Association between age and access to immediate breast reconstruction in women undergoing mastectomy for breast cancer

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ABSTRACT

Background: National guidelines state that patients with breast cancer undergoing mastectomy in England should be offered immediate breast reconstruction (IR), unless precluded by their fitness for surgery or the need for adjuvant therapies.

Methods: A national study investigated factors that influenced clinicians' decision to offer IR, and collected data on case mix, operative procedures and reconstructive decision-making among women with breast cancer having mastectomy with or without IR in the English National Health Service between 1 January 2008 and 31 March 2009. Multivariable logistic regression was used to examine the relationship between whether or not women were offered IR and their characteristics (tumour burden, functional status, planned radiotherapy, planned chemotherapy, perioperative fitness, obesity, smoking status and age).

Results: Of 13 225 women, 6458 (48.8 per cent) were offered IR. Among factors the guidelines highlighted as relevant to decision-making, the three most strongly associated with the likelihood of an offer were tumour burden, planned radiotherapy and performance status. Depending on the combination of their values, the probability of an IR offer ranged from 7.4 to 85.1 per cent. A regression model that included all available factors discriminated well between whether or not women were offered IR (*c*-statistic 0.773), but revealed that increasing age was associated with a fall in the probability of an IR offer beyond that expected from older patients' tumour and co-morbidity characteristics.

Conclusion: Clinicians are broadly following guidance on the offer of IR, except with respect to patients' age.

Introduction

The breast is the most common form of cancer for women in England[1]. Most women are diagnosed at an early stage, and undergo surgery to remove part (breast-conserving surgery) or all (mastectomy) of the breast. Patients with breast cancer often also have adjuvant treatments such as chemotherapy, radiotherapy and endocrine therapy. Mastectomy may be a primary treatment, following preoperative or neoadjuvant chemotherapy, or a completion procedure after failed breast-conserving surgery[2]. Breast reconstruction may be undertaken at the time of mastectomy (immediate) or at a later date (delayed). The rate of immediate breast reconstruction (IR) in England has increased substantially, from 7 per cent in 1997 to 23 per cent in 2013[3,4]. Similar changes have been observed in other countries[5,6]. Increasing IR rates may be related to improving breast cancer treatments, more effective reconstructive techniques, greater emphasis on aesthetic outcomes, and increased availability of appropriately trained surgeons and funding[7,8].

The National Institute for Health and Care Excellence (NICE)[9] published early breast cancer guidelines in 2002 stating that surgeons should discuss breast reconstruction with all patients and that it should be available at the initial surgical operation. Revised 2009 NICE guidelines[10] clarified that women undergoing mastectomy should all be provided with information about reconstruction, and that IR should be offered where not precluded by patients' fitness for surgery or an urgent need for adjuvant therapy. A 2011 NICE quality standard[11] confirmed that commissioners, providers and clinicians should ensure that IR is discussed with all patients with early breast cancer undergoing a mastectomy.

Previous studies have identified age discrimination in the management of early breast cancer, with a 2015 review[12] reporting a decline in both survival and the use of surgical and adjuvant treatments in older women. However, there is limited information on the extent to which patient age influences an IR offer. Several studies[13–15] have examined the offer of IR, but all were undertaken at single specialist centres and the data cannot be generalized safely. Two of these studies[13,15] also examined the reasons given for an offer not being made, but neither used multivariable analysis to determine their relative importance.

This type of analysis cannot be undertaken using administrative data, as these code only the uptake of an IR offer rather than its receipt. Information on whether an offer is made is important as it allows evaluation of whether or not IR can be accessed equitably within a healthcare system. Although older women may be presumed, other things being equal, to be less likely to take up an offer of IR, it is possible that inconsistent clinician behaviour also explains some of the age-related differences in IR uptake[15]. National guidelines indicate that increasing age on its own should not preclude an IR offer. However, age discrimination has been reported with respect to breast cancer treatments and breast cancer surgery in particular, both in England and internationally[16–18].

For these reasons, a national prospective study was undertaken to determine the proportion of women with breast cancer undergoing mastectomy in the English National Health Service (NHS) who were offered IR, and to examine how its likelihood was related to women's demographic and clinical characteristics.

Methods

The study used data submitted prospectively by all 150 English NHS acute hospital trusts during a national clinical audit[7]. The audit protocol and reports are available for review at: http://www.rcseng.ac.uk/standards-and-research/research/clinical-effectiveness-unit/documents-publications. National cancer audits are exempt from the UK National Research Ethics Committee approval process.

This study analysed the data from women (aged 16 years or over) diagnosed with breast cancer or ductal carcinoma *in situ* (DCIS), and who had unilateral mastectomy with or without IR over a 15-month interval, between 1 January 2008 and 31 March 2009. Information was collected on age at surgery and other prognostic variables that were expected to influence surgical decision-making, and possibly confound the relationship between age and access to IR. These included: tumour burden (invasive status and Nottingham Prognostic Index (NPI) score), smoking status, obesity, diabetes, and two measures of physical function: ASA grade of perioperative fitness and Eastern Cooperative Oncology Group (ECOG) functional status score[19]. Information was also collected on procedure type (mastectomy alone or mastectomy with IR) and planned adjuvant treatments (chemotherapy and

radiotherapy). For women who had not undergone IR, information was collected from the clinician on whether or not they were offered the procedure. This last variable reflected clinicians' decision-making but did not incorporate patient preference. For the present study, only women with complete information recorded on all of these variables were included in the analyses.

Statistical analysis

The proportion of women offered IR overall and among groups with different characteristics was calculated. The statistical significance of differences between group proportions was assessed using the χ^2 test.

Two logistic regression models were developed to examine the relationship between patient characteristics and planned treatments and the IR offer rate. The first incorporated only clinical factors that were consistent with the NICE guidance on which women should be offered IR (physical health and planned adjuvant therapy), and was used to explore how the dominant factors influenced the IR offer rates across different patient groups. As part of this process, tumour burden was defined using four categories: DCIS and invasive with good (NPI under 3.4), moderate (NPI 3.4–5.4) or poor (NPI over 5.4) prognosis. The second model was developed using both sociodemographic and clinical factors that might influence the decision to offer IR. This model included age at time of surgery, which was added as a continuous variable. To aid interpretation, the adjusted odds ratio associated with age was presented per year increase in age. The performance of both models was summarised using the *c*-statistic, a measure of a logistic regression model's ability to discriminate between which women would and would not be offered IR[20].

All statistical tests were two-sided and $P < 0.050$ was considered to indicate a significant result. STATA® version SE 11 (StataCorp, College Station, Texas, USA) and Microsoft Excel® 2010 (Microsoft, Redmond, Washington, USA) software were used for all analyses.

Results

Between 1 January 2008 and 31 March 2009, the audit registered 14 811 women with breast cancer or DCIS who underwent mastectomy with or without IR at 150 English NHS Trusts. Some 1586 women

for whom one or more data items were missing in the data set were excluded. After exclusions, a total of 13 225 women with complete data were included in the cohort, of whom 10 625 underwent mastectomy alone and 2600 (19.7 per cent) had IR. The final sample with complete data included in the analyses appeared representative; the women excluded owing to incomplete data had similar characteristics to those included in the study (mean age 59.3 *versus* 61.0 years respectively; proportion with invasive disease 85.2 *versus* 84.8 per cent).

Univariable analyses

Over the study interval, 6458 women (48.8 per cent) in the mastectomy cohort were offered IR. *Table 1* shows the proportion of women who received an offer of IR stratified by various demographic and clinical characteristics. Increasing age, obesity, reduced perioperative fitness (ASA grade), impaired functional status (ECOG score), greater tumour burden, and planned adjuvant radiotherapy and chemotherapy were all significantly associated with a lower IR offer rate.

Multivariable regression analyses

Among the factors directly relevant to the NICE guideline recommendations, the three most strongly related to an IR offer were tumour burden, ECOG performance status and planned radiotherapy. The effect of each factor was in the direction consistent with the NICE guidance (*Table 2*), and there were substantial differences in the proportion of women offered IR within the eight patient groups defined by combining these three factors. The observed proportions ranged from 7.4 to 85.1 per cent (*Fig. 1*).

Predicted IR rates for the individual groups were derived using the first (exploratory) logistic regression model that included only these three factors. There was a reasonable correspondence between the predicted and observed IR rates for the groups, with the exception of women with DCIS and no functional impairment having planned radiotherapy (*Fig. 1*). This exploratory model performed reasonably well at discriminating between the individual women to whom clinicians did and did not offer IR (*c*-statistic = 0.748).

The results from the second regression model, which included five additional clinical and patient factors, are shown in *Table 2*. Four of these factors can be regarded as being relevant to the

NICE guidance because they are associated with a patient's fitness for surgery; the exception is age. This model demonstrated slightly improved performance and discrimination compared with the exploratory model (*c*-statistic = 0.773). The odds ratios associated with the three factors in the exploratory model changed by varying degrees with the inclusion of these five additional items. The odds ratios associated with the tumour groups changed marginally, but the effect of the ECOG performance status categories was reduced following inclusion of other factors associated with physical function (ASA grade, obesity, smoking). The effect of radiotherapy was increased slightly following inclusion of these additional factors, with the estimated odds ratio falling from 0.42 to 0.36.

Age demonstrated a strong and persistent effect, even after adjustment for the other factors associated with physical function. The effect of age was explored by using the regression model to predict the probability of each woman being offered IR given their clinical characteristics, but assuming they were of mean age (61.0 years). The difference between the predicted and observed IR rates was plotted for women in different age groups (*Fig. 2*), showing that the IR offer rate fell further with age than would be anticipated based on concurrent changes in tumour burden and physical function.

Discussion

Clinical guidelines indicate that an offer of IR with mastectomy should be based on tumour characteristics and fitness for surgery. The results of the present study confirm that clinicians take into account tumour burden, physical function and whether or not chemotherapy and radiotherapy are anticipated when deciding to offer IR. An offer of IR was not always made to some women who appeared to be fit and who were not expected to require adjuvant therapy. Patients' age was independently associated with clinicians' decision to offer IR, despite national guidelines not specifying this as a factor. The strengths of this study include its large size, the representative sample of patients undergoing mastectomy[7], and its prospective design[3], allowing consideration of specific questions about whether or not a reconstructive offer was made.

The study also has limitations. The data were collected between 2008 and 2009, and clinical practice might have altered to some degree in the intervening years. The size of any change is likely

to have been small, however, as the evidence base and recommendations about breast reconstruction have changed minimally. In addition, IR rates have not changed substantially over the intervening time within England[4]. Although new types of IR have been introduced (such as autologous fat transfer, dermal flaps, acellular dermal matrix-assisted implants), their indications are similar to those of the techniques used during the study interval.

The NPI score used to stratify women into tumour groups was available to the clinician only after surgery[19]. Clinicians therefore made IR offers and planned adjuvant therapies based on incomplete information about tumour burden. This might have accounted for some of the differences between the observed IR offer rate and that predicted by the models. However, planned adjuvant radiotherapy and chemotherapy were included in the models to address this issue. Neoadjuvant chemotherapy was not included, as its delivery could not be affected or delayed by a subsequent IR procedure.

The impact of the diagnostic pathway (screening or symptomatic) on IR offer rates was not investigated. Older women are more likely to present symptomatically, less likely to be treated surgically, and are more likely to undergo mastectomy[12,16,21]. Although these factors were included in the regression model, it is still possible that the diagnostic pathway had an independent influence on IR offer rates, which has not been accounted for. In addition, the observed age effect might reflect unmeasured levels of poor fitness for surgery. Finally, the study relied on clinicians giving honest responses about their decision-making. The reported reconstructive decision-making was consistent with the subsequent pattern of care overall, but the possibility of social desirability bias or inaccurate responses cannot be discounted.

Most evidence on clinical decisions to offer IR with mastectomy is from single-centre studies, and provides a patchy view on factors that influence this decision. Population-based studies are rare. A prospective study[13] in Australia found that the four surgeons in a single centre focused primarily on the need for postmastectomy radiotherapy when deciding whether or not to offer IR. Studies at single centres in the USA[14] and South Africa[15] have reported a broader range of clinical factors influencing decisions to offer reconstruction, including cancer stage, axillary nodal status, smoking status, body habitus, pre-existing scars, and planned or previous radiotherapy or chemotherapy. Two qualitative

studies[22,23] suggested that decisions were also influenced by prompt access to a full range of reconstructive choices.

Other studies have examined whether clinician characteristics might predict the likelihood of an IR offer being made. Some[24–27] suggested that surgeons' age, sex and training background influenced decision-making. A French study[28] found that the characteristics of the treating surgeon were highly predictive of an IR offer, with patient co-morbidities being less important. Another North American study[29] reported preoperative counselling by the breast surgeon and preoperative review by a plastic surgeon being strongly associated with an offer of IR, with 91 per cent of those referred to a plastic surgeon proceeding to IR. This study also identified increasing patient age as being related to lower rates of reconstructive offer.

For patients undergoing mastectomy in England, the likelihood of an IR offer is broadly associated with their tumour burden, planned treatments and physical fitness. Nonetheless, a significant proportion of women without fitness-for-surgery issues or a need for urgent adjuvant therapy are still not offered IR. In particular, the likelihood of an offer decreases sharply once a woman is aged 70 years or more. This does not reflect the current national guidance. There are a number of possible reasons for this last finding, which clinicians should consider and address. Increased age may also be seen as a proxy for fitness and associated with worse outcomes, despite a lack of evidence for this. It may reflect rationing within a national healthcare system with limited resources and waiting time pressures, or reflect the broader tendency for clinicians to offer fewer treatments to older patients with cancer[16–18]. Finally, older women may be assumed by clinicians to not be interested in breast reconstruction. This last reason highlights the relationship between offer decisions and reconstructive uptake, another area about which little is currently known. Additional work should be undertaken to examine uptake of reconstruction and the role of patient preferences once an offer is made.

Overall, these results suggest a need for clinicians to audit their own (and their organization's) decision-making processes around offering IR, and to deal with any age bias found to be present. This will require clinicians to document their decision-making regarding offering access to IR; the present study demonstrates that this is possible. There is also a need for standardized patient assessment tools

to guide breast cancer multidisciplinary teams during reconstructive decision-making[30] and to support the benchmarking of IR offer rates. The regression models developed here suggest that it is possible to develop a robust and clinically appropriate audit tool that can take account of differences between patients, and so enable like-for-like comparisons across hospitals and regions within countries.

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Fig. 1 Patterns of immediate breast reconstruction (IR) offer based on three most dominant clinical factors: tumour burden, planned radiotherapy treatment and physical health (Eastern Cooperative Oncology Group (ECOG) score). DCIS, ductal carcinoma *in situ*; NPI, Nottingham Prognostic Index

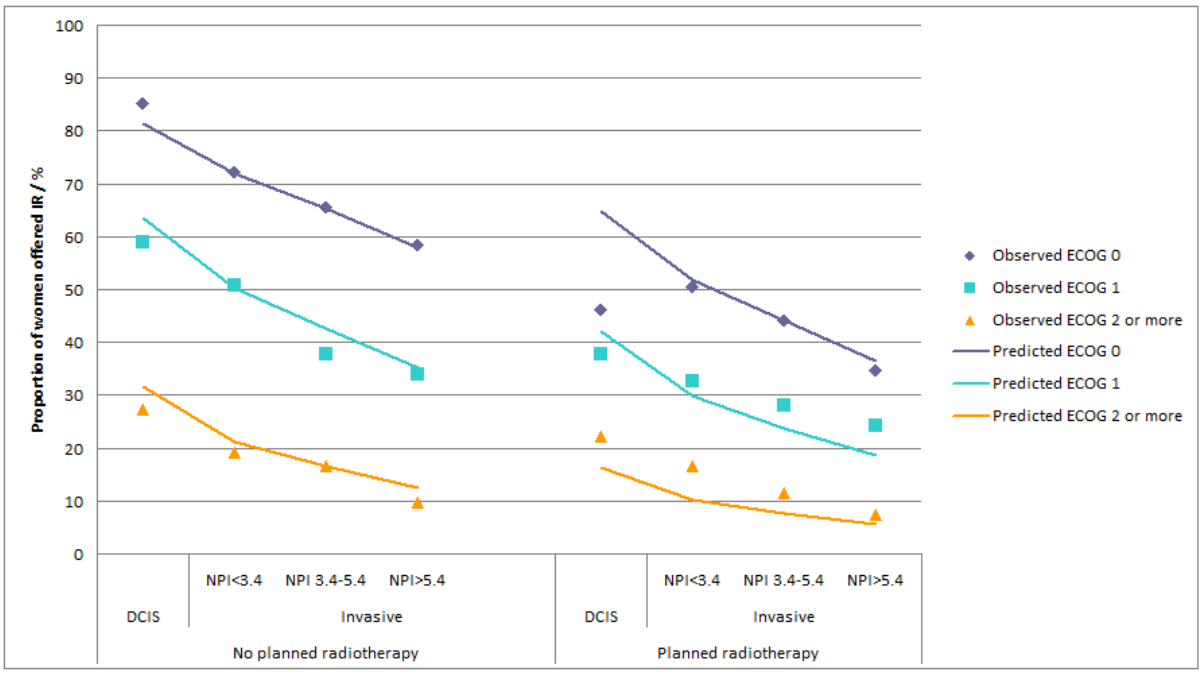

Fig. 2 Observed rates of immediate breast reconstruction (IR) offer by age at surgery compared with predicted IR offer rate from model 2 (clinical and patient characteristics) with the effect of age removed (held constant at the mean age for the group)

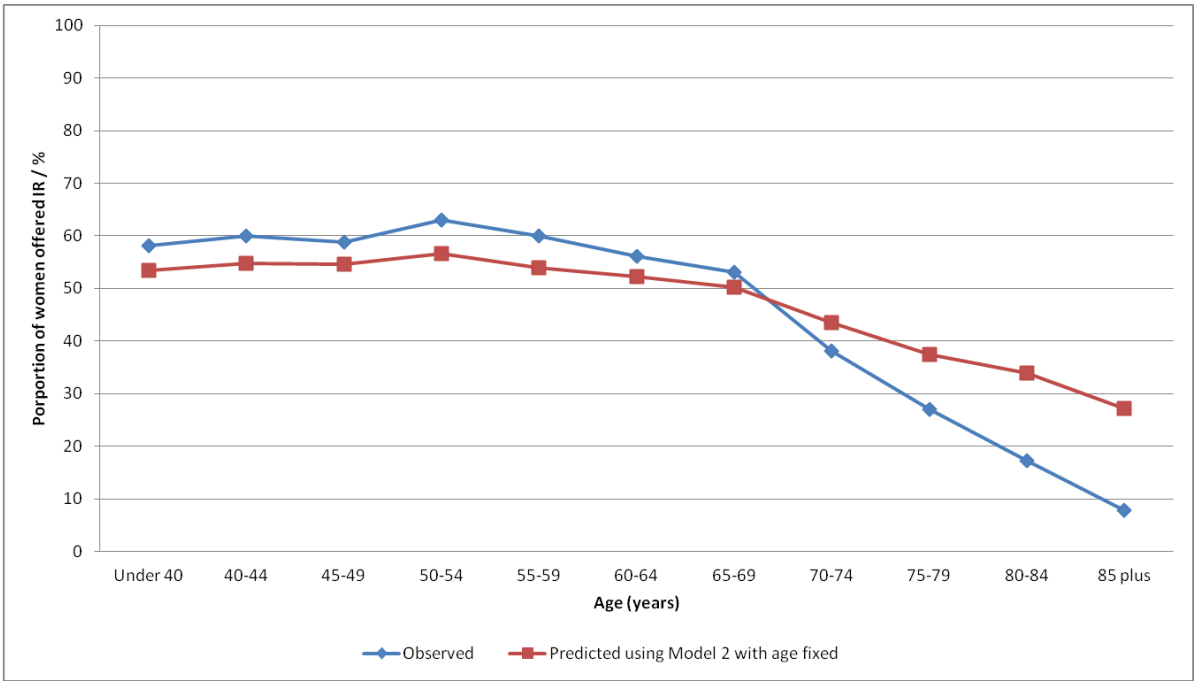

Table 1 Number and proportion of patients undergoing mastectomy to receive an offer of immediate reconstruction, stratified by sociodemographic and clinical characteristics

	No. of mastectomies	No. offered IR	*P**
Age (years)			< 0.001
< 40	677	393 (58.1)	
40–49	2364	1400 (59.2)	
50–59	3036	1866 (61.5)	
60–69	3286	1800 (54.8)	
70–79	2494	810 (32.5)	
≥ 80	1368	189 (13.8)	
Smoking status			0.398
Non-smoker	11 405	5586 (49.0)	
Current smoker	1820	872 (47.9)	
BMI			< 0.001
Not obese	9575	4909 (51.3)	
Obese	3650	1549 (42.4)	
ASA fitness grade			< 0.001
I	6262	3806 (60.8)	
II	5495	2394 (43.6)	
III or IV	1468	258 (17.6)	
ECOG score			< 0.001
0	8895	5239 (58.9)	
1	2574	962 (37.4)	
≥ 2	1756	257 (14.6)	
Tumour burden			< 0.001
DCIS	2016	1463 (72.6)	
Invasive, NPI < 3.4	2078	1219 (58.7)	
Invasive, NPI 3.4–5.4	5591	2610 (46.7)	
Invasive, NPI > 5.4	3540	1166 (32.9)	
Planned radiotherapy			< 0.001
No	8100	4718 (58.2)	
Yes	5125	1740 (34.0)	
Planned chemotherapy			0.001
No	8628	4305 (49.9)	
Yes	4597	2153 (46.8)	
Overall	13225	6458 (48.8)	

Values in parentheses are percentages. IR, immediate breast reconstruction; ECOG, Eastern Cooperative Oncology Group; DCIS, ductal carcinoma *in situ*; NPI, Nottingham Prognostic Index. *χ^2 test.

Table 2 Adjusted odds ratios from logistic regression analysis for offer of immediate breast reconstruction for women with various clinical and sociodemographic characteristics

	Odds ratio	
	Model 1 (main factors)	Model 2 (clinical and patient characteristics)
Tumour group		
DCIS	1.00 (reference)	1.00 (reference)
Invasive, NPI < 3.4	0.58 (0.51, 0.67)	0.62 (0.54, 0.72)
Invasive, NPI 3.4–5.4	0.43 (0.38, 0.48)	0.48 (0.43, 0.55)
Invasive, NPI > 5.4	0.31 (0.27, 0.36)	0.35 (0.30, 0.40)
ECOG score		
0	1.00 (reference)	1.00 (reference)
1	0.40 (0.36, 0.43)	0.62 (0.56, 0.69)
≥ 2	0.11 (0.09, 0.12)	0.26 (0.22, 0.31)
Planned adjuvant radiotherapy (yes *versus* no)	0.42 (0.39, 0.46)	0.36 (0.33, 0.39)
Planned adjuvant chemotherapy (yes *versus* no)		0.86 (0.79, 0.95)
ASA fitness grade		
I		1.00 (reference)
II		0.84 (0.76, 0.92)
III or IV		0.47 (0.39, 0.56)
BMI (obese *versus* not obese)		0.83 (0.76, 0.90)
Current smoker (*versus* non-smoker)		0.78 (0.70, 0.88)
Age (years) (linear)		0.96 (0.96, 0.97)

Values in parentheses are 95 per cent confidence intervals.

Area under receiver operating characteristic (ROC) curve (*c*-statistic) was 0.748 and 0.773 in models 1 and 2 respectively.

DCIS, ductal carcinoma *in situ*; NPI, Nottingham Prognostic Index; ECOG, Eastern Cooperative Oncology Group.