VIDAvision for lung volume analysis in emphysema

Medtech innovation briefing

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Summary

- The **technology** described is VIDAvision. It is used for lung volume analysis in people with advanced emphysema who are being considered for lung reduction procedures.

- The **innovative aspects** are that it uses fissure integrity values to assess people with severe emphysema for endobronchial lung volume reduction surgery.

- The intended **place in therapy** would be in addition to current lung function and standard CT scans or as an alternative to bronchoscopy in people with severe emphysema.

- The **main points from the evidence** summarised in this briefing are from 3 studies done in Germany, Brazil and an international multicentre study including 323 adults in hospital settings. VIDAvision may have a role in selecting patients for lung volume reduction surgery but prospective comparative studies are needed.

- **Key uncertainties** around the evidence or technology are that it is based on 3 small populations and the evidence was generated using an unvalidated prediction model for patient selection.

- The **cost** of VIDAvision is £286 to £446 per scan (excluding VAT). The **resource impact** may be less than standard care only if its use improves patient selection for lung volume reduction surgery and other invasive treatments.

The technology

VIDAvision (VIDA Diagnostics) is a suite of imaging analysis software applications that provides quantitative CT (QCT) lung volume analysis from CT datasets. It allows for 3D visualisation of lung anatomy including airways, fissures, parenchyma and a range of CT biomarkers – such as fissure integrity – and analytics. This visualisation can then be used to assess a patient's suitability for therapies.

VIDAvision can be used to do a range of analyses including:

- airway mapping for bronchoscopy biopsy

- lung cancer resection precision reports

- lung density

- air trapping information in people with chronic obstructive pulmonary disease (COPD) and asthma

- lung volume analysis to support treatment selection

- planning for endobronchial lung volume reduction (ELVR) surgery in people with emphysema.

The latter use – planning for ELVR surgery in people with emphysema – is the focus of this briefing.

VIDAvision can be used with a range of high-resolution CT scans; it can also be used with a standard CT lung screening exam if the slice thickness is between 0.5 mm and 1.25 mm. All personally identifying information is removed from the CT scan before it is uploaded to the VIDA platform. The hospital anonymises the scans and applies a unique identifier to them before sending the scans to the company. The unique identifier will be used to match

results to the patient file when the scans are returned.

Later, the company sends a report about each patient's scans to the VIDAvision platform at the hospital. From there, clinicians – such as a respiratory physician, interventional radiologist or radiology technician under the supervision of a respiratory physician or radiologist – can view and evaluate the results in the lung volume analysis function of VIDAvision. The report is received within 72 hours but usual turnaround time is about 12 hours.

Innovations

VIDAvision can help health professionals to assess if people with severe emphysema are good candidates for ELVR surgery by using interlobar fissure integrity values. Fissure integrity values are a surrogate for collateral ventilation, which is measured by forced expiratory volume in 1 second (FEV1).

VIDAvision provides QCT assessment of lung function which may be faster and more accurate than the current manual methods.

The VIDAvision test is non-invasive.

Current NHS pathway or current care pathway

People with emphysema for whom ELVR surgery may be appropriate are usually identified in secondary care. To check if this is the case, health professionals run tests with a spirometer to measure FEV1; this aims to assess how well the lungs are working. If more tests are needed to confirm the diagnosis or determine the severity of disease, people may also have any of the following tests:

- electrocardiogram

- echocardiogram

- peak flow test

- blood oxygen test

- CT scan

- phlegm.

Standard clinical assessments of BMI, smoking status, assessment of comorbidities and patient preference on treatment options are also evaluated. The specific sequence of diagnostic tests to select patients for ELVR vary in practice and few patients in the UK receive bronchoscopy to assess whether ELVR surgery is needed.

The following NICE guidance has been identified as being relevant to this care pathway:

- [Chronic obstructive pulmonary disease in over 16s: diagnosis and management](#)

- [Lung volume reduction surgery for advanced emphysema](#)

- [Insertion of endobronchial nitinol coils to improve lung function in emphysema](#)

- [Endobronchial valve insertion to reduce lung volume in emphysema](#).

Population, setting and intended user

VIDAvision would be used in patients with severe emphysema who are being assessed for lung volume reduction procedures. There is insufficient information to judge whether it would replace, or add to, current diagnostic tests. The technology would be used by respiratory physicians or thoracic surgeons.

Costs

Technology costs

An annual subscription for VIDAvision costs from £18,000 (for up to 50 scans) to £40,000 per year (for up to 200 scans). The average price per scan would be between £200 and £360, depending on the level of use. The cost of using a CT scan including the cost of reporting for 1 area without contrast is £85.69 (RD20A). The total cost of using VIDAvision would be £285.69 to £445.69.

VIDAvision is usually leased on a 1- to 5-year term. A computer with internet access and a web browser is needed to use the software. VIDAvision is sold as a subscription and includes software, scan analysis maintenance, support, installation and education. VIDAvision can operate with an existing CT scanner.

Costs of standard care

- CT scan of 1 area without contrast (RD20A) cost £85.69 on the outpatient tariff.

- Lung volume studies (DZ45Z) cost £132.87 on the outpatient tariff.

- Plain film x-ray (DAPF) costs £29.78.

Bronchoscopy:

- £686.15 for diagnostic bronchoscopy conducted as a day case (DZ69A).

- £875.13 for bronchoscopy including endobronchial ultrasound conducted as a day case (DZ64C).

Resource consequences

Introducing VIDAvision would be an additional cost. Standard assessment methods vary and it is uncertain whether VIDAvision would replace or add to current diagnostic tests. Opportunities for cost savings include improved patient selection for ELVR surgery and savings in clinician time and disposable resources needed to do bronchoscopy, lung volume studies or chest X-ray. Adopting the device would need CT machines to be set up to use the software. VIDAvision is not currently used in the NHS as part of routine practice.

Regulatory information

VIDAvision is a CE marked class IIa medical device and the company has stated that the analysis processes are compliant with the European Commission's Data Protection Directive (95/46/EC).

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).

COPD is closely associated with comorbidities such as cardiovascular disease, lung cancer, osteoporosis, muscle weakness and cachexia. People with cancer are protected under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in line 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

This briefing summarises 2 retrospective analyses and 1 randomised controlled trial that included 323 patients.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Two studies (Schuhmann et al. 2015, de Oliveira et al. 2016) assessed the accuracy of selecting patients for lung volume reduction surgery using fissure integrity (FI) values obtained using VIDAvision QCT. It is unclear how patients were selected for inclusion into the studies. Analyses were retrospective and study authors may have been aware of the patient outcome before analysis. One randomised controlled trial (RCT; Gompelmann et al. 2016) showed that patients with similar FI at baseline had different FEV1 scores at 12-month follow-up. It also showed that FI could be used to select patients for ELVR treatments. This analysis was based on post hoc analyses from a subset of patients in an RCT. Prospective studies comparing subject selection and ELVR outcome using QCT with current standard care are needed to confirm equivalence between the 2 methods.

Table 1 Summary of selected studies

Schuhmann et al (2015)	
Study size, design and location	N=146 Retrospective analysis of people with COPD (Global Initiative for Chronic Obstructive Lung Disease III or IV with residual volume) who had ELVR. Germany.
Intervention and comparator(s)	Intervention: QCT using VIDAvision software.
Key outcomes	82/146 (56%) of patients had disease that responded to ELVR. A subset analysis of 33 patients found there was no difference between Chartis and VIDAvision. FI QCT had high accuracy (75.8% both groups) of selecting people for endobronchial valve LVR between.
Strengths and limitations	Response to LVR may be because of positional errors and variations in anatomy rather than diagnostic approach. The CT protocol used for the scans was not scanner specific and not ideal for quantitative imaging evaluation.
de Oliveira et al. 2016	
Study size, design and location	N=108 (Only 38 patients with baseline and follow-up scans available for full evaluation). Single-centre retrospective study of patients with emphysema (GOLD stage III or IV) having bronchoscopic ELVR between June 2008 and May 2014. Brazil.
Intervention and comparator(s)	Intervention: QCT using VIDAvision.

Key outcomes	Mean and median ELVR was 1,223 ml (SD=907) and 663 ml in lungs with FI ≥75% (n=31).
	The accuracy of FI ≥75% to predict lung volume reduction ≥350 ml was 87.2%.
	PPV of FI values to predict LVR ≥350 ml:
	• FI≥75%, PPV=83.9%
	• FI=75 to 90%, PPV=70%
	• FI>90%, PPV=90.5%.
	Median interval between baseline and follow-up CT was 201 days.
Strengths and limitations	Retrospective study. Single-site study so does not take into account inter-rater variability. ELVR was not measured at the same time points for all patients. High loss to follow-up for repeat scan.
Gompelmann et al. 2016	N=69
	Multinational (Australia, Austria, Germany, Ireland, New Zealand and UK) RCT for patients with upper-lobe-predominant heterogeneous emphysema (>15% difference in lung density between targeted upper lobe segment and lower lobe) assigned on 2:1 ratio, with 12-month follow-up.
Intervention and comparator(s)	Intervention: BTVA; n=45. All patients had QCT using VIDAvision software at baseline and 12 months' follow-up. FI<90% used as threshold to define incomplete fissures and these patients assumed to have CV.
	Comparator: Medical management (n=24).
Key outcomes	78% and 79% of patients in the intervention and control group had CV (FI <90%).
	At 12 months' FEV1 in the intervention group improved by 9.2% but there was a decrease of 5.4% in the control group (mean difference 14.6%, p=0.014). HRQoL as measured by the St George's Respiratory Questionnaire, improved by 8.4 points in the intervention group relative to the controls (p=0.071).
Strengths and limitations	Post hoc analysis of RCT data not part of initial trial analysis plan.

Abbreviations: BTVA, bronchoscopic thermal vapour ablation; CV, collateral ventilation; ELVR, endobronchial lung volume reduction; FEV1, forced expiratory volume in 1 second; FI, fissure integrity; HRQoL, health-related quality of life; LVR, lung volume reduction; PPV, positive predictive value, QCT, quantitative computer tomography; RCT, randomised controlled trial.

Recent and ongoing studies

No ongoing or in-development trials were identified for the use of VIDAvision in determining selection for ELVR surgery.

Specialist commentator comments

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

All 3 commentators were familiar with this technology and 2 stated they had used it before. None of the commentators thought that the technology was in widespread use within the NHS.

Level of innovation

The specialist commentators generally thought that the technology was innovative and could represent a variation to current standard care particularly for people having lung volume reduction surgery. One expert thought its ability to detect FI was also novel. None of the commentators thought the device had been superseded but they were aware of other competing software with a similar function.

Potential patient impact

The specialist commentators cited the following as potential benefits to patients:

- The ability to quickly and accurately identify people whose emphysema may be suitable for ELVR surgery.

- An improvement in phenotyping patients with COPD by distinguishing between patients with predominant airway disease and emphysema.

They stated the treatment pathway could improve if there were future evidence that validated the accuracy of FI analysis for improving selection of patients for ELVR and avoiding the need for bronchoscopy, which is a more invasive treatment. The introduction of VIDAvision could also lead to fewer hospital appointments.

Potential system impact

The specialist commentators indicated that VIDAvision could remove the need to use bronchoscopy to confirm visual estimation of a CT scan. This could help to identify people whose disease may be suitable for ELVR surgery at an earlier stage. It would also provide an objective measure of emphysema progression.

They thought that the costs to implement the technology would be low because CT scans are already part of standard care in this patient population. The software could be loaded onto a computer terminal in a radiology or medical department and the need for training would be minimal; it could possibly be provided through online learning or by the company. Savings would be seen by reducing the need for bronchoscopy. One commentator thought that quantitative ventilation and a perfusion scan before video-assisted thoracoscopy may no longer be needed.

Existing picture archiving, communication system archives and CT viewing systems could all be potential barriers for use would be the integration of these systems with.

None of the commentators were aware of any safety concerns or regulatory issues surrounding the use of VIDAvision.

General comments

Views were split on whether this technology would replace, or be an addition to, the current standard care. One commentator said it might replace standard care if there were further evidence to validate the findings.

There was uncertainty about whether VIDAvision would be able to replace invasive measures of collateral ventilation but commentators thought it could be useful in providing additional information and could have a broader uses. However, using this type of

technology to define and quantify emphysema is not in any national or international guidelines. One commentator noted that currently very few patients have LVRS and they estimated that the software would only be useful for about 1% of patients with COPD.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Anand Devaraj, cardiothoracic radiologist, Royal Brompton Hospital. No conflicts of interest declared.

- Dr Deepak R Subramanian, consultant respiratory physician, Derby Teaching Hospitals NHS Foundation Trust. No conflicts of interest declared.

- Dr Imran Hussain, consultant respiratory physician, University Hospital of North Midlands. No conflicts of interest declared.

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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