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Overview

Current Controversies in Breast Cancer Surgery

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Abstract

Contemporary management of the axilla in breast cancer surgery remains in evolution. Axillary lymph node status in breast cancer is a major prognostic factor and remains integral to guiding adjuvant treatment decisions. There remains controversy regarding the management of the node-positive axilla in clinically node-negative primary breast cancer. Trials to date have suggested re-evaluation of the historical therapeutic strategy that a positive sentinel node requires axillary node dissection. However, further evidence is required before modern clinical management of the axilla should be altered. As patient awareness and technical expertise grow, national rates of breast reconstruction after mastectomy continue to rise. Oncoplastic techniques continue to evolve and many patients are suitable for a plethora of reconstructive options. Despite the widespread practice of breast reconstruction globally, there is limited randomised evidence comparing the optimal type and/or timing of breast reconstruction on which to base practice. Breast reconstruction type is either purely autologous, implant-based or a combination of these two techniques. We explore the benefits and limitations of these techniques and some of the key findings of the National Mastectomy and Breast Reconstruction Audit. The timing of reconstruction after mastectomy is either immediate (a single procedure) or delayed (for an indefinite period after mastectomy). The ideal reconstruction is one that is best aligned to the patient's expectations, as this will achieve the highest levels of long-term patient satisfaction. Selecting the optimal type of breast reconstruction at the right time for the right patient remains the key challenge in breast reconstruction.

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Key words: Autologous; axilla; implant; radiotherapy; reconstruction; sentinel node biopsy

Statement of Search Strategies Used and Sources of Information

This overview is based on a detailed review of international peer-reviewed literature found using PubMed. In addition, the reference lists from previous extensive review articles were reviewed to obtain other pertinent articles.

Introduction

Contemporary management of the axilla in breast cancer surgery remains in evolution. Axillary lymph node status in breast cancer is a major prognostic factor and remains integral to guiding adjuvant treatment decisions [1].

Axillary surgery also provides locoregional control of the disease, yet incurs morbidity to the patient, particularly lymphoedema, shoulder stiffness and skin numbness. The most controversial topic is the optimal management of the clinically or radiologically node-negative axilla in primary breast cancer that is proven to contain metastatic disease after axillary sentinel node biopsy (SNB). Traditional management would advise completion axillary clearance, although recent evidence challenges this ethos. The key controversies are selecting those patients who will (or will not) benefit from further axillary treatment and if further treatment is deemed necessary, should this be completion axillary lymph node dissection (ALND) or axillary radiotherapy (ART)?

As patient awareness and rates of breast reconstruction after mastectomy continue to rise, oncoplastic techniques continue to evolve and many patients are suitable for a plethora of reconstructive options. Despite the widespread practice of breast reconstruction globally, there is

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limited randomised evidence comparing the optimal type and/or timing of breast reconstruction on which to base practice. In the broadest sense, breast reconstruction type is either purely autologous, implant-based or a combination of these two techniques. The timing of reconstruction after mastectomy is either immediate (a single procedure) or delayed (for an indefinite period). The ideal breast reconstruction should look, feel and age naturally with the patient. It should achieve good symmetry both for size and contour, ideally without contralateral surgery. The techniques should be safe, reproducible, carry minimal morbidity and be cost-effective. The ideal reconstruction is one that is best aligned to the patient's expectations, as this will achieve the highest levels of long-term patient satisfaction. Selecting the optimal type of breast reconstruction at the right time for the right patient remains the key challenge in breast reconstruction.

Do All Patients with Positive Nodes Need Axillary Clearance?

Axillary SNB is now regarded as the standard of care to stage the clinically node-negative axilla [2]. Dual localisation SNB using blue dye and radioactive isotope offers highly accurate and technically reproducible 'targeted sampling' of the axilla. Several randomised controlled trials have confirmed accuracy rates of over 95%, removing a median of two nodes with false-negative rates of under 10% [3–7]. It is important to note that this false-negative rate exceeds the rate of axillary recurrence. For instance, NSABP B-04 showed that not all axillary metastases lead to recurrence, even when adjuvant systemic treatment was not given [8]. After 8 and 10 years of follow-up, respectively, NSABP B-32 [3] and Veronesi *et al.* [9] showed axillary recurrence rates of just 0.7 and 0.8% and overall survival rates of 90.3 and 93.5% in those with a negative SNB. SNB incurs significantly less morbidity than ALND in terms of lymphoedema, shoulder stiffness and skin numbness [3,6,7,10].

However, there is much debate regarding the significance of a positive SNB and the optimal method of managing that axilla. Axillary metastases are defined according to size as isolated tumour cells (staged as pN0 [i+], with deposits ≤ 0.2 mm), micrometastases (staged as pN1mi, with deposits >0.2 to ≤ 2.0 mm) and macrometastases (>2 mm). An SNB with isolated tumour cells is regarded as node negative and many centres recommend no further treatment. In the Dutch cohort study, MIRROR, patients who were found to have isolated tumour cells by SNB who did not subsequently undergo completion ALND ($n = 732$) had similar rates of axillary recurrence to patients ($n = 125$) who did undergo completion ALND (2.3% versus 1.6%), after 5 years of follow-up [11].

The recent ACOSOG Z0011 trial has raised the intriguing prospect that ALND may not be necessary, despite a positive SNB with macrometastases [4]. This trial randomised T1–2, clinically N0 patients who had one or two positive (micro- and macrometastatic) SNB on haematoxylin and eosin stain

to either completion ALND ($n = 445$) or no further axillary treatment ($n = 446$). No patients underwent radiological assessment of the axilla before SNB. All patients underwent wide local excision, whole breast irradiation and over 95% of patients in each arm received chemotherapy and/or endocrine therapy. At a median 6.3 year follow-up, only 0.9% of the SNB-alone group developed axillary recurrence. Interestingly, ALND did not obviate the risk of axillary recurrence entirely (0.5%), although the level of ALND carried out remained undefined [4].

In patients with clinically node-negative disease, Albertini *et al.* [12] showed that the sentinel node is the only involved node in 67% of patients undergoing SNB. ACOSOG Z0011 demonstrated that 27.4% of patients undergoing completion ALND had metastatic disease in non-sentinel nodes, but only 0.9% developed axillary recurrence in the SNB-alone arm at 6.3 years [4]. This discrepancy is thought to be due to the cumulative effects of systemic adjuvant therapy and possibly tangential whole breast irradiation, which, in aiming to treat the axillary tail of the breast, may irradiate much of the axilla. The ACOSOG Z0011 trial ultimately showed no difference in axillary recurrence or survival with SNB alone and concluded that 'routine use of ALND is not justified' in clinically N0 patients undergoing breast-conserving treatment with only one or two positive SNB, with no demonstrable survival advantage in this group [13]. Although the follow-up period of ACOSOG Z0011 (median 6.3 years) is relatively short, NSABP B-04 showed that axillary recurrence is typically an early event at a median of 14.8 months postoperatively with only seven of 68 axillary recurrences occurring after 5 years [8].

However, the findings of ACOSOG Z0011 and their relevance to UK practice have resulted in international debate among breast clinicians [4]. Proponents believe this to be a 'practice-changing' study, which has widely influenced the standard of care in some parts of the USA. However, the UK response to ACOSOG Z0011 has generally been more conservative. Although there is recognition that we may indeed be over-treating some node-positive axillae, there is caution in how to interpret the findings of this trial. ACOSOG Z0011 had several limitations, including a low accrual rate. Only 891 of a targeted 1900 patients were randomised, although the results reached statistical significance. Furthermore, patients undergoing mastectomy were excluded, preoperative axillary ultrasound was not carried out, the SNB procedure was not standardised, 70% of patients had T1 cancer, there were high rates of systemic treatment and locoregional recurrence was not a pre-determined end point.

A further study, IBCSG 23-01, randomised 931 women with clinically node-negative breast cancer and micrometastases in a sentinel node or nodes, to completion ALND or no ALND [14]. Most patients (85%) had only one or two positive sentinel nodes. Most (67%) had metastases less than 1.0 mm, and none had metastases greater than 2 mm. The 5 year overall survival rate was 97.6% for ALND and 98% for no ALND ($P = 0.35$), supporting the findings of ACOSOG Z0011 [4]. Axillary recurrence in the SNB-alone arm was only 1% at 5 years.

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