NICE advice

Archimedes for biopsy of suspected lung cancer

Medtech innovation briefing
Published: 11 June 2020

www.nice.org.uk/guidance/mib211

Summary

- The **technology** described in this briefing is the Archimedes System. It is used to take image-guided biopsies of lung lesions.
- The **innovative aspects** are that it allows healthcare professionals to see where the bronchoscope is going in real time using pattern recognition software to reconstruct CT scans and create full 3D images of the airways.
- The intended **place in therapy** would be as an alternative to CT-guided trans-thoracic biopsy for definitive diagnosis of lung lesions in people with suspicious nodules in the airways or beyond.
- The **main points from the evidence** summarised in this briefing are from 4 observational studies including a total of 59 people with lung lesions in secondary care. They showed that Archimedes enabled healthcare professionals to access lesions anywhere in the lung, with a diagnostic yield of 75% to 85%. They also showed that the risks of major complications such as pneumothorax are low using the system.

- **Key uncertainties** around the evidence are that no comparators were included, study sample sizes were small (6 to 25 people), and none of the studies were in the UK.
- The **cost** of the Archimedes System is £240,000 (exclusive of VAT). The **resource impact** would be greater than standard care (a CT-guided trans-thoracic biopsy procedure), the average cost of which is estimated at £1,357. Some of the extra costs may be offset because of fewer complications such as pneumothorax and a shorter inpatient stay. There is limited evidence to support these claims.

The technology

The Archimedes System (Broncus Medical) is an image-guided navigation system that comprises a workstation, software and optional guided sampling kit. Its purpose is to access tissue samples for biopsies of lung lesions in people with suspected lung cancer. This technology is also known as virtual navigation bronchoscopy. The system integrates bronchoscopic images, CT data and fused fluoroscopic images to provide a reconstructed real-time airway.

The system generates a 3D image during the procedure to access nodules anywhere in the lung. The bronchoscope enters the lungs through the central airways. The system creates a tunnelled path through the lung parenchyma, avoiding blood vessels, directly to the peripheral lesion, which can be sampled or treated.

Archimedes also uses the patient's high-resolution CT to create a virtual representation of their airway. This enables the healthcare professional to select the nodule of interest and see a navigation route to it. The system shows the full vascularisation of the lung so that the healthcare professional knows if they are taking the sample safely without puncturing the pleura.

The system is not intended for use in children. It may not be suitable for pregnant people, people with pacemakers or any metal implants because of the use of fluoroscopy.

Innovations

Archimedes uses pattern recognition software to reconstruct CT scans, and create full 3D images of the airway. The company notes that a potential advantage is that, unlike other technologies that access the airway through bronchioles or percutaneously to reach

peripheral lesions, Archimedes can reach them through the parenchyma with fused fluoroscopy. The system can be linked up to a C-arm (an imaging scanner intensifier) to provide a fused fluoroscopy image of the nodule, so that difficult-to-reach nodules can be accessed. The company claims that the fused fluoroscopy software is unique to Archimedes. The system can also show images of the full lung vascularisation, which is not available through other navigation systems.

Current care pathway

People with known or suspected lung cancer should be offered a contrast-enhanced chest CT scan to diagnosis and stage the disease. They should also be offered endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) for biopsy of paratracheal and peri-bronchial intra-parenchymal lung lesions. When taking samples, the healthcare professional should ensure they are adequate (without unacceptable risk to the person) to permit pathological diagnosis, including tumour subtyping and assessment of predictive markers.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on lung cancer: diagnosis and management
- NICE's quality standard on lung cancer in adults
- NICE's interventional procedures guidance on endobronchial ultrasound-guided transbronchial biopsy for peripheral lung lesions.

Population, setting and intended user

Archimedes is intended to help tissue sampling during biopsies of lung lesions in people with suspected lung cancer by allowing healthcare professionals to visualise and navigate to the lesion.

The system would most likely be used by respiratory physicians or thoracic surgeons in secondary and tertiary care in the NHS.

Costs

Technology costs

The Archimedes System costs £240,000 (excluding VAT). There is a 1-year warranty. A service contract costs £23,000 and covers repairs, site visits by an engineer and maintenance checks. If a service contract is not agreed these services have to be paid for individually.

An access kit for bronchial trans-parenchymal nodule access (BTPNA) costs an extra £1,200 (excluding VAT) per procedure. The kit consists of a FleXNeedle, Dilation Balloon and BTPNA catheter.

Costs of standard care

CT-guided trans-thoracic needle biopsy is the main alternative in the NHS and, in hospitals that have a CT scanner, there are no additional capital costs. The tariff cost for standard care is £1,357, which captures the costs of image-guided biopsy and full pulmonary function testing.

Resource consequences

The Archimedes System has been used in 7 hospitals in the UK.

Costs include the cost of the system and staff training. Training takes 2 days and is supported on site by the company.

The potential barrier to adoption is the capital cost of the system. Minimal changes in facilities or infrastructure are needed. This is because the procedure can either be done under sedation in the bronchoscopy suite by respiratory physicians, or be done under general anaesthetic in the operating theatre by thoracic surgeons. Using Archimedes for more invasive procedures such as BTPNA may require more facilities than the sedation available in a bronchoscopy suite.

There may be cost savings from fewer complications such as pneumothorax and a shorter inpatient stay. It does not take long to do a CT-guided trans-thoracic needle biopsy procedure, and it is done under local anaesthetic. But there may be some people for whom

CT-guided biopsy is too high risk because of comorbidities, or if a leading airway path to the lesions cannot be identified. One expert noted that another CT may be needed before the procedure, and this means extra hospital visits.

Regulatory information

The Archimedes System 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.

No equality issues were identified. The technology is used to investigate people who may have lung cancer. People with cancer are considered to be disabled 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

Four studies are summarised in this briefing, selected on the basis of the most relevant technology and outcomes, including 3 prospective interventional studies and 1 retrospective study. There were 59 people with lung nodules in total in the selected studies.

The clinical evidence, and its strengths and limitations, is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There is limited high-quality evidence for the Archimedes System. None of the included studies were done in the UK.

Primary outcomes include diagnostic yield and adverse events, such as incidence of procedure-related pneumothorax. The common limitations across the studies are small sample sizes and no comparative data.

There is no evidence from randomised controlled trials and the place for this technology in the NHS, alongside other guided bronchoscopy techniques, is not yet established. More evidence on benefits and costs is needed, including UK-based studies. A multicentre prospective randomised trial could address the overall risks and benefits of using the system. Archimedes may be suitable for people for whom CT guided biopsy is thought to be high risk or if a leading airway path to the lesions cannot be identified.

Herth et al. (2018) (abstract)

Study size, design and location

A prospective single-arm interventional study. The study location was not reported in the abstract. The study included 16 people with no leading airway path to the solitary pulmonary nodule.

Intervention and comparator

Archimedes was used to reconstruct CT data of eligible participants. There was no comparator in the study.

Key outcomes

Overall diagnostic yield for Archimedes was 75%, which indicated that 75% of people who underwent bronchial trans-parenchymal nodule access (BTPNA) using Archimedes had biopsy samples taken and received a definitive diagnosis. No major complications or pneumothorax were reported.

Strengths and limitations

The abstract reported diagnostic yield as a primary outcome. The sample size is small (n=16), and there was no comparator.

Ramzy et al. (2018) (abstract)

Study size, design and location

A retrospective interventional study in the US. The study evaluated 25 people (27 lesions) who had BTPNA with intra-procedure fused fluoroscopy for the biopsy of a solitary pulmonary nodule.

Intervention and comparator

Archimedes was used to reconstruct CT data of eligible participants. There was no comparator in the study.

Key outcomes

Twenty-four people completed the procedure. The diagnostic yield of the procedure was 85%. Of lesions evaluated, 8 lesions (31%) were detected as malignant and 13 lesions (54%) were benign. Four lesions (15%) were indeterminate on final pathological review. Two people had minimal biopsy airway bleeding after the procedure; no one developed pneumothorax.

Strengths and limitations

The abstract reported diagnostic yield as a primary outcome. The sample size was small (25 people with 27 lesions) and there was no comparator.

Harzheim et al. (2016)

Study size, design and location

A prospective, single-arm interventional study in Germany. The study recruited 6 people with pulmonary nodules (lesions of a diameter up to 30 mm).

Intervention and comparator

Archimedes was used to reconstruct CT data of eligible participants. There was no comparator in the study.

Key outcomes

Six people were enrolled in the study. A positive biopsy was obtained in 5 people (83%) in which BTPNA could be successfully completed. Adequate histological sampling for a histological diagnosis was obtained in 5 people. The biopsies obtained by BTPNA correlated with the final pathology in 4 surgically resected nodules.

There were no significant adverse events during the procedure. Two pneumothoraces were diagnosed by chest X-ray 2 hours after the procedure, with 1 pneumothorax requiring drainage.

Strengths and limitations

The study has a prospective design, but only 6 people were enrolled and there was no comparator.

Herth et al. (2015)

Study size, design and location

A prospective single-arm interventional study in Germany. The study recruited 12 people with pulmonary nodules (lesions of up to 40 mm diameter from suspected lung cancer or metastatic disease) when surgical resection was suitable.

Intervention and comparator

The Archimedes virtual bronchoscopy navigation system was used to reconstruct CT data of eligible participants. There was no comparator in the study.

Key outcomes

The BTPNA procedure was successfully completed in 10 people (83%), and adequate sampling for a histological diagnosis was obtained. Inspection at surgery and in the

postresection specimens showed that the tunnel path was created in the correct position and that orientation led directly to the target nodule. The histological findings from the biopsies obtained by BTPNA correlated with the final pathology in all of the surgically resected nodules. In the 2 people in whom the BTPNA procedure could not be completed, the nodules were located in the apical section of the left upper lobe.

There were no significant adverse events during the procedure. The only adverse event was a transient rise in troponin levels in 1 person after the BTPNA procedure and surgical resection. Outpatient follow up at 90 days and 180 days after the procedure did not reveal any adverse events attributable to the procedure.

Strengths and limitations

The study is a prospective design, but only 12 people were enrolled and there was no comparator.

Sustainability

The company claims that the single-use components of the technology can be disposed of by the hospital's recycling or disposing scheme. When the workstation and software come to the end of their lives, they will be recycled by the company in line with best practice at the time. There is no published evidence to support these claims.

Recent and ongoing studies

- Evaluation of the Archimedes System for Transparenchymal Nodule Access 2 (EAST2). ClinicalTrials.gov Identifier: NCT02867371. Status: recruitment completed. No interim results published. Indication: lung cancer. Devices: Archimedes. Last update on 1 November 2019. US.

Expert 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.

Three experts were familiar with or had used this technology before.

Level of innovation

One expert considered the technology to be novel, and another expert thought the technology was different to standard care (CT-guided trans-thoracic needle biopsy) because Archimedes provides navigation from inside rather than the outside. All experts were aware of the superDimension Navigation System, an alternative technology available in the NHS (see NICE's medtech innovation briefing on superDimension Navigation System).

Potential patient impact

One expert considered the Archimedes System useful, and thought it would improve accuracy and yield in diagnosing lung diseases, particularly peripheral lung lesions that are small or awkward to sample. The expert thought that using the system could have the potential to lead to fewer complications compared with CT-guided biopsy.

All experts agreed that the people most likely to benefit from the technology were those who could not have CT-guided transbronchial needle biopsy because the position of the lesion made it too risky. One expert thought that other people who would benefit were those:

- at high risk of pneumothorax, for example, if they have significant emphysema or advanced interstitial lung disease
- who have a lung nodule so deep in the lung that a trans-thoracic needle would have to travel some distance from the pleura.

Potential system impact

The experts generally agreed that the technology would shorten the current pathway by avoiding unnecessary tests.

The procedure uses fewer hospital resources than an inpatient stay and takes less time than an invasive surgical biopsy. It can also free up radiology resources for other patient workloads. The average cost per procedure may be reduced if the procedure is done under sedation in a bronchoscopy suite. Two experts thought there would be little change to current facilities or infrastructure. But the experts indicated the potential need to increase capacity in the bronchoscopy unit. For instance, surgical support and general

anaesthesia may be needed in some procedures. The procedure may be more likely to be performed in specialist centres. Experts thought that training would be needed to use the technology and to do the procedure.

General comments

All experts considered that Archimedes would be used as an add-on to current CT-guided biopsy, and one noted that patients do need an additional CT scan to plan the procedure. None of the experts was aware of any safety issues but 2 said data collection on the safety of using the technology is ongoing. One expert thought patient selection for the procedure would be important, and this should be based on experienced healthcare professionals' assessment of when the technology is most suitable for people. The main barrier to adoption identified by 2 experts was the cost of the technology. Two experts thought more studies were needed to improve the current evidence base, especially a study comparing the accuracy of the technology with that of CT-guided biopsy or other bronchoscopy in the NHS.

Expert commentators

The following clinicians contributed to this briefing:

- Haval Balata, consultant respiratory physician, Manchester University NHS Foundation Trust. No interests declared.
- Samuel Kemp, consultant respiratory physician, Royal Brompton & Harefield NHS Foundation Trust. The trust runs a hospital that has installed a system.
- Alastair Moore, consultant respiratory physician, Oxford University Hospitals NHS Trust. No interests 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.

ISBN: 978-1-4731-3720-2