NICE advice

Magseed for locating impalpable breast cancer lesions

Medtech innovation briefing
Published: 17 November 2020

www.nice.org.uk/guidance/mib236

Summary

- The **technology** described in this briefing is Magseed. It is a localisation technique that uses magnetic markers to mark the site of a breast cancer lesion for surgical removal.
- The **innovative aspects** are that it is more flexible and less intrusive than a wire guided procedure. Magseed is located using the Sentimag probe, meaning less extensive surgery.
- The intended **place in therapy** would be as an alternative to current standard care for locating cancer lesions and helping guide surgeons in a breast lumpectomy for impalpable breast cancer. Magseed could also be used in the targeted axillary dissection, to mark lymph nodes before the neoadjuvant treatment.
- The **main points from the evidence** summarised in this briefing are from 5 observational studies. These include 1,923 people who had localisation procedures, including 1,699 who had Magseed. Two studies were comparative, and re-excision rates were not significantly different between Magseed and wire guided procedures.

- **Key uncertainties** around the evidence are there is no evidence from randomised controlled trials on Magseed. The evidence would benefit from well-controlled comparative studies to capture clinical benefits.
- The **cost** of Magseed is estimated at £250 per Magseed. As an alternative intervention, the cost of the technology would be more than the cost of wire used in standard care. The company states that the cost of the wire guided localisation procedure is estimated to be between £35 and £50.

The technology

Magseed (Endomag) is a marker that commonly used for localising impalpable breast lesions. It is a small single-use metal device (seed) designed to accurately mark the site of a breast cancer lesion for surgical removal. Magseed is 5 mm long and made of surgical grade stainless steel. Magseed has a low nickel content and is non-radioactive.

Magseed is put into a person with a needle under local anaesthetic and ultrasound or stereotactic X-ray guidance. It is to help guide surgeons during a breast lumpectomy for impalpable breast cancer. At the time of surgery, Magseed's location is detected with the Sentimag probe (a magnetic sensing system). This sensing machine makes sounds of different pitches and gives a reading to let surgeons know how close they are to Magseed. The seed is then removed along with the tumour. Magseed can be implanted any time before the surgical procedure. The company and 1 expert also noted the use of Magseed to localise axillary lymph nodes in people who are having neoadjuvant chemotherapy in order to de-escalate surgical management of the axilla.

Complications may happen at any time during or after the procedure. Possible complications of Magseed may include hematoma, haemorrhage, infection, adjacent tissue injury, pneumothorax, allergic reaction and pain. It is not intended for use in the central nervous system, circulatory system, heart, eyes or brain. The device should not be placed in a tissue site with clinical evidence of infection.

Innovations

Magseed is a localisation technique with no need for a wire. The company states that Magseed allows precise and less invasive implantation to locate cancer lesions. The company also notes that Magseed could be used for marking lymph nodes where wires

could not be applied.

Wire guided localisation is standard practice for the removal of breast lesions. Wire guided localised breast surgery includes the insertion of a small wire into the breast, which guides the surgeon to the tissue in the breast. The wire is inserted by a radiologist or physician a few hours before the planned surgical removal of the tissue. They use X-ray or mammography to ensure the correct placement.

People felt less anxiety in the Magseed procedure compared with wire guided localisation (Micha et al. 2020). Experts thought the use of Magseed improved patient experience because of reduced pain and anxiety.

Current care pathway

There is an increasing trend towards breast conservation in the treatment of breast cancer. It is essential that impalpable lesions detected either on mammography or by ultrasound are accurately localised before an operation to allow them to be successfully removed in the first operation. The Association of Breast Surgery's best practise guidelines for surgeons in breast cancer screening state that localisation for impalpable lesions is needed for breast surgery, and placement of marker wires under X-ray or ultrasound guidance is the most common method. Radio-guided occult lesion localisation is also a recognised method of localisation used in a number of screening services. Any new localisation method should have an approved research trial or approved audit of practice showing equivalent results to recognised techniques before routine implementation.

Population, setting and intended user

Magseed is intended to be used as a marker to be placed in soft tissue and to be surgically removed within the target tissue after its placement. The marker that is placed into the person with impalpable breast cancer, when used with Sentimag, can help guide surgeons during a breast lumpectomy. It is also used for targeted axillary dissection procedures. It is a single-use marker. A clinical expert suggested that it is used for impalpable breast biopsy.

Magseed can be injected into the breast by the radiologists or an advanced radiology practitioner under either ultrasound or X-ray guidance before a breast cancer operation. There are some hospitals where Magseed is inserted by the surgeon. On the day of

surgery, the surgeon uses a handheld probe called Sentimag to find the Magseed location in the breast.

Costs

Technology costs

A box of 10 Magseeds costs £2,500 and the reusable Sentimag probe costs £25,000 per unit. The company states that Magseed is single use and the Sentimag unit can last for over 5 years. The cost for using Magseed is £250 per Magseed (when the cost of the Sentimag unit has been deducted). The cost of insertion of marker such as Magseed for localisation of breast lesion as an outpatient procedure is £277 (NHS tariff 2019/20).

Costs of standard care

The company states that the costs for wire used in wire guided localisation procedure is estimated at £35 to £50. The cost of insertion of wire for localisation of breast lesion is £277 as an outpatient procedure or an elective procedure (NHS tariff 2019/20).

Resource consequences

Magseed is used in 42 NHS trusts. The main barrier to implementing a Magseed localisation procedure is the cost of the individual Magseed and the Sentimag probe. The company indicated that the cost of technology itself costs more compared with the standard wire guided procedure for breast cancer. But, it could be resource releasing if it improves efficiency in clinics (that is, clinic scheduling and capacity), and re-excision rates.

A service evaluation compared the cost of 226 traditional wire guided wide local excisions with the cost of 90 traditional guided wide local excisions plus 106 Magseed-guided excisions. The results suggested a saving of £34,457 with 48% fewer further operations after the introduction of Magseed (Lake et al. 2020). Using the technology in the NHS would not need any change to facilities or infrastructure. The company provides training and support for radiologists, surgeons and theatre staff. There are also online training videos that can be used. All training is free of charge.

Regulatory information

Magseed is a CE-marked class IIb medical device. The Magseed magnetic marker is intended and calibrated for use with the Sentimag device, which is CE-marked as a 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.

Breast cancer is more common in women, and the risk of breast cancer increases with older age. People with cancer are protected under the Equality Act (2010) from the point of diagnosis. Sex and age are also protected characteristics.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement for the production of medtech innovation briefings. 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 is a wider body of evidence for Magseed, however, 5 studies are summarised in this briefing, these are considered to be the best quality and most relevant to the NHS. Two studies are comparative evaluations of Magseed for lesion localisation (n=232) compared with standard wire guided procedures (n=264) (Micha et al. 2020; Zacharioudakis et al. 2019). The other 3 studies included 1 national audit (n=1,183) and 1 local audit (n=137) of Magseed in the UK.

A systematic review was identified in the search. The review included 16 studies on a total of 1,599 Magseed insertions. It found a successful placement rate of 94.4% and a successful localisation rate of 99.9% (Gera et al. 2020). But, the quality of the review was

low because the study did not report the characteristics of the included studies and there was no quality assessment of the individual studies. Therefore, it was not included in this briefing.

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

Overall assessment of the evidence

Five observational studies included 4 full text publications and 1 abstract. All studies except Singh et al. 2020 are UK studies, and the evidence is generalisable to clinical practice in the NHS. The sample sizes of 2 comparative studies are large, but Micha et al. (2020) is a single-centre study. There is possible selection bias of study populations in both studies because the assignment to localisation technique was made by a consultant (Zacharioudakis et al. 2019) and 2 study cohorts were not matched (Micha et al. 2020).

Dave et al. (2020)

Study size, design and location

A national prospective audit of 1,183 patients from 42 units who had breast localisation procedures in the UK.

Intervention and comparator

Magseed compared with wire guided localisation procedures.

Key outcomes

There were 62% of people who had invasive cancer, 18.9% who had ductal carcinoma in situ, 12.6% mixed; and 6.4% were classed as other. Localisation methods were 33.5% Magseed guided (n=396) and 66.5% were wire guided (n=787). Bilateral localisation procedures were done in only 1.4% of cases. Of the 78 people with multifocal lesions, 10 people had 2 Magseeds and 1 person had Magseed plus wire. The was no index lesion in the excision specimen in 8 cases, of which only 1 was a localisation failure. In people with invasive or non-invasive disease, the re-excision rate for Magseed was 12.1%, and for wire guided excision was 14.8% (p=0.406). There was no significant difference (p>0.1) in

all complications between the 2 localisation methods.

Strengths and limitations

The study was designed as an audit. Strengths and limitations were not assessed because limited information was reported in the abstract.

Micha et al. (2020)

Study size, design and location

A service evaluation comparing the standard practice of guide wires with Magseed for lesion localisation in people having surgery to remove impalpable disease at a single institution in the UK.

Intervention and comparator

Magseed (n=128) compared with wire guided localisation (n=168).

Key outcomes

The study included 2 consecutive cohorts of people who had wire guided localisation or Magseed. The accuracy of the wire and seed placement (within 5 mm of the lesion) was 96% and 98%, respectively. In 1 person who had the Magseed procedure, the marker was placed more than 10 mm from the lesion and a wire was then placed to mark the correct site. Surgical excision was 97% with a wire and 95% with Magseed. No complications were reported with the wire or the Magseed.

Radiology and surgical staff reported statistically greater satisfaction with the Magseed localisation compared with the wire procedure. People felt less anxious using Magseed compared with wire (p=0.009). There was no difference in pain associated with the localisation procedure.

Strengths and limitations

This is a single-centre study. There is selection bias because Magseed should only be used for bracketing lesions that are more than 2 cm apart. There is recall bias based on

self-reported data.

Singh et al. (2020)

Study size, design and location

A prospective, open-label, single-arm phase 4 study of 107 people who had Magseed-localised breast conserving surgery at a single institution in the US.

Intervention and comparator

Magseed localisation procedure. No comparator.

Key outcomes

A total of 124 Magseeds placed; 93 people had 1 Magseed placed, 11 people had 2 Magseeds placed, and 3 people had 3 Magseeds placed. Radiographic breast lesions localised with the Magseed included masses (63%), calcifications (24%), architectural distortion (7%), and other lesions such as asymmetry. All Magseeds were placed less than 10 mm from the target lesion with 95% within 5 mm. There was a 100% Magseed retrieval rate with surgical excision, with the Magseeds retrieved in the initial resected specimen in all cases including those with more than 1 seed placed. Of the 98 malignant breast lesions, 9 cases (9.2%) had positive margins and 7 had a second procedure for margin re-excision. There were no adverse events associated with Magseed.

Strengths and limitations

No patients were lost to follow up. This was an open-label single-arm study without a direct comparison with other breast localisation techniques. Patients were recruited from 1 institution.

Thekkinkattil et al. (2019)

Study size, design and location

A prospective, single-arm, multicentre clinical audit in the UK of 137 people who had Magseed localisation for breast surgery.

Intervention and comparator

Magseed was used in the intervention group. No comparator.

Key outcomes

A total of 137 people had Magseed localisation with a total of 139 seeds. There were 16 people who had a diagnostic procedure and 121 who had therapeutic surgery. Most seeds were placed under ultrasound guidance (n=112) and 25 lesions were targeted under stereo guidance. The re-excision rate was 14.8% (n=18). All these re-excisions were carried out for ductal carcinoma in situ with or without an invasive component.

Strengths and limitations

This is a single-arm study. There was potential selection bias because people were allocated for Magseed localisation depending on service convenience.

Zacharioudakis et al. (2019)

Study size, design and location

A multicentre prospective non-randomised control trial done in the UK of 200 people having Magseed localisation or wire guided localisation.

Intervention and comparator

Magseed localisation was used in the intervention group (n=104). The comparator was wire guided localisation (n=96).

Key outcomes

Magseed localisation was planned for 104 people. A total of 4 people had wire guided localisation instead, including 2 people who had Magseed deployed at a distance from the target lesion and placement of a second Magseed was not feasible. Also, there were 2 people whose Magseeds were not localised using the Sentimag. Intraoperative identification and excision of the localised lesion was successful in 100% of people in both groups. There were no significant differences in the proportion of people who needed re-excision between the 2 groups (16% in Magseed and 14% using wire guided localisation,

p=0.692). There was 1 person in the Magseed cohort who developed a haematoma after localisation and the seed was dislodged and contained within the haematoma. In a second patient with a lesion located next to the skin the Magseed was dislodged during dissection.

Strengths and limitations

This is non-randomised study, and there is potential selection bias in patient selection.

Sustainability benefits

The company noted that improved productivity was shown by uncoupling radiology and surgical departments on the day of surgery. There is no published evidence to support these claims.

Recent and ongoing studies

- An iBRA-net study group national audit of Magseed and wire localisation of breast lesions.
- Magseed enabled long-term localisation of axillary lymph nodes (MAGELLAN). ClinicalTrials.gov Identifier: NCT03796559. Status: recruiting. No interim results published. Indication: breast cancer with biopsy-proven axillary node metastases. Devices: Magseed marker. Last update: 24 July 2020.

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 or had used this technology before.

Level of innovation

All expert commentators considered the technology innovative compared with standard

care. The experts agreed that one of the main advantages of Magseed compared with the wire procedure was Magseed could be inserted before surgery, while wires had to be placed on the morning of surgery. The other advantage of Magseed compared with wire localisation was the optimal incision placement by improving the accuracy of the localisation with less extensive excision. The experts described alternative localisation procedures available to the NHS such as radioactive iodine seeds, Scout Radar (surgical guidance system) and radio nucleotide occult lesion local excision (ROLL) localisation. They noted that these technologies all have pros and cons; for instance, the ease of use, the length of time that the markers can be kept in situ, and the cost.

Potential patient impact

The most important benefit identified by the experts was the flexibility of inserting the Magseed any time before the operation, allowing people to maintain their daily lives leading up to their surgery. Two experts thought that the Magseed procedure could improve patient experience, because patients were unlikely to experience pain and potentially reduce the feeling of anxiety before surgery. The experts suggested that people with impalpable breast cancer were most likely to benefit from the technology.

Potential system impact

The experts agreed that the cost of Magseed localisation is likely to be more expensive compared with the wire procedure. But, the potential benefits for the healthcare system were better use of radiology services, theatre time and reduced need for further surgery. Magseed could potentially free up breast radiological staff time and re-excision rates may decrease over time.

General comments

The experts thought Magseed could replace majority wire procedures. Two experts noted that Magseed may not be suitable for people with lesions deeper than 3 cm or people with multiple lesions. None of the experts were aware of any safety issues. One expert noted that when removing Magseed, the excision could be too close to the lesion, and there might be interference locating the seeds if metallic objects were near to the breast. The expert was aware that a few cases of displacements were reported. The main barrier to adoption identified by 2 experts was the technology cost. Little change to facilities or infrastructure would be needed, but training is needed to perform the technique and to

identify the seeds.

Expert commentators

The following clinicians contributed to this briefing:

- Nicola Barnes, consultant oncoplastic breast surgeon, Manchester University NHS Foundation Trust, a member of steering group for the iBRA NET localisation study.
- Christopher Holcombe, consultant breast surgeon, Royal Liverpool University Hospital, co-author of Dave et al. (2020).
- Sankaran Narayanan, consultant oncoplastic breast surgeon, University Hospitals of North Midlands, did not declare any interest.
- Paul Thiruchelvam, consultant breast and reconstructive surgeon and senior clinical lecturer, Imperial College NHS Trust, providing consultancy for stryker endoscopy.

Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-3908-4