

Intraoperative ultrasound for palpable breast cancer: the way forward?

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Breast conserving surgery (BCS) followed by radiotherapy for breast cancer is equivalent to mastectomy in terms of overall survival as is evident from Randomised Controlled Trials with long term follow up (1-3). BCS is particularly relevant to the management of breast cancer today as an increasing proportion of breast cancers are diagnosed with a size of 20 mm or less, mainly due to increased breast awareness and widespread uptake of screening mammography. With increasing acceptance, the indications to BCS have expanded in recent years; effective use of neo-adjuvant therapy to shrink the size of cancer (>3 cm) has made it an established practice to consider BCS for women with larger breast cancers.

The mainstay of conservative surgical treatment of breast cancer is to achieve a clear circumferential margin around the tumour with preservation of the cosmetic appearance of the treated breast. It is recognised that re-excision for positive margins after BCS may impact on cosmetic appearance. Thus, the success of breast conserving surgery depends upon achieving clear pathological margins in one operation with minimum volume loss. Multidisciplinary breast care teams aim to map the exact location and true extent of tumour within a breast by enhanced pre-operative imaging such as MRI and high resolution ultrasound scan, in order to facilitate adequate excision margins (4). However, it is ironic that despite all the progress in the management of breast cancer, there seem to be a complete non-uniformity in the definition of an acceptable excision margin after BCS. The definition of an adequate margin varies from unit to unit. Recently, an analysis of data from a breast cancer treatment quality assurance project confirmed that the lowest rate of local recurrence was associated with a clear excision margin of 2 mm or more (5).

Cosmetic preservation is closely related to the volume

of breast tissue excised at the time of cancer surgery. Surgeons have been proactive in researching and enhancing the surgical techniques of BCS employing a two prong approach. Firstly, the volume of normal breast tissue excised at the time of BCS is minimised by centralising the tumour in the surgical specimen and in cases where a larger excision volume is necessary for oncological reasons, volume displacement and replacement techniques are utilised to enhance the cosmetic outcome. Therefore, surgeons should be credited for making significant advances in surgical techniques to improve the cosmetic appearance. Surgical techniques have evolved from quadrantectomy (large volume resection) to complete targeted excision of the cancer (minimal volume resection). Secondly, surgeons have continually used ways to decrease the rate of re-excision such as intra-operative specimen radiograph, cavity shaves, frozen section assessment of the margins and therapeutic mammoplasty.

The treatment of local recurrence of breast cancer with surgery (largely mastectomy) and adjuvant treatment incurs significant personal and economic cost. In the current financial climate, most Healthcare systems are aware of the increasing cost and are eager to manage or even reduce the cost of delivery of health care. Therefore, the challenge faced by the Breast multidisciplinary team is to keep the cost of breast cancer treatment contained by achieving the goals of cosmetic preservation, complete excision of the tumour while limiting the volume loss of the normal breast tissue and minimising local recurrence by maintaining the lowest possible positive margin rate.

The achievement of these goals can be facilitated by the use of intra-operative ultrasound as reported in the Intraoperative ultrasound guidance for palpable cancer excision (6); a multicentre, randomised controlled trial. The

COBALT trial is a well-executed randomised controlled trial that demonstrated intra-operative ultrasound imaging to be effective in decreasing the positive margin rate after BCS (28% *vs.* 11%) in patients with palpable breast cancer. A reduction in the volume of resected breast tissue during BCS was achieved in this trial of 134 randomised patients (57 *vs.* 38 cm³). This enhanced surgical accuracy can improve the cosmetic outcome of the treated breast, which is shown to be directly proportional to the amount of breast tissue excised. The specimen weight can be regarded as a surrogate marker of enhanced cosmetic preservation. The economic analyses of the study demonstrated an effective cost saving of €195 per procedure (7).

This trial is in concordance with a non-randomised study of 381 patients, which reported a positive margin rate of 9.5% in patients undergoing US-guided BCS; the authors concluded that US is an effective modality for intraoperative tumour localization and can thus help obtain clear margins and reduce the re-excision rate in cases in which breast-conserving therapy has been performed (8).

However, in a given surgical practice there are variations in the degree of palpability of the tumour and the above studies do not differentiate between easily palpable and barely palpable breast cancers.

From the perspective of breast surgeons, intraoperative ultrasound scan could potentially be an attractive adjunct to the surgical armamentaria. The use of ultrasound during the excision of tumour can potentially lower positive margin after BCS and hence can lower re-excision rate, can enhance cosmetic outcome and can provide an overall positive patient experience. The theory is good; however the question is whether the evidence regarding the use of intra-operative ultrasound is sufficiently robust and compelling to bring about a change in clinical practice at this stage.

In order to adopt, intra-operative ultrasound scan as standard care for BCS, multidisciplinary teams will face challenges on many fronts. The training of operating surgeons would require significant investment of resources and time. Unless the effectiveness of intraoperative ultrasound in enhancing patient care can be demonstrated categorically, it will be challenging to persuade managers and surgeons alike to invest time and effort to get trained and acquire the appropriate skills in ultrasonography. In the UK there is a shortage of breast radiologists which means that training surgeons will at the very least be very challenging. It is encouraging to see that economic analysis has been carried out demonstrating the cost effectiveness of intra-operative ultrasound scan, however a downside would

be additional theatre time. This may impact on the number of cases that can be performed during any given operating session and hence the true cost savings may not be as great as originally suggested. The use of intraoperative ultrasound scan to carry out breast conserving surgery may also pose administrative challenges in managing the operating and ultrasound lists.

If intraoperative ultrasound scan was to be adopted as the standard of care in the UK, this will create some organisational challenges. The organisations that maintain information about a surgeon's activity such as NHSBSP and BCCOM may need to modify their data capture forms in order to ensure accurate data collection regarding the use of intraoperative ultrasound scan.

Having acknowledged all the challenges that may pose difficulty in adopting intraoperative ultrasound scan as standard of care for BCS, it is imperative that such a development should be welcomed albeit cautiously. When more evidence accumulates to support the effectiveness of intra-operative ultrasound to enhance patient experience, then some of the challenges regarding training, equipment and personnel may prove worthwhile. The use of intraoperative ultrasound scan to minimise the excision of normal breast tissue is a significant development from the Halstead mastectomy. The effective use and success of intraoperative ultrasound scan can reduce the number of women needing further surgery, radiotherapy boost and in some cases mastectomy after attempted BCS. Thus BCS with the use of intraoperative ultrasound scan may prove to be another step in the right direction of improving patient care, treatment and experience.

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