NICE advice

PIUR tUS for abdominal aortic aneurysm surveillance and endovascular aneurysm repair endoleak detection

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is PIUR tUS (3D tomographic ultrasound). It is for abdominal aortic aneurysm (AAA) surveillance and endovascular aneurysm repair (EVAR) endoleak detection or surveillance.
- The **innovative aspects** of the technology are the 3D imaging that can be used with any ultrasound device. This can extend the image to cover the entire length of a blood vessel at once.
- The intended **place in therapy** would be as well as ultrasound scans for AAA surveillance and instead of CT or MRI scans for EVAR endoleak detection or surveillance. The technology can be used in primary care and in tertiary referral centres.
- The **main points from the evidence** summarised in this briefing are from 2 studies including 120 adults immediately after EVAR. They show that PIUR tUS is at least as effective as CT scans for endoleak detection after EVAR.

- **Key uncertainties** around the evidence or technology is that all evidence published on PIUR tUS is on infra-renal AAA. No conclusions can be drawn for people with complex, juxta or suprarenal AAAs.
- The **cost** of PIUR tUS is £43,000 per unit (exclusive of VAT). The **resource impact** could be less than standard care because of a reduced need for CT scans, but there is no published evidence to support this.

The technology

PIUR tUS (3D tomographic ultrasound; PIUR imaging) generates 3D tomographic ultrasound images of the entire length of a blood vessel by extending regular 2D ultrasound scanners. This imaging can be used for abdominal aortic aneurysm (AAA) surveillance and endovascular aneurysm repair (EVAR) endoleak detection and classification. PIUR tUS can be used with any 2D ultrasound device and transducer. It turns the images collected into high-resolution tomographic 3D ultrasound images. The images are viewed and reported in a similar way to other 3D imaging techniques using multi-planar reconstructions and 3D volume, such as CT or MR angiography.

The company has also developed a smaller version of the device, PIUR tUS Infinity, which is designed to be more easily transported and cheaper (£450 per month). This version can currently only be used with linear transducers, but support will be added in 2020 so that it can be used for AAA surveillance.

Innovations

The company states that other 3D or 4D technologies have a limited view, whereas PIUR tUS can produce images of the entire length of vessel if needed (for example, from diaphragm to groin).

Current care pathway

AAAs may be found during screening (65-year-old men are invited for screening by the NHS AAA screening programme), when a person reports symptoms, or found during other scans (for example, CT or MRI). People with a family history of AAA may also be invited for screening. Ultrasound scanning screens for AAA, further treatment depends on the scan result:

- If the aorta is less than 3 cm wide, there is no aneurysm. No further treatment or monitoring is needed.

- If the aorta is 3 cm to 4.4 cm wide, there is a small aneurysm. The person will be invited back for scans every 12 months to monitor the growth of the aneurysm.
- If the aorta is 4.5 cm to 5.4 cm wide, there is a medium aneurysm. The person will be invited back for scans every 3 months to monitor the growth of the aneurysm.
- If the aorta is 5.5 cm or wider, there is a large aneurysm. The person will be referred to a specialist for treatment.

An endoleak is a common complication of the EVAR procedure. During EVAR, a fabric-covered stent is put in place to reinforce the areas of the aorta that are weak because of an aneurysm. The stent provides a new path for blood flow, which keeps blood from reaching the aneurysm. An endoleak is a complication that affects about 15% to 25% of patients who have EVAR. It means that some blood flow stays in the aneurysm cavity. Endoleaks are classified by type I to V:

- Type I: blood leaks around the top or the bottom of the stent. Because the blood has high flow, type I endoleaks are treated urgently.
- Type II: blood leaks into the aneurysm from small branches of the aorta. This is the most common type of endoleak. Type II endoleaks can sometimes stop without treatment but will need to be checked regularly.
- Type III: blood leaks through separations in the overlapping stent graft components into the aneurysm cavity.
- Type IV: blood leaks through the pores of the stent graft, this is rare in new stent technologies.
- Type V: these types of endoleaks are not well understood and usually result in an endograft reinforcement procedure or open surgery.

An endoleak usually has no symptoms and is often detected during routine follow-up visits (with vascular surgeons, vascular scientists or a nurse). Duplex ultrasound or CT imaging is used to examine the site of the EVAR.

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

- NICE's in development guideline on abdominal aortic aneurysm: diagnosis and management. The draft guideline states that if contrast-enhanced CT angiography is contraindicated, contrast-enhanced ultrasound should be considered for endoleak detection. The committee did not recommend colour duplex ultrasound because of variable diagnostic accuracy. The draft guideline states that further evidence is needed on surveillance after EVAR.

Population, setting and intended user

PIUR tUS could be used to diagnose AAA, for AAA surveillance and after EVAR.

PIUR tUS users should be competent in colour duplex and contrast-enhanced ultrasound and should attend a half-day training course on using the technology. This is included in the cost of the technology and provided by the company. After training, the company recommends that the first 20 uses are done under the supervision of a competent user or compared with a gold standard (for example, CT scan).

PIUR tUS would be used in outpatient tertiary referral centres by competent users such as vascular surgeons and scientists, screening technicians, sonographers and radiologists.

Costs

Technology costs

The company states that if the technology is used for endoleak detection in 100 people per year for 5 years (used 5 days a week) PIUR tUS would cost around £225.60 per patient.

Training is needed to use the technology, the company states that this will take 1 day to 2 days. Training is provided by the company at no additional cost. The company recommends that a clinician's first 20 uses of the technology should be done under supervision of a competent user or compared with a CT scan. These costs have not been included in the calculations.

- Cost of technology, £43,000. The technology can be used for 5 years and must be serviced once a year by a qualified technician. These costs were provided by the company.
- Ultrasound contrast medium (for EVAR only), £54 per patient. Cost provided by the company.
- Plaster, £0.02, 1 plaster needed to cover the site of cannula insertion.
- Alcohol wipes, £0.02. The company states that 2 wipes will be used to clean the sensors for each patient.

Costs of standard care

The Payment by Results tariff reimbursement for AAA screening and surveillance using duplex ultrasound is £49 per scan, in an outpatient setting.

For EVAR surveillance, the company estimates that contrast-enhanced ultrasound costs £105 (includes cost of contrast medium) and will need a sonographer. A CT angiogram costs £285 and will need a radiologist whose time will cost around £20 per appointment.

Resource consequences

PIUR tUS is currently used in 5 university hospitals and in 2 private healthcare centres in the UK.

The device would be an additional cost to standard care because a sonographer and ultrasound machine are needed. Adoption of PIUR tUS might reduce resource consequences overall because of a reduced need for CT scans and surgical intervention.

PIUR tUS can work with existing ultrasound systems.

Regulatory information

PIUR tUS is a CE-marked class I-m (measurement function) medical device.

No manufacturer field safety notices or medical device alerts for this technology have been identified.

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.

Abdominal aortic aneurysm and endovascular aneurysm repair are more common in men over 65 years of age. Age and gender are protected characteristics under the Equality Act 2010. PIUR tUS cannot be used in people who have a pacemaker or internal cardiac defibrillator.

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 2 studies summarised in this briefing, including 120 patients.

A number of studies have been published on similar devices that use tomographic ultrasound for abdominal aortic aneurysm (AAA) surveillance and endovascular aneurysm repair (EVAR) endoleak detection.

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

Overall assessment of the evidence

The evidence base for PIUR tUS is limited, comprising of 1 proof-of-principle study and 1 prospective study. Both studies consider the technology for endoleak detection after EVAR and were done in the NHS. There is no published evidence on the technology for AAA detection.

Rogers et al. (2019)

Study size, design and location

Study of 20 adults having infra-renal EVAR in a proof-of-principle study in the UK

Intervention and comparator(s)

Rotational angiography, contrast-enhanced ultrasound (CEUS) and contrast-enhanced tomographic 3D ultrasound (CEtUS, PIUR tUS) immediately after surgery.

Key outcomes

Presence of endoleak (10 endoleaks found by CEUS and CEtUS, 4 detected by rotational angiography. Type IIb endoleaks were not detected by rotational angiography). The authors note that CEUS and CEtUS did not produce an image that could be used for diagnosis in 1 patient because of a body mass index of 40.4 and extensive bowel gas. The imaging technique was uncertain (type of endoleak could not be determined) in another 2 patients, but no reason for the failure is provided. Rotational angiography did not detect any type IIb endoleaks, 7 and 8 type IIb endoleaks were detected by CEUS and CEtUS, respectively.

Renal artery patency was found in 27 and 26 renal arteries, respectively. Rotational angiography

found 39 patent renal arteries.

Strengths and limitations

The authors noted that it would be useful to have CEUS or CEtUS as an option for endoleak detection immediately after EVAR for patients in whom contrast agents should be minimised. They also noted that less clinician skill and time are needed for a diagnostically acceptable image using CEtUS compared with CEUS and rotational angiography. One of the authors is a founder of the company.

Lowe et al. 2017

Study size, design and location

Study of 100 adults having EVAR in a prospective study in the UK

Intervention and comparator(s)

Computed tomography angiography (CTA), CEUS and 3D-CEUS (prototype PIUR tUS) immediately after surgery. CTA, CEUS and 3D-CEUS were done on the same day and 3D-CEUS was reported independently by 2 blinded vascular scientists.

Key outcomes

Using CTA as a gold standard, 3D-CEUS detected endoleaks with 96% sensitivity, 91% specificity, 90% positive predictive value and 96% negative predictive value. The κ statistic for interoperator agreement was 0.89.

Strengths and limitations

The authors noted that that the study reached statistical power to show diagnostic accuracy when 67 comparisons (total 100) were made. CTA, CEUS and 3D-CEUS were done on the same day in 52 patients, the rest were done within 4 weeks. The authors noted that they do not expect this to have affected results.

One of the authors is a founder of the company. However, this study used a prototype device and was funded by the Wellcome Trust and Manchester Surgical Research Trust. This meant no conflicts of interest were declared at publication.

Sustainability

This technology may reduce the need for CT scans. This could reduce environmental impact, but there is no evidence to support this.

Recent and ongoing studies

Two studies are completed and will be published shortly. One is on the accuracy of PIUR tUS compared with CTA for measuring AAA diameter. The second paper is on AAA sac and wall volume and their association to AAA growth.

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 had used this technology before. One had not used the technology but had relevant expertise.

Level of innovation

All 4 expert commentators stated that the technology was novel. The commentators noted that there are other ultrasound devices that could produce 3D images, but no other technology can image an entire blood vessel at once. One commentator noted that the company will soon launch a portable version of the device that is small and light enough to be transported and used in the community.

Potential patient impact

Three expert commentators noted that using PIUR tUS avoids exposure to ionising radiation and nephrotoxic contrast media from CT scanning. Three commentators noted that using PIUR tUS would mean quicker results (because of availability of ultrasound imaging), shorter appointments and faster interpretation of results, compared with CT scans. Two commentators noted that scanning might be more convenient for patients because they would not have to travel to a centre with a CT scanner. One expert commentator stated that 3D ultrasound can measure change in aneurysm repair. This is a more sensitive marker than the diameter measurements produced by 2D ultrasound.

Potential system impact

Three expert commentators noted that PIUR tUS is significantly cheaper than CT scanning. Two commentators stated that using PIUR tUS would also increase CT scanner capacity for other patient groups and would release time for interventional radiologists. One commentator noted that patients would not need to be admitted to hospital for intravenous fluids as they would for CT angiogram. Two commentators noted that images from PIUR tUS could be directly interpreted by clinicians who would otherwise rely on reports from ultrasonographers. One commentator explained that PIUR tUS is more expensive than standard ultrasound because it is an additional technology. One commentator noted that using PIUR tUS could become cheaper than duplex ultrasound because it is quicker and needs less training, but duplex ultrasound may be preferred in some cases. One commentator felt that CT angiogram could still be needed if the images from PIUR tUS were inadequate. One commentator noted that sonographers will need training to use PIUR tUS and that standard and quality governance procedures would be needed.

General comments

One expert commentator noted that because of inappropriate reimbursement codes and not being included in guidelines, 3D ultrasound is not widely used in the NHS.

One expert commentator stated that their centre used PIUR tUS for a pilot research project. The other 2 commentators used the device regularly.

The expert commentators noted that this technology could be used in several other patient populations including those with occlusive vascular disease, asymptomatic carotid disease, and accessible tumours. It could also measure carotid plaque volume to estimate stroke risk, plan arteriovenous fistula formation for haemodialysis and select potential autologous grafts for peripheral and coronary artery bypass.

One expert mentioned that the detection rate of endoleaks for PIUR tUS is higher than for current methods (50% compared with 20%). They noted that this could mean that PIUR tUS is oversensitive and might identify clinically insignificant endoleaks.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Steven Rogers, senior clinical vascular scientist, Independent Vascular Services and University of Manchester. Dr Rogers acts as a clinical adviser to the company but receives no monetary compensation for these services.
- Professor Matthew Bown, professor of vascular surgery, University of Leicester. No conflicts declared.
- Professor Saroj Kumar Das, consultant vascular surgeon, Imperial College, London, London North West University Hospital, NHS Trust, The Hillingdon Hospital NHS Foundation Trust. No conflicts declared.

Contributors

The following clinician contributed to this briefing:

- Professor Charles McCollum, professor of surgery, University of Manchester.

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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