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Clinical Outcome Data for Symptomatic Breast Cancer: The Breast Cancer Clinical Outcome Measures (BCCOM) Project

Running title: Breast Cancer Clinical Outcome Measures (BCCOM) Project

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Abstract

Aims: Data collection for screen-detected breast cancer in the UK is fully funded which has led to improvements in clinical practice. However data on symptomatic cancer is deficient and the aim of this project was to monitor current practice.

Methods: A dataset was designed together with surrogate outcome measures to reflect best practice. Data from cancer registries initially required the consent of clinicians but in the third year anonymised data were available.

Results: Data quality improved but this varied by region and only a third of cases were validated by clinicians. Regional variations in mastectomy rates were identified and one third of patients treated with conservative surgery for invasive breast cancer were not recorded as receiving radiotherapy.

Statement: National data are essential to ensure that all patients receive appropriate treatment for breast cancer but variations still exist in the UK and further improvement in data capture is required.

Introduction

The NHS Breast Screening Programme (NHSBSP) which was set up in 1988 on the strength of the Forrest Report (Forrest, 1986) has had a number of important effects. At that time, the management of patients with breast cancer in the UK lay in the hands of general surgeons and, although many had a special interest in the disease, the concepts of the breast care nurse and the multi-disciplinary team (MDT) were yet to come in most hospitals. With the passage of time, the occasional operator came to accept that the overall management of breast cancer required the attention of a dedicated team working out of a specialty breast unit and the disciplines required of the screening process for specialist radiologists, surgeons and pathologists gradually took hold. However, the need for complete, accurate and timely data took longer to gain acceptance.

The collection of data on screen-detected breast cancer was funded from the outset by the NHSBSP, and has been facilitated by having a single, breast screening computer system. In addition, the Regional Breast Screening Quality Assurance Reference Centres (QARCs) have been instrumental in providing good quality data for audit (NHS Breast Screening Programme, 2008). The feedback of variations in practice at annual audit meetings organised both regionally and nationally, has identified outliers in clinical practice and, although peer pressure has proved a slow process in establishing a consensus, it has been possible to demonstrate major changes in clinical practice over time (Sauven *et al*, 2003). The appointment of regional representatives for the screening programme led to the formation of the Breast Group of the British Association of Surgical Oncology (BASO), which in turn developed into the Association of Breast

Surgery at BASO (ABS), and the presentation of NHSBSP/ABS audit data at the ABS Annual Meeting has become the main focal point for breast surgeons in the UK.

As the screening data became more robust the lack of data for the majority of breast cancers which present symptomatically became more obvious and with this recognition there was a growing concern that variations in the standard of care and sub-optimal practice might well be obscured. The lack of a national breast cancer database has been a limiting factor since, although a BASO database was initially funded by Zeneca and latterly by the Department of Health, the software included all breast consultations and focussed on communication with the general practitioner rather than systematic data collection. As a result, the database was not used widely and support was eventually withdrawn.

In response to these concerns, in 2000 the ABS started the systematic collection of data for symptomatic breast cancers and, with the support of those units with good data collection systems, achieved about one third of the estimated national caseload. However, it became apparent with each year of this unfunded initiative that, as new units started to submit data as many collaborators failed to continue, often due to the withdrawal of funding for data managers. There was also a move by some acute hospital Trusts to meet their responsibility to provide cancer waiting times data by extending the duties of established breast cancer data managers which also had a negative effect. Over the same period the Association of Coloproctology of Great Britain and Ireland (ACGBI) had a similar initiative to collect data on the management of colorectal cancer, and more recent attempts to collect data on oesophago-gastric and thyroid cancers by the respective professional associations (the Association of Upper Gastrointestinal Surgeons [AUGIS] and the British Association of Endocrine and

Thyroid Surgeons [BAETS]), have suffered the same constraints, with retrieval rates of little more than a third of national data.

It therefore became clear that requests to individual clinicians or units were not the way forward, and in 2003 it was suggested that the data held by the regional cancer registries could be used to resolve the problem. Fears were expressed that data collection was less than complete in some registries and it subsequently became apparent that permission for the release of data by individual clinicians and the requirement for anonymisation might be barriers to progress. It was at this stage that the Breast Cancer Clinical Outcome Measures (BCCOM) Project was established using a subset of the national breast cancer dataset in order to maximise the ability of regional cancer registries to participate. Since it is recognised that it takes some years before it becomes apparent whether variations in treatment lead to differences in disease free and overall survival, a series of surrogate clinical outcome measures or "key performance indicators" has been developed to monitor the extent to which best practice is followed.

Methods

A breast cancer dataset was designed in consultation with the ABS and the UK Association of Cancer Registries (UKACR). Data on all newly-diagnosed primary symptomatic breast cancers are obtained from the UK cancer registries and include basic demographic details, diagnostic information, tumour characteristics and the type of surgical and adjuvant treatment for each case. Male breast cancers are included, but screen-detected cases are excluded as far as possible. In order to reduce contamination of symptomatic cases with screen-detected breast cancers, cases flagged by cancer registries as screen-detected breast cancers (as required in the national cancer registry peer review measures (Department of Health, 2005)) are excluded from the BCCOM dataset. Cancer registries were asked to flag cases as having had a pre-operative diagnosis of breast cancer if the case record contained a cytology or core biopsy diagnosis that pre-dated the first therapeutic operation.

To validate the accuracy of data collection, cancer registries send the data held to the responsible consultant breast surgeon. The surgeons in turn are asked to check the validity of their data by comparing them with those held on local systems, to make amendments if necessary and to return the data without patient identifiable details to the BCCOM Project team at the West Midlands Cancer Intelligence Unit (WMCIU). Surgeons may submit unchecked data if they do not have the necessary support mechanisms or if they are satisfied that the quality of the data is high. Cases are not included if the surgeon sees less than six symptomatic cases in the year, chooses not to participate or is unknown.

From Year 2 onwards, the initial protocol for data collection was modified to ensure

compliance with Section 60 of the Health and Social Care Act 2001. It was observed

that, whilst non-identifiable data were stored in the BCCOM central database, the flow

of information at the beginning of the audit cycle, from cancer registry to surgeon for

validation, was at an individual patient level. The updated protocol therefore requested

that cancer registries obtain the written consent of individual consultant surgeons prior

to their data being released to the lead breast surgeon in each hospital. In Year 2 all

consultant breast surgeons, whether members of the ABS or not, were invited to take

part in the BCCOM audit. The regional symptomatic surgical representatives contacted

the lead breast surgeon in each hospital, asking for help in collecting their colleagues'

written consent to release data. In Year 3 the process for data transfer from the cancer

registries to the relevant consultant surgeon was altered such that for all registries apart

from South West, Northern Ireland and Scotland, the data were distributed by the

BCCOM team at the WMCIU. In addition, cancer registries provided the BCCOM

team with data on all the breast cancers diagnosed in each region for that audit year

(2004) so that an accurate denominator could be identified.

The data collected was analysed against the surrogate Clinical Outcome Measures

devised by the BCCOM steering group (Table 1).

Results

Recruitment

Table 2 shows participation levels in the BCCOM Project in each region and country. In Year 2 (cases diagnosed in 2003) there was a 14% reduction in the total number of cases submitted (14,120 compared with 16,407) and very large reductions in some regions. These decreases are in part due to the more reliable exclusion of ineligible screen-detected cases in Year 2, but mainly result from changes in the protocols for data collection in Year 2 which required written consent from all surgeons prior to data for their patients being released to the lead surgeon in each hospital for validation purposes. In Year 3 (cases diagnosed in 2004) the UK cancer registries supplied the BCCOM team with data on all 48,983 breast cancers diagnosed. This provided a denominator of the total number of eligible cases against which participation could be compared (Table 3) and an estimate of the annual breast cancer burden in the UK. Wales had the highest recruitment of cases, at 94% and the Thames Region, which has the highest number of surgeons and the most cases, had by far the lowest recruitment, at 29%. Figure 1 shows that, in addition to the 1,219 cases (3%) which were excluded in Year 3 because the surgeon had treated fewer than 6 symptomatic cases, a further 21,220 symptomatic cases (54% of the total number of symptomatic cases identified by the cancer registries) could not be included either because the surgeon was non-compliant (15,471 cases) or unknown (5,749 cases).

In Year 3 (cases diagnosed in 2004), 16,611 female breast cancers were included and 128 breast cancers arose in males. Slightly more breast cancers presented in the left breast (52% versus 48%). 25% of cases were diagnosed in patients aged less than 50, 28% in those aged 50 – 64, 9% in those aged 65 – 69 and 37% in patients aged 70 or older.

Screening flag

In Year 3 (cases diagnosed in 2004), of the 48,983 breast cancers cases registered by cancer registries, 9,805 (20%) were flagged as screen-detected (Figure 1). From the NHSBSP/ABS audit of screen-detected cancers it is known that 14,057 cases would have had a date of first offered appointment to screening in 2004, indicating that the cancer registries had accurately assigned only 70% of the screen-detected cases. Those regions which did not have the robust communications between cancer registries and breast screening QA reference centres required to flag screen-detected breast cancers accurately tended to have the highest rates of non-invasive breast cancers (up to 10% in Year 1) and the greatest proportion of cases in the then screening age group (50-64) included in their BCCOM cohorts. The proportion of non-invasive breast cancers fell from 6.3% in Year 1 to 5.8% in Year 3, but this is still higher than is expected from the literature which suggests that only 3% of non-invasive breast cancers present symptomatically (Blamey *et al*, 2000) compared with 21% (including micro-invasion) of screen-detected cases (NHS Breast Screening Programme, 2008). This provides surrogate evidence of continuing contamination by screen-detected breast cancers in some regions. The recent requirement in the national cancer registry peer review measures for registries to obtain details of screen-detected breast cancers from breast screening QA reference centres has greatly improved the situation compared with 2003, and it is hoped that in the Year 4 (cases diagnosed in 2005), all registries will have correctly identified their screen-detected cases.

Histological Type

Of the 47,266 breast cancer cases submitted to BCCOM in Years 1-3, invasive ductal carcinoma was the commonest histological type (68%), followed by invasive lobular carcinoma (12%), Ductal carcinoma *in situ* (5%), mixed invasive (5%), mucinous carcinoma (2%) and tubular carcinoma (1%). These proportions will probably change

slightly when all screen-detected cases have been eliminated, but they illustrate how the audit could provide a source of a relatively large number of rarer tumours for research.

Nodal Status

Of the breast cancer cases submitted in Year 3 (cases diagnosed in 2004), 31.8% were lymph node positive, 34.3% were lymph node negative and 33.9% had unknown nodal status (Table 4). For surgically treated cases, 40.5% were lymph node positive and the proportion with unknown lymph node status was 14.4%. The relatively high proportion of surgically treated cases with unknown lymph node status may be due to the fact that some cancer registries do not record data on lymph node status and tumour size for patients who receive neo-adjuvant chemotherapy or radiotherapy. This is because the use of such data to determine the Nottingham Prognostic Index (Haybittle *et al*, 1982) or the pathological TNM stage at diagnosis could result in inaccurate under-staging of the cancer. Recording of the axillary node status increased in Years 2 and 3 of the audit for all age groups, but was higher in those under 50 (89%) than in those over 80 (72%), largely because the latter group are less likely to have surgery.

Tumour Size

In Year 3, for 31.4% of the cancers included in the cohort, the maximum diameter of the invasive tumour component was less than 20mm and for 24.6% of cases the invasive size was unknown. For surgically treated cases, the invasive tumour size was unknown for only 7% of cancers. In most of the latter cases, the invasive size at diagnosis was not recorded either because the patient had neo-adjuvant treatment which may have reduced the original size at diagnosis or because the tumour was removed in several pieces from more than one operation.

Tumour Grade

In Year 3, 12.0% of invasive cancers were Grade 1, 41.0% were Grade 2 and 33.2% were Grade 3. For surgically treated cases, these proportions were 12.8%, 43.3% and 37.9% respectively. Grade was unknown for 13.9% of all cases, but this decreased to 6.0% for surgically treated cases. Pathologists are reluctant to report grade after neo-adjuvant treatment, which may partly explain the latter shortfall. There was little variation in tumour grade over the three years of the study. There was a clear association between nodal status, tumour grade and size; with grade 1 cancers being smaller and more likely to be node negative (Figure 2).

Nottingham Prognostic Index

In Year 3, the Nottingham Prognostic Index (NPI) score could be calculated for the 80% of surgically treated invasive breast cancers. The NPI could not be calculated in 20% of cases due to missing grade (6%), size (7%) and/or nodal status (14%).   Nodal status was not available in 28% of patients over 80.   Of those cases with a known NPI, 51% were early breast cancers with an NPI score below 4.4 and fell into the Excellent Prognostic Group (EPG), Good Prognostic Group (GPG) or Moderate Prognostic Group 1 (MPG1) categories. 49% were categorised in the Moderate Prognostic Group 2 (MPG2) or Poor Prognostic Group (PPG) (Blamey *et al*, 2007). These data are in marked contrast to screen-detected breast cancers. In the NHSBSP/ABS audit of screen-detected breast cancers diagnosed in 2004, 83% of cases had an NPI score below 4.4 (24% in the EPG, 36% in the GPG, 22% in the MPG1), 11% were in the MPG2 and 6% in the PPG. The variation in NPI with age at diagnosis for surgically treated screen-detected and symptomatic breast cancers is shown in Figure 3.

Surrogate Clinical Outcome Measures

The surrogate clinical outcome measures proposed by the BCCOM Project team are shown in Table 1. The number of cases treated in each breast unit cannot be calculated from BCCOM data as not all surgeons agreed to participate in the audit. Pre-operative diagnosis rates varied between 12% in Scotland and 87% in the West Midlands and were 40% or less in five regions. The NHSBSP/ABS audit of screen-detected breast cancer has demonstrated an improvement in pre-operative diagnosis from 63% in 1996/97 to 94% in 2006/07 (NHS Breast Screening Programme, 2008). Reliable pre-operative diagnosis data were only available from at most three cancer registries. because many only record data from pathology reports for resection specimens and do not record details from any preceding cytology or core biopsy reports. The numbers of nodes reported in what proved to be a negative sample are shown in Figure 4. In those patients treated with breast conserving surgery, the majority with negative axillae had 8 or more nodes reported.

Surgical Treatment

Variations in treatment of invasive cancers with age at diagnosis in Year 3 are shown in Figure 5. The proportion of women not receiving surgery increased with age from 3.5% in women aged less than 50 to 47.7% in women aged 80 or above. The proportion receiving breast conserving surgery decreased with age from 51.4% in women aged less than 65 to 41.9% in women aged 65 or above. For cases surgically treated, in each region, the breast conserving surgery rate was higher in younger patients, but this difference between age groups was most marked in Oxford (58% v 43%) and Wales (54% v 26%). The proportion of cases receiving breast conserving surgery was lower than the UK average of 47.6% in Trent, Northern Ireland and Northern & Yorkshire and was higher than the UK average in the Thames Region. Figure 6 shows the regional variation in the operation types recorded for invasive breast cancers with a diameter less

than 15mm. At 42%, the Trent Region had the highest mastectomy rate for this group

of small tumours, and Northern Ireland and the North West Region the lowest (19% and

23% respectively). However, as the proportion of cases with unknown operation type

was high in these areas, care should be taken in the interpretation of these reported

patterns of care.

Adjuvant Treatment

Figure 7 shows, for all breast cancer patients with known adjuvant therapy included in

BCCOM Years 1-3, how the proportions of cases receiving adjuvant radiotherapy,

chemotherapy and hormone therapy vary with age at diagnosis. The recorded use of

hormone therapy increases with age, with 85.6% of patients aged 80 and over receiving

hormone therapy compared with 66.4% of patients aged less than 50. This older age

group is less likely to receive surgical intervention and as such hormone therapy may be

the only form of active treatment provided. In contrast, the recorded use of radiotherapy

decreases with increasing age. 78.3% of the patients aged less than 50 received

radiotherapy compared with 30.6% of patients aged over 80. The effect of age on

recorded treatment modality is most marked for chemotherapy, where 77.2% of patients

aged less than 50 received chemotherapy but only 21.9% of patients aged 65-79 and

16% of patients aged 65 and over.

In the three year period 2002-04, radiotherapy was recorded as having been received by

68.7% of the 16,487 patients included in the audit who were treated with conservative

surgery. 1,126 cases (6.8%) were recorded as not having received radiotherapy, but for

a further 4,029 cases (24.4%), it was not known whether or not radiotherapy was given.

Fewer elderly patients were recorded as having had radiotherapy after conservative

surgery, with the proportion known to have received radiotherapy falling from 70% in patients aged under 50 to 43% in those aged 80 and above.

In the three year period 2002-04, chemotherapy was recorded as having been received by 53% of the 13,100 patients with invasive breast cancer who were node positive (Figure 8). 2,630 cases (20.1%) were recorded as not having received chemotherapy and for a further 3,524 cases (26.9%), it was not known whether or not chemotherapy was given. In node positive patients under 70, the proportion known to have received adjuvant chemotherapy was 68% compared with only 12% in those aged 70 or over.

Of the cases with known hormone treatment that were receptor positive (oestrogen receptor [ER] positive and/or progesterone receptor [PR] positive), 11% (1,241 cases) did not receive any form of hormone treatment. For 16% (2,418 cases) of the receptor positive invasive cancers, it was not known whether or not hormone treatment was given. Only 3,961 cases were receptor negative and of these, 9% (367 cases) were known to have been prescribed hormone therapy. Of the 5,112 invasive breast cancer cases who did not have surgery, 3,106 (61%) were recorded as having received hormone therapy but only 2,176 (43%) had known ER status. It would be anticipated that the majority of these mostly elderly patients who did not have an operation would have had strong contraindications to surgery and would have been treated with hormonal therapy. Unfortunately, for all cases where hormone therapy data are recorded, tamoxifen is not distinguished from aromatase inhibitors and switches are not identified.

Discussion

Participation by breast surgeons in the BCCOM Project is not mandatory, but it is strongly encouraged by their professional body, the ABS. Previous experience with the NHSBSP/ABS audit of screen-detected breast cancer has demonstrated that regular audit of surgical practice drives up standards and highlights outliers where local protocols are not in keeping with accepted best practice (Sauven *et al*, 2003). ABS regional symptomatic representatives are encouraged to review participation in their own areas and to identify ways in which this could be improved. Although progress in data collection has been improved by central notification of surgeons in most regions, the data in Figure 1 underline the continuing difficulty in depending on the voluntary and active participation of individual surgeons in the submission and validation of data. The surgeon does not own the data and although their written permission for the release of details of patients under their care has been a prerequisite of the BCCOM audit to date, it seems clear that the collection of cases will not approach completeness on this basis. Furthermore, patients are increasingly managed by a multi-disciplinary team rather than an individual consultant surgeon, who will be involved with the initial management plan but who may have little or no responsibility for the subsequent treatment.

At a national level, cancer registry data are now matched to data held in national datasets such as Hospital Episode Statistics (HES). From those cancer registries which routinely compare their data with those on HES, it has become apparent that the latter can provide useful information on operations for which the pathology reports may not have been transferred to or accessed by cancer registries because no malignancy is reported. These include additional operations to remove nodes which are negative for tumour deposits and repeat operations on the breast such as delayed reconstruction

which have a benign pathological outcome. Most importantly, matching cancer registration and HES data also allows the identification of surgeons and hospitals for each type of treatment if these data have not been collected by the cancer registry; thus increasing the number of cases that can be returned to surgeons for checking.

It has been possible to derive the surrogate outcome measures proposed by the BCCOM Project team for a high proportion of the symptomatic breast cancers included in the audit. The surrogate outcome measures developed to date are restricted, to an extent, by the common data items available from all cancer registries. As yet, quality of life data and/or patient reported outcome measures (PROMs) have been collected on a research basis only, but it is clear they should become part of the standard outcome measures in the future. The inclusion of reconstruction post mastectomy as a key performance indicator should also be considered, and it is hoped that the inclusion of a surrogate outcome measure for this area will be possible once HES data are obtained for all breast cancer cases treated in England.

Regional variations in surgical practice, especially with respect to mastectomy rates, have been highlighted in the BCCOM audit, but variations in individual clinical practice are more difficult to identify since collection of data has been by hospital or unit (Moritz *et al*, 1997). The reasons for regional variations are unclear, but mastectomy rates tend to be higher in rural areas and this association is not confined to the UK (Craft *et al*, 1997; Gort *et al*, 2007). The data for 2002-2004 indicate that patients with lymph node negative disease had a large number of nodes removed even when the surgical procedure was conservative (Figure 4). This time period reflects practice prior to and including the wide scale introduction of sentinel lymph node biopsy (SLNB) where the audit protocol required a nodal clearance for all patients undergoing SNLB,

and future data should demonstrate a change in this practice. Variations in practice style by individual surgeons are well-recognised (Craft *et al*, 1997; Hawley *et al*, 2006), but in breast cancer, any consequent variation in patient outcomes such as recurrence rates or overall survival rates may take many years to become apparent (Purushotham *et al*, 2001). It is for this reason that surrogate clinical outcome measures have been proposed to reflect best practice, in order that publication of the data may bring pressure to bear on outliers.

The place of radiotherapy after conservative surgery for invasive breast cancer is well-established (Clarke *et al*, 2005) and yet there is evidence that this treatment has been under-utilised. There may occasionally be good reason not to give post-operative radiotherapy but, if the BCCOM data are correct, a third of such patients did not have prophylactic treatment and a third of these would be expected to develop local recurrence. The indications for radiotherapy for patients with in situ breast cancer are less well-defined, but current variations in practice are not always based on the available evidence (Dodwell *et al*, 2007). There is also concern that 20% of patients with node positive disease under age 50 did not receive adjuvant chemotherapy (Figure 7). There is now a requirement that the treatment of all breast cancer patients should be considered at a multidisciplinary meeting and any failure to consider appropriate adjuvant treatment should be a thing of the past. Reflection on performance data such as those provided by audits such as BCCOM should assist local breast teams in identifying any non compliance with national practice in their protocols and facilitate the targeting of areas requiring modifications in order to make them consistent with best clinical practice.

Acknowledgements

Conflict of interest statement

The authors and the members of the BCCOM Project Steering Group have no conflict of interest.

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