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Clinical Practice Guidelines - Breast Disease Site

Guideline Title:	Hormonal Treatment of In-situ Breast Carcinoma	**Date:**	**(O):**	Mar 31, 2011
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Tumor Group:	Breast Disease Site Group	**Page:**		1 of 4
Issuing Authority:	Dr. Kara Laing Clinical Chief, Cancer Care Program	**Date Signed:**		May 23, 2012
Adapted From:	New Zealand Guidelines Group "management of early breast cancer: evidence-based best practice guideline", 2009 (14).			

Introduction:

Ductal carcinoma in situ (DCIS) is a proliferation of 'malignant appearing' cells of the ducts and terminal lobule units of the breast. Its presence predisposes women to an increased risk of invasive cancer.

The potential benefit of using tamoxifen for in situ breast carcinoma would be primarily to help reduce the risk of developing invasive breast cancer. Tamoxifen may also have favorable effects on blood lipids and bone density. The risks, though relatively small, include development of endometrial cancers, thromboembolic events and cataract formation, while unpleasant side effects such as a notable increase in hot flashes are known to influence quality of life.

Patients are assessed for candidacy for hormone manipulation either by medical oncology, or occasionally by radiation oncology, during the consultation regarding breast irradiation. The oncologist will also determine whether the patient will require follow-up in the cancer center, or be followed by their family physician or referring physician.

Question:

What is the role of tamoxifen in the management of DCIS (Ductal Carcinoma In situ) and LCIS (Lobular Carcinoma In situ)?

Target Population:

These recommendations apply to patients with a diagnosis of DCIS or LCIS.

Supporting Evidence:

Presently, it is unclear whether or not testing for estrogen and progesterone receptors should be performed routinely on DCIS or LCIS specimens. The group recommends that testing should

not be performed on LCIS, since 99% are known to be estrogen and progesterone receptor positive (1). Currently, testing for hormone receptor status on DCIS/LCIS specimens is not standard practice, and limited retrospective evidence exists to suggest that knowing this result will affect the outcome (2). The American Society of Clinical Oncology/College of American Pathologists, however, believes that the result of this one retrospective study is "…scientifically reasonable and consistent with previous studies of invasive and metastatic breast cancer" but does acknowledge that there are unlikely to be any validation studies performed, therefore the decision for testing should be left up to the patient and physician (3). The Breast Disease Site Group has decided to **not** recommend carrying out routine receptor testing on DCIS. However, if an individual physician requests it, the pathology department will refer the specimen for testing to an outside laboratory on a case-by-case basis following referral.

The oncologist will discuss the treatment option of tamoxifen 20mg/daily, taken orally, for five years as per the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-24 clinical trial (4,5), with those patients deemed to be candidates. NSABP B-24 found that tamoxifen reduced the risk of both ipsilateral and contralateral breast recurrences. The proportional reduction of breast cancer events, in this study, was found to be approximately 38% with the addition of tamoxifen to standard treatment.

Patients with high grade DCIS, regardless of age should be considered for tamoxifen. Patients, including those less than 50 years of age, with low or moderate grade disease, may also be considered. Those patients who have undergone bilateral mastectomies, do not require tamoxifen. Those who have undergone a unilateral mastectomy may derive a small benefit for the remaining breast (6).

NSABP B-24 also revealed that tamoxifen may not be appropriate for patients with existing cardiovascular comorbidities such as stroke or deep vein thrombosis. In all cases, a discussion with the patient should include the potential risks associated with tamoxifen versus their individual benefit.

Recommendations:

All patients, with no contraindications, deemed to be candidates for hormonal treatment for DCIS or LCIS will be offered tamoxifen 20mg/daily, taken orally, for five consecutive years.

Search Strategy:

Literature searches, for this guideline, were conducted in Pubmed, CINAHL, and the Cochrane Library and using keywords "ductal carcinoma insitu," AND "breast" AND "tamoxifen". Guideline searches were also carried out on the websites of the world's most highly respected cancer organizations and agencies. All selected literature articles and source guidelines were in English and dated after the year 2000 (unless the selection was an earlier landmark study) up to March 2011. The inclusion/exclusion process consisted of selecting guidelines from reputable cancer organizations with preference given to those from Canadian sources, where possible. Eleven source guidelines were identified but only five were chosen to be reviewed due to currency of content (7-17).

The five identified source guidelines (13-17) were put through the ADAPTE process (18) (including an AGREE assessment) (19), and the New Zealand Guidelines Group (NZGG) "management of early breast cancer: evidence-based best practice guideline" was chosen to be adapted for use in our guideline (14). The NZGG guideline was selected as the optimal choice due to its applicability, quality and currency of content.
There has been much debate but no consensus on the 'grading of evidence' in Canada. Presently, Canadian experts in the field of guideline development are involved in an ongoing in-depth analysis of the functionality of grading. Until such time as a report is released of their findings, and a consensus reached on whether to assign a grade of recommendation to a guideline, this group has decided to forgo the use of grading.

No competing or conflicts of interest were declared.

Disclaimer:

These guidelines are a statement of consensus of the Breast Disease Site Group regarding their views of currently accepted approaches to diagnosis and treatment. Any clinician seeking to apply or consult the guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

Contact Information:

For more information on this guideline, please contact Dr. Joy McCarthy MD FRCPC, Dr. H. Bliss Murphy Cancer Center, St. John's, NL; Telephone 709-777-8515. For access to any of our guidelines, please visit our Cancer Care Program website at www.easternhealth.ca

Literature Support:

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