INAHTA Briefs

Issue 2010/038

Title **Multi-Centre Randomized Controlled Trial Examining the Cost-Effectiveness of Contrast-Enhanced High Field Magnetic Resonance Imaging in Women Scheduled for Wide Local Excision (COMICE)**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

Reference Volume 14.01. ISSN 1366-5278. www.hta.ac.uk/project/1216.asp

Aim

To determine if adding magnetic resonance (MR) imaging of the breast to current patient evaluation by triple assessment (clinical, radiological [x-ray mammography and breast ultrasound] and pathological [fine needle aspiration cytology/core biopsy]) would; a) help localize tumors in the breast and reduce the reoperation rate in women with primary tumors scheduled for wide local excision (WLE) and b) be economically worthwhile from the perspective of the NHS.

Conclusions and results

In total, 1623 patients were randomized between Dec 2001 and Jan 2007 (816 MR imaging, 807 no MR imaging). No differences in reoperation rates were found between the two groups of patients (MR imaging patients 18.75%, no MR imaging patients 19.33%, difference=0.58%, 95% confidence interval (CI) [-3.24%, 4.40%]). Adding MR imaging to conventional triple assessment alone was not found to be statistically significantly associated with reduced reoperation (odds ratio=0.96, 95% CI=[0.75, 1.24], p=0.7691). Sixteen patients in the MR imaging arm (2.0%) underwent a pathologically avoidable mastectomy at initial surgery, as did two patients in the no MR imaging arm (0.2%) that received an MR scan.

Overall, the best agreement between all imaging modalities and histopathology, with respect to tumor size and extent of disease, was found in patients who were over 50 years of age, had ductal tumors NST, and were node negative. Considering the effectiveness of imaging, the sensitivity and positive predictive values of MR imaging (as regards determining patient management) were 50.0% (95% CI [42.65, 57.35]) and 61.8% (95% CI [53.87, 69.74]) respectively. In the MR imaging arm, of the 58 patients undergoing a mastectomy 16 (27.6%) were classed as being pathologically avoidable. Weighted kappa statistics ranged from 0.3803 for ultrasound to 0.4767 for MR imaging, when assessing agreement between imaging methods and pathology. No significant differences were identified between the groups in the proportion of patients receiving chemotherapy, radiotherapy, or additional adjuvant therapies (p=0.3699, p=0.7439, p=0.5591). None of the 25 patients with MR-only detected <5mm lesions had a clinically significant lesion evident at their 12-month repeat MR scan. Of the 66 patients with MR-only detected ≥5mm biopsy negative lesions, only 3 had potentially clinically significant lesions at their 12-month repeat MR scan (based on overall lesion score as these lesions were not biopsied). Kaplan Meier estimates of the local recurrence-free interval rate were 99.87% (95% CI [99.05%, 99.98%]) for patients randomized to MR imaging, compared to 99.73% (95% CI [98.93%, 99.93%]) for patients randomized to no MR imaging. We found no differences in QoL between the two groups of patients (measured by FACT-B). It proved possible to develop a reliable and acceptable nonscheduled standardized interview (NSSI) for use in this patient population. Satisfaction and reassurance levels were high in patients randomized to receive MR imaging, despite reported levels of distress secondary to the procedure.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1216.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1216.asp.

Further research/reviews required

The introduction of 3T MR systems offers significant improvements in signal-to-noise and fat suppression compared to 1.5T systems. See Executive Summary link at www.hta.ac.uk/project/1216.asp.

Written by Professor Lindsay Wilson Turnbull, NETSCC, United Kingdom

ISSN 1654-501X