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ORIGINAL ARTICLE

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## SURGICAL MANAGEMENT OF INVASIVE BREAST CANCER: A 5-YEAR PROSPECTIVE STUDY OF TREATMENT IN THE AUSTRALIAN CAPITAL TERRITORY AND SOUTH-EASTERN NEW SOUTH WALES

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**Background:** Breast cancer is a major health problem in Australia. The aim of the present report is to evaluate the surgical management of invasive breast cancers in our region.

**Methodology:** As part of a multidisciplinary quality assurance project, data were collected for the majority of breast cancers treated in our region between July 1997 and June 2002. Participants included surgeons, medical and radiation oncologists, pathologists and general practitioners.

**Results:** Over the 5-year period, 1069 invasive breast cancers were treated. Mastectomy (52%) was more common than breast conservation. For cancers less than 2 cm in diameter (61%), breast conservation was achieved in 62%. High nuclear grade cancers (27%) resulted in mastectomy in 60%. This treatment pattern was the same for patients living in urban and rural areas and in all age groups. Those patients requiring two or more operations (30%) to achieve surgical clearance still had a 33% rate of breast conservation. Over the last 5 years there has been an increase in sentinel node biopsies (16 sentinel node biopsies during 1998–1999; 64 during 2001–2002) and axillary dissections started to decrease. A small group has had no axillary node biopsy or dissection, mainly patients over 70 years of age. Multimodality treatments increased over the 5-year period of our study with the use of post-operative radiotherapy increasing from 60% to 65% and chemotherapy from 36% to 55%.

**Conclusions:** The project has mapped treatment trends for breast cancer in our region and documented the implementation of new treatment methods as well as the increasing use of multidisciplinary management, multimodality treatment and the implementation of best practice guidelines.

**Key words:** breast, invasive cancer, lymph nodes, mastectomy, multidisciplinary, sentinel node.

Abbreviations: NHMRC, National Health and Medical Research Council; SE NSW, South-Eastern New South Wales.

### INTRODUCTION

Breast cancer is the most common cancer affecting women in Australia.<sup>1</sup> The life-time risk of breast cancer for an Australian woman is one in 11. Breast cancer control remains one of the major public health concerns among medical professionals, policy makers, and Australians in general.

Studies in Australia<sup>1</sup> and overseas<sup>2</sup> have shown important variations in treatment practices amongst clinicians caring for women with breast cancer. Such variations have been associated with measurable differences in treatment outcomes. To improve the quality of breast cancer treatment and aid standardization of practice, the National Breast Cancer Centre of the National Health and Medical Research Council (NHMRC) developed Clinical Practice Guidelines for the management of early breast cancer in 1995.<sup>3</sup> These guidelines were further revised in 2001.<sup>4</sup> A breast cancer treatment group was formed in the Australian

Capital Territory (ACT) and South-Eastern New South Wales (SE NSW) during 1995. The aim of the group was to enhance the quality of breast cancer management across our region, particularly by assisting in the implementation of guidelines and the development of multidisciplinary management of breast cancer. A prospective, longitudinal community-based study of breast cancer treatment in the ACT and SE NSW was established by the group to map the patterns of care and the implementation of evidence-based breast cancer best practice treatment guidelines across our region.<sup>5</sup>

The purpose of this paper is to outline changes in surgical management of invasive breast cancer in our region since the implementation of our group.

### METHODS

Surgeons, radiation oncologists, medical oncologists, radiologists, pathologists, nurses and other health professionals involved or interested in the treatment of breast cancer in the ACT and SE NSW were invited to participate in a multidisciplinary breast cancer treatment group. Consumer representatives from The Bosom Buddies, a community organization of women with a history of breast cancer and a general practitioner representative from the ACT Division of General Practice were also invited to join. Currently the group includes approximately 50

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members. Meetings are held every 3 months and attract between 20 and 30 attendees. In 1996, the group adopted treatment guidelines based on the NHMRC Clinical Practice Guidelines, commenced a community-based audit, and later developed a set of agreed practice indicators against which treatment decisions could be compared.

A prospective study of breast cancer was commenced in May 1997. This study was designed as a quality assurance project and notified as such under section 7 of the Health Act 1993 (ACT) in June 1997. The ACT Health and Community Health Human Research Ethics Committee also approved the study. Participating clinicians agreed to approach all of their patients presenting with newly diagnosed breast cancer requesting permission to include them in the study. Eligible patients were women or men with newly diagnosed invasive or *in situ* breast cancers. For each eligible patient a brief notification form was completed and submitted by mail to the study centre at the Cancer Treatment Quality Assurance Project of ACT Health and Community Health. Written informed consent was obtained from the patient by the notifying clinician, and subsequently a detailed data form was completed giving details of presentation, clinical and pathological staging, and treatment. The dataset was based on a prior survey conducted by the Provincial Surgeons of Australia (Dr David Adamthwaite, President of the Provincial Surgeons of Australia, pers. comm., 1996). Additional data relating to enrolled patients were obtained from treatment units in the region. Information from the survey forms, supplemented where necessary from pathology reports and treatment facility records, was entered into a secure database developed by the project officer. Patients with address postcodes included within the ACT were classified as urban; those postcodes not including any part of the ACT were classified as rural. As well as facilitating project management, the database allows individualized, confidential reports to be produced for each participating clinician, providing detailed audit of each clinician's practice, with comparisons across the group and against the agreed criteria. Aggregated data across the whole clinician group are presented at regular meetings of the treatment group.

Surgically related data collected during the period from July 1997 to June 2002 form the basis of this report. Proportions were compared using  $\chi^2$  or Fisher's exact test where appropriate. Accrual of patients to the project is ongoing.

## RESULTS

Breast surgery was performed by 21 participating surgeons. All surgeons providing breast cancer care within the region participated in the study. The average number of patients per surgeon was 51 over the 5-year period (range 1–238). Those surgeons who were recorded as treating only a single patient generally practised outside the region, were locums or retired early in the course of the project. Nearly two-thirds of the operations were performed at Calvary Hospital, located in Canberra.

In 1998 the estimated populations of the ACT and of SE NSW were 311 000 and 118 000, respectively. During the 5-year period of the study 1266 patients were registered with newly diagnosed breast cancer. There were 36 additional patients for whom written consent was not obtained, including three patients who specifically declined to participate. Of patients with newly diagnosed breast cancer notified to the study, the participation rate was 97%. An approximate estimate of the overall patient participation rate was derived for the ACT only. The number of patients registered

into the study was compared with the number of incident cases expected through reference to the population based ACT Cancer Registry for the 5 years to December 2000.<sup>6</sup> During this period 742 cases of invasive breast cancer were reported to the ACT Cancer Registry, compared with 716 women enrolled into the study for the 5 years 1997–2002. From this indirect comparison of overlapping, but different time periods, the overall participation rate for women with invasive cancer is estimated to be up to 96% and relatively unbiased, apart from some evidence of under representation of older patients and patients with metastatic breast cancer. It was not possible to develop an estimate of the participation rate for SE NSW women.

Of the 1266 registered patients, the majority (817 or 64%) resided within the ACT with the remainder residing in SE NSW. One thousand and seventy-eight were women with unilateral invasive cancer without metastatic disease. Of this group with invasive cancer, 1069 women underwent some form of surgical resection for a unilateral operable tumour. The following results refer to this operated group of patients. There were nine patients with invasive cancer who did not undergo surgery who were not included in our analysis. In addition, eight men with breast cancer, 24 women with distant metastases at presentation and 38 with synchronous bilateral cancers were not included.

Figure 1 shows the numbers of breast conservation procedures and mastectomies performed over the 5-year period for women with invasive breast cancer. The rates of breast conservation (47%) and mastectomy (53%) were similar throughout the 5 years of the study ( $P = 0.77$ , Fig. 1). Breast conservation was achieved in 62% when tumour size was less than 20 mm but in only 26% with tumours measuring more than 20 mm ( $P < 0.001$ , Fig. 2).

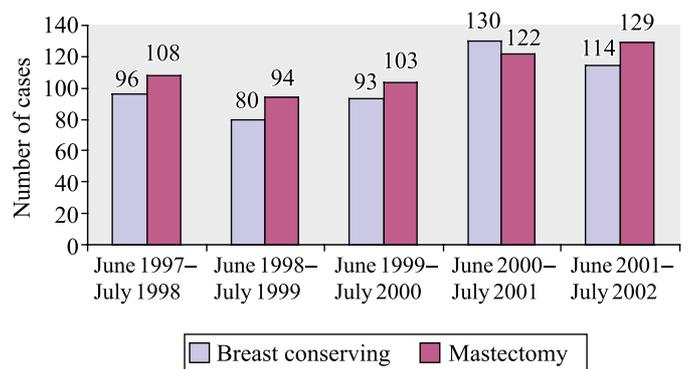


Fig. 1. Breast cancer and treatment in the 5 years.

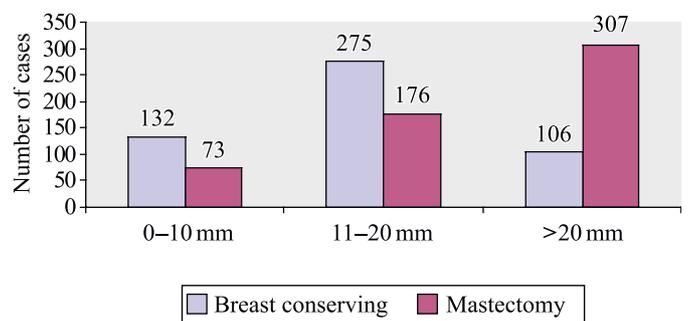


Fig. 2. Breast conservation and mastectomy by size.

Tumour grade is an important prognostic indicator. Low tumour grade was associated with more breast conservation. High tumour grade resulted in more mastectomies ( $P = 0.001$ , Fig. 3).

One of the aims of our breast cancer treatment group was to achieve uniform treatment patterns across the whole region. In the ACT there were 310 breast conserving operations and 354 mastectomies whereas in SE NSW there were 203 breast conserving operations and 202 mastectomies ( $P = 0.3$ ).

When the reason for performing mastectomy was examined, the most frequent response by the notifying clinician was ‘clinical’ reasons 441 (79.6%). Clinical reasons refers to tumour size, multifocality or central position. Patient preference was indicated as the reason for a mastectomy in 100 instances (18.1%). Notably, 23% of rural women made this personal choice for mastectomy compared with 15% of urban women ( $P = 0.09$ , Fig. 4).

Adequate surgical clearance was achieved with a single surgical procedure (mastectomy or wide excision) in 743 out of our total of 1069 patients. In this group 55% underwent breast conservation surgery and 45% mastectomy. Two operations were required to achieve clear margins in 305 patients of which 33% underwent breast conserving surgery. However, in this group the first operation was only an open diagnostic biopsy in 68 patients. Three operations were required to achieve clear resection margins in 21 patients. Even in this group breast conservation was achieved in 24%.

Some form of axillary dissection was performed in 93%. Women aged greater than 70 years were less likely to undergo axillary surgery than younger women ( $P < 0.001$ , Figs 5, 6). Twenty-five patients aged less than 70 years in the breast conser-

vation group did not undergo axillary surgery. Of these, 17 had a tumour less than 10 mm, six were between 11 and 20 mm and one measured over 50 mm. One patient refused axillary surgery.

Early in our study the procedure of sentinel node biopsy was undergoing evaluation in the management of breast cancer and was often accompanied by axillary clearance. Sentinel node biopsy without axillary clearance has been performed more frequently as it has become regarded as an acceptable alternative to axillary dissection when detailed histopathology fails to demonstrate metastatic disease in the sentinel node (Figs 5, 6).

Sentinel node biopsy became much more frequent in the last 12 months of the project (2001–2002) (Fig. 7).

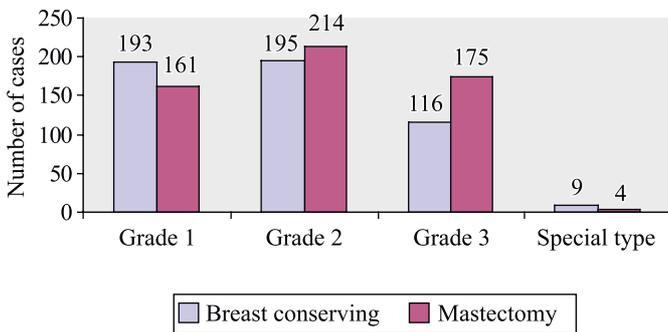


Fig. 3. Breast conservation and mastectomy by grade.

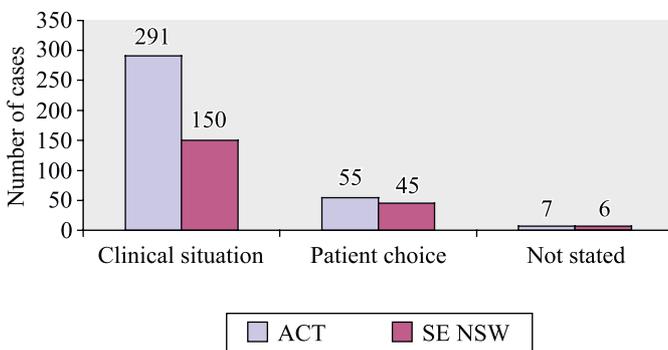


Fig. 4. Reason for mastectomy.

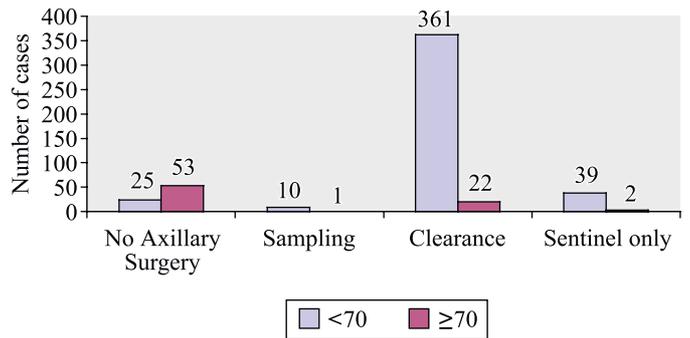


Fig. 5. Axillary surgery in the breast conservation group (513/1069).

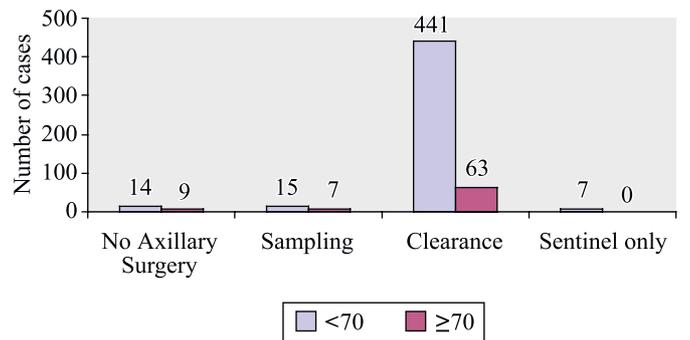


Fig. 6. Axillary surgery in mastectomy group (556/1069).

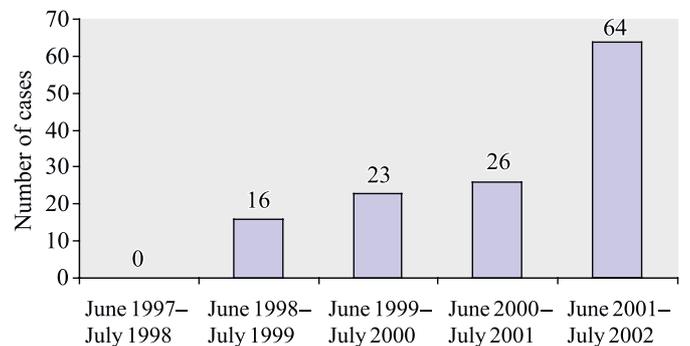
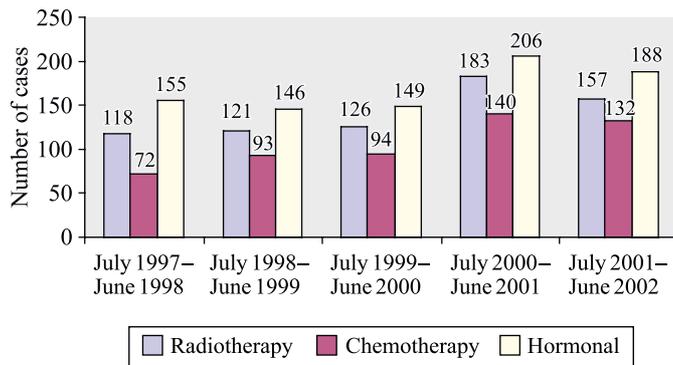


Fig. 7. Sentinel node biopsy.



**Fig. 8.** Number of patients receiving multimodality therapy.

Multidisciplinary management has increased over the 5-year study period (Fig. 8). The use of adjuvant radiotherapy has increased from 60% to 65% of patients whose tumours met the guideline indications for it. When the 513 patients undergoing breast conservation were analysed, 485 (96.5%) had undergone adjuvant radiotherapy. The use of adjuvant chemotherapy increased from 36% to 55% over this 5-year period and there was a gradual increase in hormonal therapy.

## DISCUSSION

Surgery is the primary modality for the treatment of localized breast cancer.<sup>7</sup> The guiding principles of the group's surgical management are early diagnosis, accurate staging and best treatment outcomes with minimum number of operations, less axillary dissection and more sentinel node biopsies and offering the same management to urban and rural women. Adopting clinical practice guidelines is important in achieving uniform treatment patterns and better outcomes for our patients.<sup>2,8</sup> The project demonstrates the potential for regionally based multidisciplinary groups to assist in the adoption of treatment guidelines and in the assessment and mapping of their implementation. Strong concordance of practice was observed. Despite one-third of patients living in rural areas, there were similar mastectomy rates and high rates of postoperative radiotherapy after breast conservation surgery.

The 2001 NHMRC<sup>4</sup> guidelines for the management of early breast cancer suggest that clinical features and patient preference are the main determinants of the type of breast surgery performed. We have shown that certain conditions such as size and grade influence the choice of mastectomy. Also patient preference has influenced the mastectomy rate. Women residing in rural areas were more likely to choose mastectomy, although this factor alone did not increase the mastectomy rate in this cohort. Rural women face greater costs, both monetary and social, when choosing breast conserving surgery because of the need for protracted courses of postoperative radiotherapy, necessarily given at a location remote from home.

Simply producing and publishing high quality, evidence-based guidelines for breast cancer treatment does not ensure their uptake into clinical practice. In an Australian survey of clinicians, most respondents supported the NHMRC Clinical Practice Guidelines, but only 20% believed the guidelines had influenced clinical practice.<sup>9</sup> The introduction of guidelines has been a stimulus for institutionally focused audits of surgical practice. Organ-

izations such as the Royal Australasian College of Surgeons have recognized audit as an important tool in the treatment of breast cancer and implemented a national breast cancer audit.<sup>10</sup> Audit incorporating structured feedbacks to clinicians may be a critical strategy in implementing guidelines. One of the aims of such audits is to develop and implement performance indicators. An example of an indicator could be the rate of reoperation for breast conservation in early breast cancer. The National Breast Cancer Audit recently reported their results, including a reoperation rate lower than in our series.<sup>11</sup> For such studies to have relevance, participation rates have to be high. A low participation rate could imply sample error. The participation rates observed in our study may allow more accurate reflections of actual clinical practice across a region than does the national audit where the geographical, demographic and resource base is very wide and within which the participation of surgeons who manage breast cancer is currently only 35% (Cuncins-Hearn A (Senior Researcher, ASERNIP-S), pers. comm., 2004). To be effective, national audits will need to ensure full and unbiased collection of data<sup>2</sup> and yet not compromise the ownership, integrity and potential for publication of the data from smaller regional or hospital based audit programmes.

Surgical removal of lymph nodes from the axilla has been a standard part of management and staging. However, the procedure causes significant side-effect risks including ipsilateral stiffness of the shoulder and lymphoedema of the arm. During the 5-year study period the technique of sentinel node biopsy was introduced into breast cancer management. This has allowed women with a negative sentinel node biopsy to avoid axillary dissection and its attendant morbidity.<sup>12</sup> Our results demonstrate regional groups can implement new techniques and technologies such as sentinel node biopsy and then assess their application and impact. In the next 5-year audit period we predict that there will be a greater number of sentinel node biopsies carried out with a consequent reduction in axillary clearance in the node negative group and we will be able to evaluate the morbidity and recurrence rates of such new technologies.

This study was prospective and was regionally based (rather than focused on a single institution or health service). It was inclusive of all health professionals involved in breast cancer management, and was specifically designed to include the private sector. By incorporating a patient consent process, the study was able to access information from various treatment facilities and pathology laboratories. In the past, surgical audits have generally been based on retrospective case note review and, as such, have sometimes been hampered by unreliable and missing data. Other large studies assessing the process of treatment have relied on secondary analysis of administrative data, sometimes with linkage to population-based cancer registries.<sup>9</sup>

The prospective audit model employed here requires considerable clinician support and trust. The data collection and consent process is time consuming for clinicians. Funding support from regional health authorities is required to ensure data are accurate and complete, and to perform timely analysis. Demonstrating incremental change in treatment practice in response to new knowledge is an important outcome, worthy of the resources provided.

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