmoVista 500 measured ventilation compared with helium dilation technique measures of recruitment and ventilation in 18 people with critical illness. Italy.
Intervention and comparator(s)	PulmoVista 500. Helium dilation technique.

Key outcomes	When PEEP was higher changes in EELV and recruitment measured using helium dilation technique ($p<0.001$ for both) and PulmoVista 500 ($p<0.001$ for both). A significant correlation was reported between PulmoVista 500 measures and helium technique measures of EELV ($r=0.84$; $p<0.001$) and recruitment estimated ($r=0.78$; $p<0.001$). High PEEP resulted in decreased compliance of non-dependent lung regions ($p<0.001$) and increased tidal volume in dependent lung regions ($p<0.001$). Increase in dependent lung region tidal volume correlated with PulmoVista 500 measures of recruitment ($r=0.58$; $p=0.01$). Patients with higher percentage of potentially recruitable lung had more severe baseline lung injury ($p<0.05$) and increased length of stay ($p=0.01$).
Strengths and limitations	This study compares the PulmoVista 500 with a comparative lung-monitoring technique. The study was well designed with a randomly assigned crossover of measures. Outcome measures are clinically and systematically relevant. The abstract presented does not report patient demographic data, method of randomisation or details regarding statistical analyses.
Abbreviations: ARDS, acute respiratory distress syndrome; EELV, end-expiratory lung volume; PEEP, positive end-expiratory pressure; ROC, receiver operating characteristic; SBT, spontaneous breathing test.	

Recent and ongoing studies

- Assessment of the capability of PulmoVista 500 to continuously monitor changes of ventilation over time. ClinicalTrials.gov identifier: NCT03076983. Status: completed. Indication: people having ventilator care. Devices: PulmoVista 500, Drager. Study completed April 2018. Germany.
- Electrical impedance tomography for optimization of positive End-Expiratory Pressure: Acute Respiratory Distress Syndrome. ClinicalTrials.gov identifier: NCT03793842. Status: recruiting Indication: coronary artery disease. Devices: PulmoVista 500, Drager. Estimated completion date January 2021. US.

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.

Four specialists were familiar with PulmoVista 500, 2 had used this technology before.

Level of innovation

Three specialists felt the technology is a novel concept, 2 commented that the technique of electrical impedance tomography (EIT) has been available for a long time, 1 considered the technology similar to other EIT devices. One was not aware of any comparators and another felt the technology bridged a gap in current standard of care imaging.

Potential patient impact

Three specialists believed the technology could help inform the optimal settings for mechanical ventilation but 2 commented that more evidence is needed in this area. Two commented that the technology allows for non-invasive monitoring of a section of the lungs. One felt it would be useful to support endobronchial intubation and 1 expert felt this technology would be useful in people with acute respiratory distress syndrome. Another expert felt it would be most useful for people at risk of atelectasis or ventilator-induced lung injury; 1 believed it would be useful to wean people off mechanical ventilation. Three commented that the technology could reduce ventilator-induced lung injury, 1 also believed it could prevent lung collapse.

Potential system impact

Three specialists believed the technology would cost more than standard care; 1 specialist believed the cost was similar to current imaging costs. Two believed the technology could result in downstream savings but the potential is not well established. All feel that increased training in using the device and interpreting the results would be needed. One specialist raised a safety concern that using the same belt between patients could increase risk of infection.

General comments

Two specialists commented that fitting the device would be challenging, another commented that the device could complicate repositioning patients because electrodes could lose contact. Two raised concerns about the purpose of the technology, 1 raised concerns about the training needed to use the technology and 3 believed the cost could stop adoption. All specialists felt further evidence was necessary.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Jonathan Ball, consultant and honorary senior lecturer in general and neuro intensive care, St George's University Hospital NHS Foundation Trust. Declared no interests.
- Professor Gary H Mills, consultant in intensive care medicine and anaesthesia honorary professor in critical care medicine, University of Sheffield. Declared no interests.
- Dr Peter Macnaughton, consultant in intensive care medicine, University of Plymouth Hospitals NHS Trust. Declared no interests.
- Dr Alastair Glossop, consultant in critical care and anaesthesia, Sheffield Teaching Hospital NHS Foundation Trust. Dr Glossop is a paid consultant, public speaker and adviser to Armstrong Medical UK Ltd since 2014.

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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