Reconstructive utilisation and outcomes following mastectomy surgery in women with breast cancer treated in England

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ABSTRACT

INTRODUCTION Breast cancer usually necessitates breast-conserving surgery or mastectomy, which adversely affect appearance and wellbeing. Immediate reconstruction restores the breast mound but its availability and efficacy are uncertain.

MATERIALS AND METHODS Two discrete datasets were used to evaluate mastectomies in England: Hospital Episode Statistics to measure overall activity and variation over time and by region and a national prospective audit to evaluate immediate reconstruction decision making, complication rates and patient-reported satisfaction with information, choice and outcomes.

RESULTS The 2005–08 Hospital Episode Statistics analyses identified 20% breast-conserving surgery reoperation rates nationally, frequently involving mastectomy. Rates were higher with in-situ disease present (30% vs 18%) and varied across NHS trusts (10th–90th centiles 12–30%). The 2008–09 national audit examined 18,216 women. The 19% immediate reconstruction rate varied regionally (9–43%), as did 2006–09 Hospital Episode Statistics data (8–32%). A total of 48% of women were offered immediate reconstruction, again varying regionally (24–75%). Offer likelihood fell with increasing age. National immediate reconstruction rates increased from 10% to 23% from 2000 to 2014, but regional variation persisted. Despite high care satisfaction, just 65% of mastectomy patients received the right amount of reconstructive information (90% for immediate reconstruction). Women from deprived areas experienced higher complication rates. Flap-based immediate reconstruction led to greater satisfaction with breast area appearance, emotional and sexual wellbeing and overall outcome than mastectomy; implant-only immediate reconstruction scored no better.

CONCLUSION Reconstruction is central to improving breast cancer outcomes. The differential outcomes and persistent regional inequalities identified should facilitate decision making, support improved access to all reconstructive options and inform the development of an optimal patient pathway.

KEYWORDS

Breast neoplasms – Mastectomy – Breast reconstruction – Patient satisfaction – Outcomes

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Introduction

In 2016, 45,656 women were diagnosed with breast cancer in England.¹ Most women require surgery to remove part (breast-conserving surgery) or all (mastectomy) of the affected breast, which can impact on their appearance and their physical, emotional and sexual wellbeing.

Reconstruction to restore the shape and appearance of the breast mound can be undertaken using a wide range of techniques, either at the time of the mastectomy (immediate reconstruction) or later (delayed reconstruction).

While breast reconstruction may not be deemed appropriate for certain patients (eg those with other health

problems), women should not be prevented from undergoing breast reconstruction if their hospital does not provide their preferred technique. The relevant National Institute for Health and Care Excellence (NICE) guidelines state that ‘all appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are all available locally’.²

Two discrete datasets were used to evaluate mastectomy and immediate reconstruction in England, to formally test hypotheses related to reconstructive access and the outcomes of mastectomy surgery and to define the optimal patient pathway.

Materials and methods

Patient populations and statistical analyses

The national Hospital Episode Statistics (HES) database, incorporating all English NHS hospital admissions, was used to quantify surgical practice and identify both geographical variation and longitudinal trends. A national prospective cohort study of mastectomy and breast reconstruction was designed and implemented to evaluate immediate reconstruction offers and uptake across English cancer networks, complication rates and patient-reported satisfaction with information provision, reconstructive choice and quality of life outcomes – items that could not be evaluated using HES.

Patients were identified within HES based on relevant diagnostic (International Classification of Diseases, 10th revision) and procedural (OPCS-4) codes within the complete and anonymised extract held within our research unit. Further data were collected purposefully from clinicians and patients through the national prospective audit. Data collected on mastectomy and reconstruction patients from these disparate sources was cleaned robustly, with all analyses and statistical tests undertaken using Microsoft Excel and STATA statistical software.

Multivariable logistic and linear regression models were used to examine the relationship between discrete and continuous outcome variables and relevant patient characteristics, tumour type and procedure undergone. These models were then used to compare observed treatment patterns across the treating hospital or network, with formal hypothesis testing undertaken where appropriate.

Clinical outcomes

Mastectomy and breast reconstruction procedures are comparatively safe. However, short-term minor complications related to the removal of breast tissue, the transfer of reconstructive tissue away from a donor site and the reconstructive procedure itself are relatively common. Data were collected on those complications that were serious or required therapeutic intervention and that arose during the initial admission or after discharge. These data were analysed nationally and at the hospital provider level, stratified by procedure type and timing.

Patient-reported outcomes and experience of care

Patients can provide a valid and reliable perspective with respect to their experience and outcomes. Patients' care experience is a key dimension of healthcare quality, alongside safety and clinical effectiveness, and this was evaluated through follow-up questionnaires.

This work also investigated how women's quality of life (including breast area appearance, emotional, physical and sexual wellbeing and satisfaction with outcomes) was affected by mastectomy surgery.

Geographical analyses

In England, breast cancer services were previously organised and provided within regional cancer networks that have recently been replaced by cancer alliances based on the new sustainability and transformation plans. Networks

covered a geographically discrete area and included all NHS hospital trusts that provided mastectomy and reconstruction procedures. Patients were referred to other hospital trusts within these networks to access reconstructive procedures that were not available locally. Networks therefore constituted the most appropriate organisational framework on which to base analyses of reconstructive practices at the time of this work.

Results

Breast-conserving surgery

Breast-conserving surgery is the predominant surgical treatment modality for women diagnosed with breast cancer and when it is provided together with adjuvant radiotherapy is as effective as mastectomy. However, mastectomy is still required where conservation is not technically possible or where it has failed to achieve adequate clearance. Owing to the link between breast-conserving surgery and mastectomy use, preliminary work was undertaken to examine breast-conserving surgery practice and help interpret mastectomy and immediate reconstruction rates.

HES analyses were undertaken using data on 55,297 women treated within the NHS in England from 2005 to 2008.³ These revealed 20% failure rates nationally, rising to 30% if an in-situ carcinoma component was present. Of these women whose breast-conserving surgery procedure failed, 40% went on to have a completion mastectomy. Substantial variation was identified across NHS hospital trusts, with reoperation rates varying from 12–30% from the 10th to the 90th centiles. This variation suggests continuing issues with the selection criteria for breast-conserving surgery and variation in the thresholds for reoperation. Women who went on to have a mastectomy following failed breast-conserving surgery were more likely to undergo immediate reconstruction, highlighting the role of this underlying failure rate in reconstructive decision making.

Reconstructive utilisation

HES analyses undertaken on 44,837 women who underwent mastectomy from 2006 to 2009 identified significant variation in immediate reconstruction rates across English cancer networks (national rate 17%, network range 8–32%).⁴ The variation persisted following adjustment for patient casemix. However, HES data could not be used to evaluate to what extent this variation represented clinicians' thresholds for making an immediate reconstruction offer rather than patients' thresholds for accepting it.

Regional variation in immediate reconstruction offer and uptake was therefore examined through a national prospective cohort study of 18,216 women.⁵ Clinicians provided specific information on whether they made an offer to each patient enrolled and this information was examined in relation to patient age, fitness for surgery, tumour characteristics, anticipated need for adjuvant therapies and cancer network of treatment. Regional variation was again identified in immediate reconstruction offer and uptake rates and immediate reconstruction rates which persisted

after casemix adjustment. The 19% national immediate reconstruction rate varied by network (9–43%), while just 48% of mastectomy patients were offered immediate reconstruction, again varying regionally (24–75%). There was little correlation between immediate reconstruction offer and uptake rates across networks, with great variation in uptake for a given offer rate, suggesting either intrinsic differences between regional patient populations and their views of immediate reconstruction or differing clinician approaches to providing immediate reconstruction information and offers.

As part of this work, the appropriateness of clinician decision making was examined nationally to see to what extent different patient characteristics acted as inappropriate or appropriate predictors of an immediate reconstruction offer being made.⁶ In general, women who were more fit for surgery and had lower tumour burdens were more likely to receive an offer. However, increasing patient age reduced the likelihood of an immediate reconstruction offer beyond that which could be expected based on operative fitness or tumour burden, suggesting inappropriate reconstructive decision making based on a conscious or unconscious bias among clinicians.

Complication rates

Inpatient complication rates were evaluated nationally and at NHS trust and independent hospital level as part of the national audit.⁵ Casemix adjusted complication and adverse event rates were examined with funnel plots using standard 99.8% confidence intervals (CI). Few outliers were found, but those that were identified underwent further investigation and review through a formal quality assurance process organised by the Association of Breast Surgery, British Association of Plastic, Reconstruction and Aesthetic Surgeons and The Royal College of Surgeons of England.

Numerous patient factors were found to be independently associated with higher rates of inpatient complications, as would be expected.⁷ However, after adjusting for all these factors in a multivariable logistic regression model, increased socioeconomic deprivation was found to be independently predictive of complications, despite treatment within a national health service free at the point of use.

Patient experience

Overall, 90% of patients rated their care as excellent or very good and 85% felt that they were always treated with respect and dignity, far higher proportions than in the NHS inpatient survey.⁵ However, just 65% of mastectomy patients reported receiving the right amount of reconstructive information compared with 90% of reconstruction patients.

Quality of life outcomes

Data from the national prospective cohort study was used to evaluate the association between procedure type and subsequent quality of life outcomes reported by patients at 18 months.⁸ Flap-based reconstruction was found to be

associated with higher scores for breast area appearance, emotional wellbeing, sexual wellbeing and satisfaction with outcomes (all *P*-values less than 0.001). No significant differences in physical wellbeing were identified across patient groups. Notably, implant-only reconstruction resulted in quality of life scores no better than mastectomy alone, in both the immediate and delayed settings.

Complications and quality of life outcomes were examined to identify any long-term effects of experiencing one or more complications.⁹ The overall complication rate was 10% in the national cohort study. The incidence of one or more complications was associated with little or no impairment in women undergoing mastectomy or delayed reconstruction, but quality of life outcome scores following flap-related immediate reconstruction complications fell significantly. The adjusted mean reduction in scores following immediate reconstruction flap complications was 24 (95% CI –31 to –17) for breast area appearance and 14 (95% CI –22 to –6) for emotional wellbeing. Implant-related complications were not associated with worse quality of life outcomes, but this may have been partly due to the similar outcome scores attained following implant-only reconstruction in comparison with mastectomy alone.

The national study also enabled us to look at a specific aspect of flap-based reconstruction; namely morbidity associated with the latissimus dorsi flap donor site.¹⁰ New latissimus dorsi flap donor site scales for the Breast-Q were piloted and validated during the audit. Initial psychometric testing confirmed their reliability and validity. Patients reported higher levels of aesthetic and functional bother with autologous latissimus dorsi reconstruction in comparison to latissimus dorsi flap and implant reconstruction, suggesting that the additional tissue harvest required for the former adversely affected the donor site.

Longitudinal trends

Prophylactic and contralateral risk-reducing surgery trends were evaluated using HES.¹¹ The number of women without breast cancer undergoing bilateral mastectomies within the NHS in England increased from 71 in 2002 to 255 in 2011. The proportion of women with breast cancer undergoing bilateral mastectomies increased from 2.0% in 2002 to 3.1% in 2011. Immediate reconstruction rates for these patient groups increased from 59.2% to 90.6% over this period, reflecting improved access.

A final piece of work was undertaken using HES to examine the impact of the national audit on clinical practice and to look for evidence of the Hawthorne effect.¹² Longitudinal HES analyses were undertaken on 167,343 mastectomy patients treated between 2000 and 2014. The national immediate reconstruction rate remained stable at 10% until 2005, but then increased to 25.3% by 2013–14. It is unclear to what extent the audit led to this, and to what extent this longitudinal trend was continuing and persisted throughout the audit. Overall cancer network-level variation in immediate reconstruction rates persisted over this period, although the changes within individual networks were not uniform, with great variation in the extent and

direction of immediate reconstruction rate changes at the network level.

Discussion

This body of work has facilitated the process of defining an optimal and evidence-based patient pathway for breast cancer patients. Women need to be provided with optimal reconstructive information rapidly and ideally at the time of diagnosis or shortly after. Neoadjuvant therapies should be considered in those for whom it may be appropriate, to minimise delays and to provide decision-making time. The primary surgery undertaken should be uncomplicated, effective and enduring, whether in the form of successful breast-conserving surgery or mastectomy with immediate reconstruction using a flap. Adjuvant therapies should be provided with minimal delays and with increased immediate reconstruction use, secondary surgery should be both less extensive and undertaken promptly and effectively.

There are numerous barriers to achieving this goal. In England, breast and plastic surgeons are moving towards implant-only reconstruction (with or without acellular dermal matrix) and autologous free flap reconstruction and away from latissimus dorsi flap and implant reconstruction.¹⁵ Although immediate reconstruction rates are rising, most of these procedures involve implant-only reconstruction. While indications do exist, there is little to no evidence of its cost or clinical effectiveness in a unilateral, therapeutic setting. Implant-only reconstruction is associated with high failure and revision rates and patient-reported outcomes no different to mastectomy alone. To address these barriers, further research is required to evaluate the long-term outcomes of flap and implant-based reconstruction and the efficacy of new reconstructive techniques and to update cost-effectiveness analyses to inform decision making and commissioning.

The breast and plastic surgery communities need to lead in and facilitate patient advocacy, with widespread dissemination of these findings to all key stakeholders involved in breast cancer care. In addition, they need to enable informed patient decision making (information content, format, timing), improve access to autologous free-flap reconstruction irrespective of geographical location, and work to improve efficiency and lower associated costs in the face of rising demand and limited resources (clinics, theatres, wards).

Conclusions

Reconstruction is key to improving outcomes for women with breast cancer, who will often require a mastectomy primarily due to the extent of their tumour or secondarily following failed breast-conserving surgery. The national audit of mastectomy and breast reconstruction may have changed practice in England but did so incompletely. The differential outcomes and persistent regional inequalities identified should inform reconstructive decision making and support improved women's access to the full range of reconstructive options, and specifically to flap-based

reconstruction. This body of work has demonstrated the feasibility of using a multi-method approach to evaluate practice in these and other areas of health services research.

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Ethical approval

These works were exempt from UK National Research Ethics Committee approval as they involved analysis of an existing dataset of anonymised data for service evaluation. Approvals for the use of Hospital Episode Statistics data were obtained as part of the standard Hospitals Episode Statistics approval process.

National cancer audits are exempt from obtaining approval from the National Research Ethics Service. Approval to prospectively collect patient identifiable data for analysis and reporting was obtained from the Patient Information Advisory Group under Section 60 of the Health and Social Care Act 2001. Informed written consent was obtained additionally from women before they were sent the 3- and 18-month questionnaires.

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Hunterian lecture

I was awarded a Hunterian Lectureship by the Royal College of Surgeons of England for my proposed lecture entitled, 'Reconstructive utilisation and outcomes following mastectomy surgery in England', together with the courtesy title of professor for the year in which the lecture was

delivered. I delivered the lecture on 1 December 2017 at the British Association of Plastic, Reconstructive and Aesthetic Surgeons Winter Scientific Meeting in London. It was based on the body of work submitted for this article, although distinct in content and style.

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