NICE advice

Butterfly iQ+ for diagnostic ultrasound imaging

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the Butterfly iQ+. It is used for external diagnostic ultrasound imaging in adults and children.
- The **innovative aspects** are that it is the first handheld device that can be used for multiple applications, with a single probe emulating different probe types. It is powered by a single silicon chip, 'ultrasound on a chip', and connected to a smartphone. It could be used in settings where there is no access to alternative ultrasound equipment.
- The intended **place in therapy** would be as an alternative to point-of-care ultrasound devices for people who need diagnostic ultrasound imaging.
- The **main points from the evidence** summarised in this briefing are from 5 observational studies including 174 people. They show that the Butterfly iQ+ can be effective as a diagnostic ultrasound tool across a variety of indications.

- **Key uncertainties** around the technology are that experts expressed concerns about image quality and size on a smartphone screen. Key uncertainties around the evidence are that there were only 2 comparative studies, and these did not report patient outcomes. Also, only 1 study was done in the UK.
- The **cost** of Butterfly iQ+ is £1,699 per unit, plus £360 per year as a membership fee (excluding VAT). Standard care costs between £6,000 and £19,500 for point-of-care ultrasound devices and between £30,000 and £100,000 for traditional cart-based ultrasound devices.

The technology

Butterfly iQ+ (Butterfly Network Inc) is a pocket-sized portable external ultrasound scanner. It is a handheld, single-probe, whole-body ultrasound system, powered by a single silicon chip and is connected to a smartphone. Butterfly iQ+ is designed to be used in all areas of medicine. It has 20 imaging pre-sets that can be used in abdominal, cardiac, lung, bladder, nerve, vascular, musculoskeletal, ocular and obstetric point-of-care imaging.

Innovations

The company claims that Butterfly iQ+ is the world's first handheld, single-probe point-of-care whole-body ultrasound scanner. Other handheld ultrasound scanners have multiple probes for different applications. Conventional ultrasound machines use piezoelectric crystals to transmit soundwaves to produce an image. But, the Butterfly iQ+ uses ultrasound-on-chip technology that can emulate any type of probe (linear, curved or phased), enhancing the accessibility of ultrasound imaging. The Butterfly iQ+ also has capability for teleguidance functionality built in, alongside artificial intelligence tools including auto ejection fraction calculation and auto bladder volume calculation.

Current care pathway

An ultrasound scan can be used to diagnose a condition, monitor a condition, monitor an unborn baby, or guide a physician during certain procedures. Scans can be done using traditional ultrasound scanners that are based in a specific department. These are cart-based or handheld point-of-care ultrasound devices, depending on the setting and condition. External ultrasounds are used to examine the heart, lungs, liver, kidneys, an unborn baby in the womb and tissues that can be assessed through the skin, including

muscles and joints. During the scan, a handheld probe is placed onto the skin and moved over the part of the body being examined.

Most ultrasound scans will take place in a hospital radiology department and be done by either a radiologist or sonographer. Ultrasound scans can also be done in other hospital departments and community locations such as GP practices. They also may be done by other healthcare professionals, such as doctors, midwives and physiotherapists with specialist training in ultrasound. Scans normally last between 15 and 45 minutes.

Population, setting and intended user

The Butterfly iQ+ is for both adults and children who need diagnostic ultrasound imaging and measurement of anatomical structures and fluids. In adults, it can be used for a wide range of indications including abdominal, bladder, cardiac, focused assessment with sonography for trauma, gallbladder, lung, musculoskeletal, nerve, obstetric, ophthalmic, small organs, soft tissue and vascular. In children, it can be used for abdominal, cardiac and lung assessments.

The technology is used in anaesthesiology, emergency medicine, acute medicine and critical care. The company states that in the NHS, the technology is currently used in primary, secondary and tertiary care.

The company states that for an ultrasound-trained healthcare provider, the technology is easy to use. Training on how to operate the device is included in the purchase cost and provided by the company. It takes about 1 hour and can be delivered on site or remotely by an online meeting. Further training resources are available through the company app or on their website.

Costs

Technology costs

The Butterfly iQ+ costs £1,699, plus £360 per year as a Pro Individual membership fee. This fee covers unlimited cloud storage.

Costs of standard care

- Point-of-care ultrasound devices range from £6,000 to £19,500.
- Traditional cart-based scanners cost between £30,000 and £100,000.

Resource consequences

The company states that the technology is currently used in 21 NHS trusts. It claims that the Butterfly iQ+ costs less than traditional systems. Because this device is more affordable than traditional systems, the company also claims that this could make point-of-care imaging more widespread, which could benefit patient care.

The company claims that the technology is easy to use and connects directly into a compatible smart device, so no changes in facilities or infrastructure are associated with the introduction of Butterfly iQ+ in the NHS. The Butterfly iQ+ is compatible with a wide range of smartphones and tablets from both iOS and Android platforms, explained on the website for Butterfly iQ+. These devices need to be supplied by the institution or end user.

Regulatory information

Butterfly iQ+ is a CE-marked class 2a medical device.

The following manufacturer field safety notice or medical device alert for this technology has been identified:

US Food and Drug Administration MAUDE Adverse Event Report: Butterfly Network inc. Butterfly iQ charger wireless system charger (September 2020). A potential adverse event report was identified by 1 user. While charging, the ultrasound charging pad melted a port. The report states that the Butterfly iQ+ ultrasound system design prevents the probe from being used for scanning while charging, so this event does not represent a hazard to patients. The investigation is ongoing to identify the root cause.

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.

Butterfly iQ+ is intended for both adults and children who need diagnostic ultrasound imaging and measurement of anatomical structures and fluids. This includes lung, cardiac, musculoskeletal, and abdominal scans, and obstetric scans for pregnant women. Older people, men, and people with diabetes, high blood pressure or obesity are more likely to develop coronary heart disease. People with poor health or pre-existing conditions including respiratory conditions are more likely to be admitted to hospital and in need of an ultrasound. Age, sex, pregnancy and maternity and disability are protected characteristics under the Equality Act (2010).

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 5 studies summarised in this briefing, including 174 people.

All studies are observational, of which 3 were done retrospectively. The clinical evidence and its strengths and limitations are summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence for the technology is of low to moderate methodological quality, and most of the studies have small patient numbers. All studies evaluated the prognostic value of the Butterfly iQ+. Two studies had comparators, but they did not report patient outcomes. One study was done in the UK. The studies show that the Butterfly iQ+ can be effective as a diagnostic ultrasound tool across a variety of indications. Further evidence is needed comparing the Butterfly iQ+ with standard care, using a large sample size and reporting patient outcomes.

Bennett et al. (2020)

Study size, design and location

Retrospective observational study of 18 people with symptoms compatible with COVID-19, a positive SARS-CoV-2 nasal-pharyngeal swab and radiologic evidence of interstitial pneumonia, in Italy.

Intervention and comparator

Butterfly iQ+ and Venue Go (GE Healthcare).

Key outcomes

In total, 34 paired lung ultrasound scans (LUS) on 18 people with COVID-19 were included. There were 16 scans done in the severe respiratory impairment group, 11 in the moderate respiratory impairment group and 9 in the mild respiratory impairment group. LUS scores in individuals with mild respiratory impairment were significantly lower than in those with moderate and severe cases. No significant differences were found between LUS scores obtained with the Venue Go point-of-care ultrasound, and the Butterfly iQ+ portable pocket-sized ultrasound, with a mean difference in score of 0.018 (plus or minus 0.018 points). The 2 technologies showed an excellent degree of concordance for all computed parameters.

Strengths and limitations

The authors state that this is the first study showing use of the Butterfly iQ+ portable pocket-sized ultrasound in daily clinical practice in people with COVID-19. It confirms the possible use of Butterfly iQ+ for this group. However, the authors recommend further research, because study findings are not specific and may not correlate with clinical outcomes.

Burleson et al. (2020)

Study size, design and location

Retrospective observational study in 33 people with a range of indications needing

ultrasound assessment including cardiac, lung, musculoskeletal and abdominal scans, in rural east Africa.

Intervention and comparator

Butterfly iQ+, no comparator.

Key outcomes

Five emergency physicians evaluated the performance of the Butterfly iQ+ and found that it performed well and met their needs for a point-of-care ultrasound. Advantages of using the Butterfly iQ+ included using a single probe for multiple modalities, good image quality in most indications and that it is relatively inexpensive. Disadvantages included large probe footprint, lower quality for cardiac imaging and frequent overheating.

Strengths and limitations

This study suggests that Butterfly iQ+ is an effective, but imperfect, point-of-care ultrasound device in a low resource emergency setting. This study has several limitations including not evaluating patient outcomes and having potential selection bias because patients were scanned at the discretion of the clinician.

Rajendram et al. (2020)

Study size, design and location

Prospective observational study in 4 people with COVID-19 in whom significant shunt was suspected, in Saudi Arabia.

Intervention and comparator

Butterfly iQ+, no comparator.

Key outcomes

Image quality was interpretable by all the study sonographers. The backup ultrasound machine was not needed. There were no disagreements between the study sonographers

in any of the ultrasound findings. As a result, all investigators considered that the objectives of the present study had been fulfilled, and that further investigation was unnecessary.

Strengths and limitations

This study combined Butterfly iQ+ with lung ultrasound, vascular ultrasound and limited transthoracic echocardiography with saline microbubble contrast. It suggested that this combined approach can identify the aetiology of shunt. Results for Butterfly iQ+ were presented separately and then combined with the results of the other approaches.

Houze et al. (2020)

Study size, design and location

Observational study in 19 people with kidney disease in Grenada.

Intervention and comparator

Butterfly iQ+ and traditional examination and diagnosis.

Key outcomes

Butterfly iQ+ confirmed clinical diagnosis in 9 out of 19 people. In 10 people, Butterfly iQ+ led to new diagnoses. Some examples include clinical diagnosis of kidney failure, which was changed to bilateral hydronephrosis in 1 case and renal cyst with no hydronephrosis in another case after point-of-care ultrasound (POCUS).

Strengths and limitations

This study is reported in conference abstract form only so is limited in detail.

Knight et al. (2020)

Study size, design and location

Retrospective service evaluation in 100 people when COVID-19 was suspected in the UK.

Intervention and comparator

Butterfly iQ+ or LOGIQ E9 machine, no comparator.

Key outcomes

In 92 people, the clinical features and ultrasound examination were considered to be consistent with COVID-19. Quality of image acquisition was rated as good in 55.4% (n=51), average in 41.3% (n=38), and poor in 3.3% (n=3). SARS-CoV2 nasopharyngeal swab results were positive in 42.4% of cases (n=39). The risk of all-cause mortality in people with scores in the lowest quartile was 2.5% (95% confidence interval [CI] 0.12% to 12.95%) compared with 42.9% (95% CI 15.8% to 75.0%) in the highest quartile. POCUS-assessed severity correlated with length of stay and duration of supplemental oxygen therapy.

Strengths and limitations

This study suggests that this new POCUS severity scale showed good discriminatory performance in predicting a range of adverse outcomes in people with suspected COVID-19. POCUS was done on an ad hoc basis at the discretion of the clinician, allowing for selection bias. This study used 2 POCUS devices, the Butterfly iQ+ and the LOGIC E9 machine. However, the results are not stratified by device, so it is unclear how often each device was used and what the outcomes for each device were. There was also no comparison between the 2 devices.

Sustainability

The company claims the single probe is reusable but has to be cleaned with approved disposable liquid saturated wipes and disinfected with approved disposable wipes or disinfection solution. At the end of life, the probe and accessories can be recycled. There is no published evidence to support these claims.

Recent and ongoing studies

- COVID-19 and lung ultrasound utility. ClinicalTrials.gov Identifier: NCT04591158. Status: recruiting. Indication: lung infection, COVID-19. Devices: Butterfly iQ+. Last updated: October 2020. Country: Canada.

- Pain after preoperative ultrasound guided hip injections for total hip arthroplasty (PUSH). ClinicalTrials.gov Identifier: NCT04219098. Status: not yet recruiting. Indication: total hip replacement, arthroplasty. Devices: Butterfly iQ+ and standard care. Last updated: January 2020. Country: US.
- Comparing an inexpensive handheld ultrasound machine and a large mobile ultrasound system. ClinicalTrials.gov Identifier: NCT03764111. Status: completed. Indication: pregnant women needing a routine obstetric scan. Devices: Butterfly iQ+ and Sonosite M-turbo. Completed: December 2020. Country: US.
- Preclinical medical student echocardiography training American Society of Echocardiography curriculum. ClinicalTrials.gov Identifier: NCT04083924. Status: completed. Indication: cardiac ultrasound in people who are healthy. Devices: Butterfly iQ+. Completed: May 2020. Country: US.
- Implementing digital health in a learning health system (ASE-INNOVATE). ClinicalTrials.gov Identifier: NCT03713333. Status: unknown. Indication: cardiovascular diseases, hypertension, heart failure, atrial fibrillation, metabolic syndrome, genetic disease. Devices: Butterfly iQ+. Last updated: October 2018. Country: 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.

All 4 experts were familiar with the technology and 3 had used this technology before.

Level of innovation

All 4 experts said that the Butterfly iQ+ is innovative compared with standard care. This is because it is silicon chip-based, meaning a single probe can be used for multiple applications. Experts also said that this device can securely store and share images with other clinicians, and that it can be used in primary care. All 4 experts are aware of other portable ultrasound devices. However, these devices use traditional piezoelectric-based technology, which means they need multiple probes for different modes.

Potential patient impact

Two experts said that the Butterfly iQ+ can improve diagnostic accuracy and support rapid diagnosis. Two experts also said that it can improve patient care because the ultrasound can be used immediately at a patient's bedside.

Experts said that the Butterfly iQ+ would benefit people who are acutely ill. This includes people with acute respiratory difficulties (such as COVID-19), musculoskeletal conditions, suspected kidney problems, abdominal pain and deep vein thrombosis. One expert noted that this device can also be used for people having procedures that need ultrasound guidance.

Experts estimated that hundreds of thousands of people would be eligible for an intervention with this device (ranging from 200,000 to 1 million).

Potential system impact

Three experts agreed that the Butterfly iQ+ could improve patient outcomes and reduce hospital visits. One expert also said that it can increase accessibility to ultrasounds because of its portability and connectivity. Another expert said that it can lead to system benefits by allowing clinicians to share images. One expert noted that it can improve clinician confidence in their diagnosis.

All experts agreed that this technology could be cost saving compared with current cart-based and handheld ultrasound devices. One expert said that it costs less because the diagnosis can be supported in selected people using home care models without the need for hospital transfer.

All experts agreed that training is needed to use the technology safely and effectively. None of the experts were aware of any safety issues. However, one expert raised concerns about the image quality and the potential to miss pathology or misinterpret the images.

General comments

Two experts raised concerns about the image quality, stating that it is not yet as good as its competitors. One expert also said that the probe has a large footprint, which is a

limitation when using it for cardiac ultrasounds. Experts identified potential barriers to adoption including costs, IT challenges, the organisational structure and image quality. One expert said that it needs to work on different smartphone technologies.

Two experts noted that the Butterfly iQ+ would be in addition to current standard care (cart-based ultrasounds) because these may be needed for more detailed scanning. All experts agreed that it could replace current standard care in GP surgeries, care home and home settings because ultrasounds are currently not available in these settings.

Two experts said that this device would benefit from further research to help with clinical decision making. One expert said that comparative studies examining clinical outcomes are needed, specifically using radiologists to review the images.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Shwan J Maroof, primary care GP lead, Reading Response Hub and Reading Walk-in Health Centre. Has been provided with a Butterfly iQ+ device for professional development to support clinically interesting cases.
- Dr Ashley SC Miller, consultant in anaesthesia and intensive care, Royal Shrewsbury Hospital. Has received honoraria for educational ultrasound work for Fujifilm/Sonosite, General Electric (GE) and Phillips.
- Dr John M Butler, consultant in accident and emergency, Manchester Royal Infirmary. Did not declare any interests.
- Prof Daniel Lasserson, professor of acute ambulatory care, Warwick Medical School, University of Warwick and Department of Geratology, Oxford University Hospitals NHS Foundation Trust. Has published research supporting the use of point-of-care ultrasound, including using Butterfly iQ+.

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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