For immediate release

PRESS RELEASE

NICE recommends controlled use of targeted breast cancer radiotherapy treatment alongside further research

The National Institute for Health and Care Excellence (NICE) has today published draft guidance recommending the Intrabeam Radiotherapy System (Carl Zeiss UK) for people with early breast cancer[1] for controlled use with the collection of further data on its effectiveness.

The committee was aware that it is not certain whether this technology – a type of targeted radiotherapy – is as effective as conventional radiotherapy in preventing the recurrence of the disease. However, the committee heard the risk of local recurrence is low in the patients who would receive Intrabeam and they heard that people may be prepared to accept a level of uncertainty in order to avoid having to have radiotherapy after their surgery.

For this reason, the committee has also recommended that patients are provided with information on the treatment options available, including their associated risks and benefits so that they can make an informed choice about their treatment.

With Intrabeam only one 30 minute dose is required and is given at the same time as surgery to remove the tumour, eliminating the need for multiple hospital visits for most patients. The committee heard from the patient expert that this would be considered a major advantage by some patients and might outweigh the fact that much less is known about the long term outcomes of Intrabeam treatment compared with conventional radiotherapy.

Regular radiotherapy typically requires numerous doses over a 3 week period and is performed weeks after surgery when the wounds have healed.

Some patients, who are found to have a higher risk of recurrence, might still need to have conventional radiotherapy after they have had Intrabeam.

The Committee also heard that Intrabeam was associated with better cosmetic outcomes and that the side effects of conventional radiotherapy such as local tenderness, breast pain, swelling, reduced range of movement or change in breast appearance and texture were avoided or reduced with Intrabeam. The patient expert highlighted that cosmetic outcomes can have a big effect on patients' quality of life.

The committee was aware that the clinical trials for Intrabeam had been conducted in some centres in the UK and that some machines are already available. Each machine costs £435,000 to buy and £35,000 a year to maintain, so the committee was keen to emphasise the importance of using the existing machines as effectively

as possible.

Over 50,000 women and around 340 men are diagnosed with breast cancer each year in the UK[2]. Figures suggest that about 86% of them – 43,300 people each year[3] - will potentially have early breast cancer.

Professor Carole Longson MBE, director of the centre for health technology evaluation at NICE, said: "This is a promising new way of providing radiotherapy but the evidence needs to develop and the committee therefore recommended that its use is carefully controlled and accompanied by gathering additional information on its clinical effectiveness."

Consultees, including the company, healthcare professionals and members of the public are able to comment on the draft recommendations via the NICE website until 1 March 2017.

Ends

For more information call Phil Ranson at the NICE press office on 0300 323 0142 or out of hours on 07500 605228.

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Notes to Editors

References

1. Early stage breast cancer is when the tumour is confined to the breast area and has not spread beyond the lymph nodes to other parts of the body.
2 These figures have been taken from Cancer Research UK's website and were calculated from data provided by the Office for National Statistics, the Northern Ireland Cancer Registry, Welsh Cancer Intelligence and Surveillance Unit and ISD Scotland. More information can be found at: http://www.cancerresearchuk.org/cancer-info/cancerstats/types/breast/incidence/.
3 Lyratzopoulos G, Abel GA, Barbiere JM, et al. Variation in advanced stage at diagnosis of lung and female breast cancer in an English region 2006-2009. Br J Cancer 2012. 106(6):1068-75:http://www.ncbi.nlm.nih.gov/pubmed/22382691.

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Br J Cancer. 2012 Mar 13;106(6):1068-75. doi: 10.1038/bjc.2012.30. Epub 2012 Mar 1. Research Support, Non-U.S. Gov't

About the draft guidance on Intrabeam Radiotherapy System

1. The draft guidance on Intrabeam will be available on the NICE website from Wednesday, 8 February.
2. The draft guidance recommends Intrabeam Radiotherapy System:

• using machines that are already available

• with managed evidence collection developing a national data set of all patients with early invasive breast cancer having adjuvant treatment with the Intrabeam radiotherapy system in the NHS. This should include data on:

o histology of the cancer and patients' characteristics (including type, size, side of tumour, grade, lymph node status, oestrogen receptor status, progesterone receptor status, human epidermal growth factor receptor 2 status and age of the patient)

o local recurrence

o treatment after local recurrence

o metastatic disease

o disease-free survival

o overall survival

o adverse effects of treatment

o health-related quality of life (including ED-5D)

• providing information to patients to aid shared decision making that informs the patient of the evidence available on the range of treatment options available and their associated risks and benefits.

About Intrabeam Radiotherapy System

1. Intrabeam is a locally applied treatment. It is given to people with breast cancer during the surgery to remove their tumour. Unlike conventional radiotherapy, it only targets the breast tissue close to the tumour, leaving other tissue alone, and people will only require one dose.
2. Intrabeam was granted a CE (Conformité Européene) mark in 1999 for use in radiotherapy.

3. Intrabeam can be used as an intraoperative radiotherapy system given as the sole treatment or as a boost treatment followed by conventional external beam radiotherapy (EBRT). When intraoperative radiotherapy is given as a boost treatment with Intrabeam and followed by EBRT, there is no need for further external boost treatment.
4. Six NHS centres in the UK have used Intrabeam for adjuvant treatment of early breast cancer.

Issued By: Phil Ranson – Media Relations Manager Tel: 020 7045 2173 Press office: 0300 323 0142 Email: philip.ranson@nice.org.uk

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07 February 2017