## Clinical practice guidelines for the care and treatment of breast cancer: Mastectomy or lumpectomy? The choice of operation for clinical stages I and II breast cancer (summary of the 2002 update)

## Hugh Scarth, Jacques Cantin, Mark Levine, for the Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer

his article provides a summary of the changes along with the updated recommendations (Table 1) made by Health Canada's Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer to the article "Clinical Practice Guidelines for the Care and Treatment of Breast Cancer: 3. Mastectomy or lumpectomy? The choice of operation for clinical stages I and II breast cancer," originally published in 1998¹ (the 2002 update can be found online at www.cmaj.ca/cgi/content/full/158/3/DC1).

In the 1998 guideline, breast-conserving surgery (BCS) followed by radiotherapy was recommended, and the choice between BCS and mastectomy was to be made according to the patient's circumstances and personal preferences. This recommendation was based on the results of 6 randomized trials that showed no difference in survival between patients who received BCS plus radiotherapy and those who underwent mastectomy. In the 2002 update, results of longer follow-up from 2 of these trials are presented. There continues to be no difference in survival between BCS and mastectomy patients. In the National Surgical Adjuvant Breast Project (NSABP) B-06 trial, after an average of 12 years of follow-up, the survival was 62% in the BCS and breast irradiation group and 60% in the mastectomy group.2 In the European Organization for Research and Treatment of Cancer (EORTC) trial, at 10 years of follow-up, the survival was 65% in the BCS and radiation therapy group and 66% in the mastectomy group.<sup>3</sup> Hence, our 1998 recommendation concerning the type of surgery has not changed.

In the 1998 guideline, the importance of having tumour-free margins following BCS was discussed. The steering committee feels that this point needs emphasizing. In the update, data from 2 randomized trials is included showing that positive margins following lumpectomy and breast irradiation is a predictor of local breast cancer recurrence. In the EORTC trial involving women who underwent lumpectomy, the local recurrence rate was 14% among women with positive margins compared with 8% among those with negative margins.<sup>4</sup> In the Milan II trial, the corresponding rates were 17% and 9%.<sup>5</sup> Finally, data

from 2 NSABP randomized trials involving women with ductal carcinoma in situ who had lumpectomy provide supporting evidence that positive margins even in cases of noninvasive breast cancer are associated with an increased risk of local breast cancer recurrence. In the NSABP B-17 trial<sup>6</sup> breast irradiation was compared with no radiation, and in the NSABP B-24 trial breast irradiation plus tamoxifen was compared with breast irradiation plus placebo.<sup>7</sup> In both of these studies the presence of positive margins was associated with an approximate two-fold increase in the rates of local breast cancer recurrence. Hence, the steering committee reaffirms its recommendations that tumour-involved margins should be re-excised and that mastectomy be considered if margins remain positive after re-excision.

The role of preoperative (neo-adjuvant) chemotherapy for shrinking large tumours to allow BCS has been clarified sufficiently to allow for a new recommendation. In the NSABP B-18 trial over 1500 women with early breast cancer were randomly assigned to receive chemotherapy consisting of 4 cycles of adriamycin and cyclophosphamide either preoperatively or postoperatively. 8,9 No difference was detected in disease-free or overall survival between the 2 groups. Sixty-seven percent of women in the preoperative chemotherapy group underwent lumpectomy compared with 60% in the postoperative chemotherapy group. Among the patients with tumours > 5 cm in diameter, the rates of lumpectomy were 22% and 8%, respectively. There was a trend for a higher rate of local breast cancer recurrence among the lumpectomy patients who received preoperative chemotherapy than among those who received postoperative chemotherapy (10.7% v. 7.6%, p = 0.12). In the EORTC 10902 trial 698 women with breast cancer were randomly assigned to receive 4 cycles of fluorouracil, epirubicin and cyclophosphamide either preoperatively or postoperatively.<sup>10</sup> No difference was detected in overall survival between the 2 groups. In the preoperative chemotherapy group 57 patients (23%) who were scheduled to undergo mastectomy had their cancer downstaged and had BCS.

## Table 1: Updated recommendations from the clinical practice guideline for the care and treatment of breast cancer: Mastectomy or lumpectomy? The choice of operation for clinical stages I and II breast cancer

- For patients with stage I or II breast cancer, breast-conserving surgery (BCS) followed by radiotherapy is generally recommended. In the absence of special reasons for selecting mastectomy, the choice between BCS and mastectomy can be made according to the patient's circumstances and personal preferences.
- Mastectomy should be considered in the presence of any of the following:
  - (a) factors that increase the risk of local recurrence such as extensive malignant-type calcifications visible on the mammogram, multiple primary tumours or failure to obtain tumour-free margins;
  - (b) physical disabilities that preclude lying flat or abducting the arm, thus preventing the use of radiotherapy;
  - absolute contraindications for radiotherapy such as pregnancy in the first or second trimester or previous irradiation of the breast, or relative contraindications such as systemic lupus erythematosus or scleroderma;
  - (d) large tumour size in proportion to breast size;
  - (e) the patient's clear preference for mastectomy.
- The following factors are not contraindications for BCS: the presence of a centrally located tumour mass, axillary lymph-node involvement or the presence of breast implants.

- In some cases, preoperative chemotherapy can shrink a large primary tumour and allow for BCS.
- Before deciding between BCS and mastectomy, the physician must make a full and balanced presentation to the patient concerning the pros and cons of these procedures.
- Whenever an open biopsy is performed on the basis of even modest suspicion of carcinoma, the procedure should be, in effect, a lumpectomy using wide local excision of the intact tumour surrounded by a cuff of tumour-free tissue (determined by palpation and visual inspection).
- The following recommendations should be observed to provide optimum clinical and cosmetic results:
  - (a) tumour-involved margins should be revised;
  - separate incisions should be used for removal of the primary tumour and for the axillary dissection except when these coincide anatomically;
  - (c) curvilinear incisions, concentric with the areolar margin, or transverse incisions are recommended over radial incisions;
  - (d) drains and approximation sutures should not be used in the breast parenchyma.

Additional experience with BCS has led to some refinements in surgical technique with respect to incision placement. In addition, it has become evident that the proportion of women eligible for BCS has increased. It is estimated that 80% of women with clinically detected tumours and nearly all women with mammographically iden-

Dr. Scarth is Assistant Professor in the Department of Surgery, Dalhousie University, and is with the Atlantic Health Sciences Corporation, Saint John, NB. Dr. Cantin is Associate Professor in the Department of Surgery, University of Montreal, and is with the Centre hospitalier de l'Université de Montréal, Montreal, Que. Dr. Levine is Professor in the Departments of Clinical Epidemiology and Biostatistics and of Medicine and is the Buffet Taylor Chair in Breast Cancer Research, McMaster University, Hamilton, Ont.

Competing interests: None declared.

Drs. Scarth, Cantin and Levine contributed equally to the writing and revising of this commentary.

tified tumours may be eligible for BCS.

## References

- Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer. Clinical practice guidelines for the care and treatment of breast cancer. CMAJ 1998;158(Suppl 3):S71-81. Available: www.cmaj.ca/cgi/content/full/158/3/DC1
- 2. Fisher B, Anderson S, Redmond CK, Wolmark M, Wickerham DL, Cronin

- WM. Reanalysis and results after 12 years of follow-up in a randomized clinical trial comparing total mastectomy with lumpectomy with or without irradiation in the treatment of breast cancer. N Engl J Med 1995;333:1456-61.
- Van Dongen JA, Voogd AC, Fentiman IS, Legrand C, Sylvester RJ, Tong D, et al. Long-term results of a randomized trial comparing breast-conserving therapy with mastectomy: European Organization for Research and Treatment of Cancer 10801 Trial. *J Natl Cancer Inst* 2000;92:1143-50.
  Van Dongen JA, Bartelink H, Fentiman IS, Lerut T, Mignolet F, Olthuis G,
- Van Dongen JA, Bartelink H, Fentiman IS, Lerut T, Mignolet F, Olthuis G, et al. Factors influencing local relapse and survival and results of salvage treatment after breast conserving therapy in operable breast cancer: EORTC Trial 10801, breast conservation compared with mastectomy in TNM stage I and II breast cancer. Eur J Cancer 1992;28A:801-5.
- Veronesi U, Luini A, Galimberti V, Zurrida S. Conservation approaches for the management of stage I/II carcinoma of the breast: Milan Cancer Institute trials. World J Surg 1994;18:70-5.
- Fisher ER, Dignam J, Tan-Chiu E, Constantino J, Fisher B, Paik S, et al. Pathologic findings from the NSABP eight-year update of protocol B-17: intraductal carcinoma. *Cancer* 1999;86:429-38.
- Fisher B, Dignam J, Wolmark N, Wickerham DL, Fisher ER, Mamounas E, et al. Tamoxifen in treatment of intraductal breast cancer: NSABP B-24 randomised controlled trial. *Lancet* 1999;353:1993-2000.
- Fisher B, Bryant J, Wolmark N, Mamounas E, Brown A, Fisher ER, et al. Effect of preoperative chemotherapy on the outcome of women with operable breast cancer. J Clin Oncol 1998;16:2672-85.
- Wolmark N, Wang J, Mamounas E, Bryant J, Fisher B. Preoperative chemotherapy in patients with operable breast cancer: nine-year results from National Surgical Adjuvant Breast and Bowel Project B-18. J Natl Cancer Inst Monogr 2001;30:96-102.
- 10. Van der Hage JA, van de Velde CJH, Julien JP, Tubiana-Hulin M, Van-

Correspondence to: Dr. Mark Levine, Rm. 9, Wing 90, Main floor, Henderson Hospital, 711 Concession St., Hamilton ON L8V 1C3; fax 905 389-9288