

CADTH Reference List

# Whole-Breast Radiotherapy as Part of Breast-Conserving Therapy

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## Key Messages

- No evidence was identified about the clinical effectiveness of hypofractionated whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer.
- Four evidence-based guidelines regarding whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer was identified.

## Research Questions

1. What is the clinical effectiveness of hypofractionated whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer?
2. What are the evidence-based guidelines regarding whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer?

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were breast cancer, radiotherapy, hypofractionation, and breast-conserving therapy. CADTH-developed search filters were applied to limit retrieval to guidelines for a secondary search of the concepts breast cancer and radiotherapy. Comments, newspaper articles, editorials and letters were excluded. The search was completed on June 22, 2022 and limited to English-language documents published since January 2017. Internet links were provided, where available.

### Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in [Table 1](#). Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications. Open access full-text versions of evidence-based guidelines were reviewed when available, and relevant recommendations were summarized.

## Results

Four evidence-based guidelines addressing whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer were identified for this report.<sup>1-4</sup> No health

**Table 1: Selection Criteria**

| Criteria             | Description   |
|----------------------|---|
| <b>Population</b>    | People (aged $\geq 50$ years) with breast cancer who have had breast-conserving surgery (i.e., lumpectomy)  |
| <b>Intervention</b>  | Q1. Whole-breast radiotherapy delivered with a hypofractionated radiation schedule (i.e., $< 25$ fractions over $< 5$ weeks of therapy) as part of breast-conserving therapy<br>Q2. Whole-breast radiotherapy as part of breast-conserving therapy  |
| <b>Comparator</b>    | Q1. Whole-breast radiotherapy delivered with a conventionally fractionated radiation schedule (e.g., $\geq 25$ fractions, over 5 to 6 weeks) as part of breast-conserving therapy<br>Q2. Not applicable   |
| <b>Outcomes</b>      | Q1. Clinical benefits (e.g., local [and regional] recurrence [breast tumour relapse], relapse-free survival, normal tissue effects, cosmetic outcome [clinician- and patient- reported], function, quality of life, patient preference) and harms (e.g., mortality, toxicity, breast pain, breast induration, fatigue, unwanted cosmetic changes, other adverse events)<br>Q2. Recommendations regarding best practices (e.g., appropriate time courses of therapy, considerations for shorter schedules) |
| <b>Study designs</b> | Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, evidence-based guidelines  |

technology assessments, systematic reviews, randomized controlled trials or non-randomized studies were identified about the clinical effectiveness of hypofractionated whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer.

Additional references of potential interest that did not meet the inclusion criteria are provided in [Appendix 1](#).

## Overall Summary of Findings

Four evidence-based guidelines addressing whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer were identified.<sup>1-4</sup> Whole-breast radiotherapy is generally considered safe and is recommended as a part of breast-conserving therapy<sup>1,2,4</sup>. All guidelines<sup>1-4</sup> recommend a hypofractionated radiation schedule for people who are receiving whole-breast radiotherapy and have had breast-conserving treatment. Three guidelines<sup>1-3</sup> discussed the use of a boost for those who are receiving whole-breast radiotherapy and have had breast-conserving treatment. A detailed summary of the recommendations and their corresponding strength and evidence quality is presented in [Table 2](#).

No relevant literature was found regarding the clinical effectiveness of hypofractionated whole-breast radiotherapy as part of breast-conserving therapy in people with breast cancer; therefore, no summary can be provided.

**Table 2: Summary of Recommendations in Included Guidelines**

| Summary of recommendations   | Quality of evidence and strength of recommendations  |
|--|--|
| <b>Meattini et al. (2022)<sup>1</sup></b>  |  |
| <p>“Moderate hypofractionated whole breast irradiation should be offered regardless of:</p> <ul style="list-style-type: none"> <li>I. age at breast cancer diagnosis</li> <li>II. pathological tumour stage</li> <li>III. breast cancer biology</li> <li>IV. surgical margins status</li> <li>V. tumour bed boost</li> <li>VI. breast size</li> <li>VII. invasive or pre-invasive ductal carcinoma in situ disease.</li> <li>VIII. oncoplastic breast-conserving surgery</li> <li>IX. use of systemic therapy.”</li> </ul> | <p>Rather than grading evidence and evaluating the strength of recommendation, consensus from the panel was established.</p> <ul style="list-style-type: none"> <li>I. 91.3% Consensus agreement; Strong consensus</li> <li>II. 91.3% Consensus agreement; Strong consensus</li> <li>III. 91.3% Consensus agreement; Strong consensus</li> <li>IV. 100% Consensus agreement; Unanimous consensus</li> <li>V. 100% Consensus agreement; Unanimous consensus</li> <li>VI. 91.3% Consensus agreement; Strong consensus</li> <li>VII. 91.3% Consensus agreement; Strong consensus</li> <li>VIII. 91.3% Consensus agreement; Strong consensus</li> <li>IX. 95.6% Consensus agreement; Strong consensus</li> </ul> |
| <p>“Ultrahypofractionated (26 Gy in five fractions) whole breast irradiation can be offered as (1) standard of care or (2) within a randomized controlled trial or prospective registration cohort.”</p>   | <p>86.9% Consensus agreement; Consensus</p>  |
| <b>Biganzoli et al. (2021)<sup>2</sup></b>   |  |
| <p>“WBRT remains the standard of care for most older patients following BCS and omission of radiotherapy in low-risk patients can be safe and reasonable; in patients older than 60 years, the use of a boost is advised only for those at higher risk of recurrence.”</p>   | <p>Level 1 (requires at least a RCT as part of the collection of studies, with overall good quality and consistency, and support for the clinical recommendation)</p>  |
| <p>“Hypofractionated schedules (40 Gy in 15 fractions over 3 weeks, 42.5 Gy in 16 fractions over 3.5 weeks or 26 Gy in five fractions over 1 week) are recommended for older patients.”</p>  | <p>Level 4 (requires expert judgment, particularly in the absence of good quality, relevant clinical studies)</p>  |
| <b>Cancer Australia (2020)<sup>3</sup></b>   |  |
| <p>“In patients who have undergone breast-conserving surgery and who are at high risk of local recurrence (age ≤50 years with any grade, age 51-70 years with higher grade, or a positive margin), offer radiation therapy boost following whole-breast radiation therapy.”</p>  | <p>NR</p>  |
| <p>“Offer a hypofractionated course of radiation therapy to women with breast cancer who have undergone breast-conserving surgery with clear surgical margins and who require post-operative whole breast radiation therapy.”</p>  | <p>NR</p>  |

| Summary of recommendations   | Quality of evidence and strength of recommendations           |
|--|---|
| <b>Brazilian Society of Radiotherapy (2018)<sup>4</sup></b>  |   |
| <p>“Hypofractionated radiotherapy is considered to be safe and effective for women who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• have underwent conservative treatment for breast cancer</li> <li>• are over 50 years old</li> <li>• have invasive carcinoma of no special type, grades I and II</li> <li>• have clinical stages T1 and T2</li> <li>• have negative axillary lymph nodes</li> <li>• experience no particularity regarding the laterality of the affected breast</li> <li>• experience no restriction regarding the immunohistological profile (patients with positive hormone receptors, HER2 super-expressed or triple negative)”.</li> </ul> | <p>Level of agreement: 100%<br/>Level of evidence: Strong</p> |
| <p>“The models of moderate fractionation of 42.5 Gy in 16 fractions and of 40 Gy in 15 fractions are equally safe and effective.”</p>  | <p>Level of agreement: 100%<br/>Level of evidence: Strong</p> |

BCS = breast-conserving surgery; HER2 = human epidermal growth factor receptor-2; NR = not reported; RCT = randomized controlled trial; WBRT = whole-breast radiotherapy.

## References

### Health Technology Assessments

No literature identified.

### Systematic Reviews

No literature identified.

### Randomized Controlled Trials

No literature identified.

### Non-Randomized Studies

No literature identified.

### Guidelines and Recommendations

1. Meattini I, Becherini C, Boersma L, et al. European Society for Radiotherapy and Oncology Advisory Committee in Radiation Oncology Practice consensus recommendations on patient selection and dose and fractionation for external beam radiotherapy in early breast cancer. *Lancet Oncol.* 2022;23(1):e21-e31. [PubMed](#)  
See: Panel: Final consensus statements, 1. Whole breast irradiation, p. e25
2. Biganzoli L, Battisti NML, Wildiers H, et al. Updated recommendations regarding the management of older patients with breast cancer: a joint paper from the European Society of Breast Cancer Specialists (EUSOMA) and the International Society of Geriatric Oncology (SIOG). *Lancet Oncol.* 2021;22(7):e327-e340. [PubMed](#)  
See: Radiotherapy, p. e329d
3. Cancer Australia. Guidance for the management of early breast cancer: recommendations and practice points. Surry Hills (NSW): Cancer Australia; 2020: [https://www.canceraustralia.gov.au/sites/default/files/publications/guidance-management-early-breast-cancer-recommendations-and-practice-points/pdf/guidance\\_for\\_the\\_management\\_of\\_early\\_breast\\_cancer\\_recommendations\\_and\\_pps\\_2020.pdf](https://www.canceraustralia.gov.au/sites/default/files/publications/guidance-management-early-breast-cancer-recommendations-and-practice-points/pdf/guidance_for_the_management_of_early_breast_cancer_recommendations_and_pps_2020.pdf). Accessed 2022 Jun 28.  
See: Second and Fifth "Recommendation" box under Radiation therapy after breast-conserving surgery, p.20
4. Brazilian Society of Radiotherapy (SBRT), Freitas NMA, Rosa AA, et al. Recommendations for hypofractionated whole-breast irradiation. *Rev Assoc Med Bras.* 2018;64(9):770-777. [PubMed](#)  
See: Section I – Optimal scenario for the indication of whole-breast hypofractionated RR, p. 772

## Appendix 1: References of Potential Interest

### Systematic Reviews

#### *Population Age Not Specified*

5. Andrade TRM, Fonseca MCM, Segreto HRC, Segreto RA, Martella E, Nazario ACP. Meta-analysis of long-term efficacy and safety of hypofractionated radiotherapy in the treatment of early breast cancer. *Breast*. 2019;48:24-31. [PubMed](#)
6. Valle LF, Agarwal S, Bickel KE, Herchek HA, Nalepinski DC, Kapadia NS. Hypofractionated whole breast radiotherapy in breast conservation for early-stage breast cancer: a systematic review and meta-analysis of randomized trials. *Breast Cancer Res Treat*. 2017;162(3):409-417. [PubMed](#)

#### *Unclear Intervention - Whole-Breast Radiotherapy Not Specified*

7. Marta GN, Riera R, Pacheco RL, et al. Moderately hypofractionated post-operative radiation therapy for breast cancer: systematic review and meta-analysis of randomized clinical trials. *Breast*. 2022;62:84-92. [PubMed](#)

### Randomized Controlled Trials

#### *Mixed Population – Older and Younger Than 50 Years of Age*

8. Offersen BV, Alsner J, Nielsen HM, et al. Hypofractionated versus standard fractionated radiotherapy in patients With early breast cancer or ductal carcinoma In situ in a randomized phase III trial: the DBCG HYPO Trial. *J Clin Oncol*. 2020;38(31):3615-3625. [PubMed](#)

#### *Population Age Not Specified*

9. Arsenault J, Parpia S, Goldberg M, et al. Acute toxicity and quality of life of hypofractionated radiation therapy for breast cancer. *Int J Radiat Oncol Biol Phys*. 2020;107(5):943-948. [PubMed](#)
10. Schmeel LC, Koch D, Schmeel FC, et al. Acute radiation-induced skin toxicity in hypofractionated vs. conventional whole-breast irradiation: an objective, randomized multicenter assessment using spectrophotometry. *Radiother Oncol*. 2020;146:172-179. [PubMed](#)
11. Wang SL, Fang H, Hu C, et al. Hypofractionated versus conventional fractionated radiotherapy after breast-conserving surgery in the modern treatment era: a multicenter, randomized controlled trial from China. *J Clin Oncol*. 2020;38(31):3604-3614. [PubMed](#)
12. Zhao S, Liu Y, Huang F, Chen X, Cao X, Yu J. The long-term outcome of adjuvant hypofractionated radiotherapy and conventional fractionated radiotherapy after breast-conserving surgery for early breast cancer: a prospective analysis of 107 cases. *J Thorac Dis*. 2017;9(10):3840-3850. [PubMed](#)

#### *Unclear Intervention – Number of Weeks of Radiotherapy Not Specified*

13. Weng JK, Lei X, Schlembach P, et al. Five-year longitudinal analysis of patient-reported outcomes and cosmesis in a randomized trial of conventionally fractionated versus hypofractionated whole-breast irradiation. *Int J Radiat Oncol Biol Phys*. 2021;111(2):360-370. [PubMed](#)

### Non-Randomized Studies

#### *Alternative Population – People Older and Younger than 50 Years of Age*

14. Meattini I, Poortmans P, Kirova Y, et al. Hypofractionated whole breast irradiation after conservative surgery for patients aged less than 60 years: a multi-centre comparative study. *Acta Oncol*. 2020;59(2):188-195. [PubMed](#)

#### *Population Age Not Specified*

15. Chuang WK, Cheng SH, Hung CF, et al. Comparison between the use of hypofractionated and conventionally fractionated radiotherapy in early breast cancer: a single-center real-world study in Taiwan. *J Formosan Med Assoc*. 2022. [PubMed](#)
16. Lee A, Kim HY, Kim TH, et al. Hypofractionated radiotherapy for early-stage breast cancer: a propensity score matched analysis. *J Korean Med Sci*. 2022;37(8):e64. [PubMed](#)
17. De Rose F, De Santis MC, Meduri B, et al. Comparing hypofractionated and conventionally fractionated whole breast irradiation for patients with ductal carcinoma in situ after breast conservation: a propensity score-matched analysis from a national multicenter cohort (COBCG-02 study). *J Cancer Res Clin Oncol*. 2021;147(7):2069-2077. [PubMed](#)
18. Dong J, Yang Y, Han D, et al. Hypofractionated simultaneous integrated boost radiotherapy versus conventional fractionation radiotherapy of early breast cancer after breast-conserving surgery: clinical observation and analysis. *Technol Cancer Res Treat*. 2021;20:15330338211064719. [PubMed](#)
19. Saksornchai K, Jaruthien T, Nantavithya C, Shotelersuk K, Rojpornpradit P. Long-term results of hypofractionation with concomitant boost in patients with early breast cancer: a prospective study. *PLoS ONE*. 2021;16(10):e0258186. [PubMed](#)
20. Yoshida-Ichikawa Y, Horimoto Y, Shikama N, et al. Ipsilateral breast tumor control following hypofractionated and conventional fractionated whole-breast irradiation for early breast cancer: a long-term follow-up. *Breast Cancer*. 2021;28(1):92-98. [PubMed](#)
21. Lertbutsayanukul C, Pitak M, Ajchariyasongkram N, Rakkiet N, Seuree F, Prayongrat A. Long-term patient-rated cosmetic and satisfactory outcomes of early breast cancer treated with conventional versus hypofractionated breast irradiation with simultaneous integrated boost technique. *Breast J*. 2020;26(10):1946-1952. [PubMed](#)

22. Butler-Xu YS, Marietta M, Zahra A, TenNapel M, Mitchell M. The effect of breast volume on toxicity using hypofractionated regimens for early stage breast cancer for patients. *Adv Radiat Oncol*. 2019;4(2):261-267. [PubMed](#)
23. Kawaguchi H, Tsujino K, Miki M, et al. Patient preference study comparing hypofractionated versus conventionally fractionated whole-breast irradiation after breast-conserving surgery. *Jap J Clin Oncol*. 2019;49(6):545-553. [PubMed](#)
24. Yamazaki H, Takenaka T, Aibe N, et al. Comparison of radiation dermatitis between hypofractionated and conventionally fractionated postoperative radiotherapy: objective, longitudinal assessment of skin color. *Sci Rep*. 2018;8(1):12306. [PubMed](#)

### **Unclear Intervention – Number of Weeks of Radiotherapy Not Specified**

25. Sarria GR, Welzel G, Polednik M, Wenz F, Abo-Madyan Y. Prospective comparison of hypofractionated versus normofractionated intensity-modulated radiotherapy in breast cancer: late toxicity results of the Non-Inferiority KOSIMA trial (ARO2010-3). *Front Oncol*. 2022;12:824891. [PubMed](#)
26. Isfahanian N, Al-Hajri T, Marginean H, Chang L, Caudrelier JM. Hypofractionation is an acceptable alternative to conventional fractionation in the treatment of postlumpectomy ductal carcinoma in situ with radiotherapy. *Clin Breast Cancer*. 2017;17(2):e77-e85. [PubMed](#)

### **Mixed Population – People who have had a Lumpectomy or Mastectomy**

27. Issoufaly I, Petit C, Guihard S, et al. Favorable safety profile of moderate hypofractionated over normofractionated radiotherapy in breast cancer patients: a multicentric prospective real-life data farming analysis. *Radiat Oncol*. 2022;17(1):80. [PubMed](#)

### **Alternative Population – Age and Breast-Conserving Surgery Not Specified**

28. Jagsi R, Griffith KA, Vicini F, et al. Toward improving patients' experiences of acute toxicity from breast radiotherapy: insights from the analysis of patient-reported outcomes in a large multicenter cohort. *J Clin Oncol*. 2020;38(34):4019-4029. [PubMed](#)

### **Alternative Outcome – Timely Completion of Radiotherapy**

29. Lamm R, Woodward SG, Varshney K, et al. A comparison of timely completion of hypofractionated and traditional adjuvant radiation therapy in early-stage breast cancer: evidence of impact on reducing racial and socioeconomic disparities. *Surgery*. 2022;172(1):31-40. [PubMed](#)

## **Guidelines and Recommendations**

### **Unclear Methodology**

30. Royal College of Radiologists. Postoperative radiotherapy for breast cancer: hypofractionation: RCR consensus statements. 2021; <https://www.rcr.ac.uk/publication/postoperative-radiotherapy-breast-cancer-hypofractionation-rcr-consensus-statements>. Accessed 2022 Jun 28.
31. Coles CE, Aristei C, Bliss J, Boersma L, Brunt AM, Chatterjee S, et al. International guidelines on radiation therapy for breast cancer during the COVID-19 pandemic. *Clin Oncol (R Coll Radiol)*. 2020;32(5):279-281. [PubMed](#)  
See: 4. Nodal RT can be omitted in post-menopausal women requiring whole breast RT following sentinel lymph node biopsy and primary surgery for T1, ER positive, HER2 negative G1-2 tumours with 1-2 macrometastases, p.280
32. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology (NCCN guidelines): breast cancer. Version 5.2020. Plymouth Meeting (PA): NCCN; 2020 July 15: <https://www2.tri-kobe.org/nccn/guideline/breast/english/breast.pdf>. Accessed 2022 Jun 28.  
See: Whole Breast Radiation, p.BINV-I; Radiation Therapy after Lumpectomy in Older Adults

### **Population Age Unclear**

33. Cardoso F, Kyriakides S, Ohno S, Penault-Llorca F, Poortmans P, Rubio IT, et al. Early breast cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2019;30(8):1194-1220. [PubMed](#)  
See: Surgery for in situ malignancy, Recommendations, p. 1201-1202; Whole-breast RT after BCS, p. 1202-1203; RT for in situ malignancy, Recommendations, p.1204.
34. National Institute for Health and Care Excellence. Early and locally advanced breast cancer: diagnosis and management. London(UK): NICE; 2018: <https://www.nice.org.uk/guidance/ng101/resources/early-and-locally-advanced-breast-cancer-diagnosis-and-management-pdf-66141532913605>. Accessed 2022 Jun 28.  
See: 1.10.3 Offer whole-breast radiotherapy to women with invasive breast cancer who have had breast-conserving surgery with clear margins.

### **Whole-Breast Radiotherapy Not Specified**

35. Eraso, A., Sanz, J., Mollà, M. et al. Evidence-based guidelines for hypofractionated radiation in breast cancer: conclusions of the Catalan expert working group. *Clin Transl Oncol*. 2022. [PubMed](#)
36. German Guideline Program in Oncology (GGPO). Evidence-based guideline for the early detection, diagnosis, treatment and follow-up of breast cancer. Version 4.4. 2021; [https://www.leitlinienprogramm-onkologie.de/fileadmin/user\\_upload/S3\\_Guideline\\_Breast\\_Cancer.pdf](https://www.leitlinienprogramm-onkologie.de/fileadmin/user_upload/S3_Guideline_Breast_Cancer.pdf). Accessed 2022 Jun 28.  
See: 4.4.2 Breast Conserving therapy, p. 87-88; Fractionation, 4.87 Evidence-based Recommendation, p.134

### **Breast-Conserving Surgery Not Specified in Relation to Whole-Breast Radiotherapy**

37. Yamauchi C, Yoshimura M, Sekiguchi K, et al. The Japanese Breast Cancer Society clinical practice guideline for radiation treatment of breast cancer, 2018 edition. *Breast Cancer*. 2020;27(1):9-16. [PubMed](#)  
See: CQ1: In WBI, is hypofractionated RT recommended as an equivalent treatment than conventional fractionation?, p.2
38. Smith BD, Bellon JR, Blitzblau R, et al. Radiation therapy for the whole breast: executive summary of an American Society for Radiation Oncology (ASTRO) evidence-based guideline. *Pract Radiat Oncol*. 2018;8(3):145-152. [PubMed](#)

## Additional References

39. Gu L, Dai W, Fu R, et al. Comparing hypofractionated with conventional fractionated radiotherapy after breast-conserving surgery for early breast cancer: a meta-analysis of randomized controlled trials. *Front Oncol.* 2021;11:753209. [PubMed](#)