

## Guideline 1-10 Version 4

## A Quality Initiative of the Program in Evidence-Based Care (PEBC), Ontario Health (Cancer Care Ontario)

# Management of Ductal Carcinoma in Situ of the Breast

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# Management of Ductal Carcinoma in Situ of the Breast

## Section 1: Recommendations

This section is a quick reference guide and provides the guideline recommendations only. For key evidence associated with each recommendation, see <u>Section 2</u>.

#### **GUIDELINE OBJECTIVES**

The objective of this guideline was to determine the most effective therapy options for patients with ductal carcinoma in situ (DCIS) of the breast.

#### TARGET POPULATION

These recommendations apply to women with DCIS, including women with DCIS with microinvasion (DCIS-M) (< 1 mm through the duct).

#### **INTENDED USERS**

Intended users of this guideline are clinicians and other healthcare professionals involved in the management of patients with DCIS.

#### RECOMMENDATIONS, KEY EVIDENCE, AND JUSTIFICATION

#### A) Primary Treatment of DCIS: Surgical Treatment

#### Recommendation 1

1.1. Women with DCIS of the breast (with or without microinvasion) who are candidates for BCS should be offered the choice of BCS or mastectomy with the option of reconstruction. The decision of whether to have one surgery over another should be made in consultation with the patient and should consider the balance of benefits and risks and patient preferences.

#### **Qualifying Statements for Recommendations 1**

- Benefits and harms may vary depending on patient and disease characteristics such as patient factors/comorbidities, patient's preferences, tumour characteristics, life expectancy, and any contraindication to or unwillingness to receive radiation therapy (RT).
- When BCS is performed, all mammographically suspicious calcifications should be removed and margins should be microscopically clear of DCIS. RT options after BCS are described in Recommendation 5 below.
- The option of immediate lumpectomy reconstruction in the case of BCS should be offered if a patient is deemed an appropriate candidate.
- Mastectomy, with the option of reconstruction (immediate or delayed), should be considered for those women who have an area of DCIS large enough that BCS would leave them with an unacceptable cosmetic result.
- Patients eligible for genetic testing should be referred so that results may be considered before a surgical treatment plan is finalized (this may include a bilateral risk-reducing mastectomy).
- Active surveillance is an area of ongoing investigation; it is not a standard option currently. This might be an area of consideration for certain patients.

• The use of imaging modalities to assess for residual disease in patients with positive markings post BCS is outsider the scope of this guideline. The Working Group consensus favours positive margins being treated surgically given perceived low sensitivity for detecting residual disease versus postoperative changes in patients having undergone recent surgery with all imaging modalities.

#### Recommendation 2

2.1. In patients undergoing BCS or mastectomy, a margin width of at least 2mm is optimal to minimize the risk of local recurrence (LR).

#### Qualifying Statements for Recommendations 2

- It remains entirely appropriate in pathology practice to report only DCIS at inked margin as "positive", and to provide distance to closest margin(s) when margins are negative.
- DCIS-M should be considered as DCIS when considering the optimal margin width and additional surgery.
- Patients who have close or positive margins are directed to the recommendation on the benefits of re-excision prior to receiving RT.

#### Recommendation 3

3.1. In patients with negative margins (at least 2 mm) undergoing BCS, routine additional surgery may not be warranted for patients if undergoing RT, but re-excision of wider excisions should be considered if the patients forego RT.

3.2. In patients with close margins (<2 mm) from BCS or mastectomy, a discussion should occur with the patient to weigh the risks of further surgery (re-excision or mastectomy) with the risk of recurrence for the individual patient. Patients with close margins where re-excision versus boost RT is being considered should be discussed in multidisciplinary discussions involving surgical and radiation oncologists to tailor the optimal treatment plan.

3.3. In patients with positive margins from BCS or mastectomy, re-excision should be considered as soon as information is available.

#### Qualifying Statements for Recommendation 3

- The potential risks of cancer recurrence versus additional surgical procedures should be discussed between the patient and surgeon.
- Benefits and harms of re-excision may vary depending on patient and disease characteristics such as patient factors/comorbidities, patient's preferences, tumour characteristics, life expectancy, and any contraindication to or unwillingness to receive RT.
- For patients whose close or positive margins are anterior or posterior, there may be no benefit for reexcision in areas where there is no remaining breast tissue. Multidisciplinary discussion is encouraged to discuss the benefit of boost RT.
- DCIS-M should be considered as DCIS when considering margin width and additional surgery.

### B) Primary Treatment of DCIS: Surgical Treatment and/or RT

#### Recommendation 4

4.1. There are insufficient data to recommend or not recommend molecular profile testing as routine standard practice in women with DCIS. Molecular profile testing should only be performed as part of a research study.

#### Recommendation 5

5.1. Women with DCIS who have undergone BCS with negative margins should be offered adjuvant WBI (regardless of the grade of DCIS).

5.2. Women with DCIS who have undergone BCS with close margins (< 2mm) for whom reexcision surgery was not performed, multidisciplinary discussion regarding the option of radiation boost in addition to WBI to optimize local control should occur.

5.3. Post-mastectomy radiation therapy (PMRT) is not indicated for women with DCIS who have undergone mastectomy but may be considered if there are multiple positive margins (tumour on ink), that cannot be surgically excised.

#### Qualifying Statements for Recommendation 5

- The potential risks of cancer recurrence versus adjuvant irradiation should be discussed between the patient and clinicians post BCS and post-mastectomy. Fully informed patients with low-risk DCIS may prefer to avoid RT.
- Hypofractionated RT (HFRT) of 42.5 Gy in 16 fractions for 3.5 weeks or equivalent regimen (e.g., 40 Gy in 15 fractions in 3 weeks) should be offered. We acknowledge that even shorter regimens (e.g., 26 Gy in 5 fractions in 1 week) may also be offered (see recommendation justification below).
- Although there was a benefit for boost across all patients' subtypes, the dose of 16 Gy in eight fractions may be associated with increased toxicity over time and the risks and benefits of a boost need to be weighed, as well as other potential options using lower doses (10 Gy/4-5 fractions to 16 Gy/8 fractions).
- The risk of adverse effects associated with tumour bed boost following WBI should be discussed.
- For patients with low-risk DCIS patients with mammographically detected low or intermediate-grade DCIS measuring 2cm or less and who are 40 years old or older, partial breast irradiation (PBI) may be considered.
- It was the expert opinion of the Working Group that one could safely extrapolate the benefits of adjuvant radiation with more than 5cm of DCIS where complete excision is achieved. Patients were originally excluded from these studies [12,13] because advanced surgical breast conserving techniques did not exist at that time (e.g. oncoplastic reduction mammoplasty). In these cases, multidisciplinary discussion is encouraged for those presenting with more than 5 cm of disease.
- There is a lack of data around adding adjuvant chestwall irradiation after mastectomy as close or positive margin after mastectomy is quite rare. There are however studies showing higher risk of LR in patients with close or positive margins compared to negative margins [5,6]. It is not clear if PMRT is beneficial in this setting given there are few studies that specifically examine the LR risk post-mastectomy with positive margins with or without PMRT. Furthermore, while close or positive margins increase the risk of LR in this setting, overall, the LR risk is relatively low (5.3%) [6]. It was the expert opinion that PMRT is not indicated in this setting, but it is reasonable to consider chestwall irradiation in patients who have undergone mastectomy with multiple positive margins (tumour on ink) that cannot be surgically excised.

### C) Management of DCIS after Primary Treatment

#### Recommendation 6

6.1. The risks and benefits of endocrine therapy, either tamoxifen or an aromatase inhibitor, after BCS should be discussed for women with estrogen receptor (ER)-positive DCIS.

#### Qualifying Statements for Recommendation 6

- This does not pertain for women with bilateral mastectomy for DCIS, but is relevant for unilateral mastectomy, whether they have had or not had RT.
- Possible risks could include increased toxicity and adverse events, with no survival benefit. There are higher reported rates of endometrial, ovarian, and non-melanoma skin cancer in tamoxifen use and higher rates of fractures, strokes and transient ischemic events with aromatase inhibitors use.
- Possible benefits include prevention of ipsilateral recurrences and contralateral events. This is true for pre-invasive and invasive disease.
- Tamoxifen or aromatase inhibitor for five years taken as once-daily tablet.
- For post-menopausal women younger than 60 years of age, there may be a greater benefit to anastrozole compared to tamoxifen.
- Shared decision-making process to discuss individual risk patient value, preference of agent, duration of agent, and cost.