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HYPOFRACTIONATED VERSUS CONVENTIONAL RADIOTHERAPY IN BREAST CANCER: AN INTEGRATIVE REVIEW

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ABSTRACT

Introduction: adjuvant radiotherapy is an essential component of locoregional control in breast cancer, but the conventional schedule of 50 Gy in 25 fractions requires five weeks of daily treatment, imposing high costs on patients and pressure on services with limited equipment capacity.
Objectives: to analyse the evidence comparing hypofractionated schedules with conventional fractionation in women who underwent surgery for breast cancer.
Methods: integrative review with a structured search of the PubMed database, covering randomised clinical trials, systematic reviews and meta-analyses published between 2008 and 2024; selection was carried out independently by two reviewers, with disagreements resolved by consensus.
Results: of the 436 records retrieved, 12 made up the final sample, comprising eight randomised clinical trials, which included around 14 thousand patients treated in Europe, North America and Asia, and four systematic reviews or meta-analyses. Hypofractionated schedules, particularly 40 Gy in 15 fractions delivered over three weeks, were not inferior to the conventional schedule in tumour control, overall survival or disease-free survival. Acute and late toxicity was equivalent or more favourable in the hypofractionated arms, and aesthetic outcomes did not differ between groups.
Conclusions: the evidence supports moderate hypofractionation as the preferred schedule for most patients with an indication for adjuvant breast irradiation, with relevant implications for widening access to treatment in public health systems.

Keywords: Radiation dose fractionation, Hypofractionation of radiation dose, Breast neoplasms, Adjuvant radiotherapy, Segmental mastectomy.

INTRODUCTION

Every year, approximately 2.3 million women are diagnosed with breast cancer, making it the most common malignancy among women worldwide. Adjuvant radiotherapy is an essential component of breast-conserving treatment, as it reduces locoregional recurrence by 50% to 75% and contributes to improved overall survival, as demonstrated by the meta-analysis conducted by the Early Breast Cancer Trialists' Collaborative Group, which pooled individual patient data from 10,801 women.[1]

For many years, the standard treatment consisted of 50 Gy delivered in 25 fractions over five weeks. Although effective, this regimen poses practical challenges related to patient adherence due to its prolonged duration and to the capacity of radiotherapy services to deliver treatment sessions within the prescribed timeframe. In this context, hypofractionation emerged as an established approach: increasing the dose per fraction, reducing the total number of treatment sessions, and adjusting the total dose. The rationale for this approach is based on the linear-quadratic model, according to which tissues with a low alpha/beta ratio, as appears to be the case for breast cancer, estimated at between 3.0 and 4.6 Gy, tend to respond to increases in fraction size similarly to late-responding normal tissues.[2–4]

Over the past two decades, several large randomized trials have tested this hypothesis, and the accumulating evidence has led international organizations to recommend hypofractionation as the preferred treatment option.[5] Nevertheless, its adoption in clinical practice varies considerably across regions and countries. This gap between the available evidence and clinical practice is particularly relevant in public healthcare systems with limited radiotherapy capacity, where the number of fractions per patient effectively determines how many individuals can receive treatment within a given period.

The contribution of this review lies in bringing together, in a single synthesis, evidence from randomized trials and secondary evidence syntheses conducted in widely differing healthcare settings, encompassing the two relevant surgical scenarios: breast-conserving surgery and mastectomy. The objective was to analyze the evidence comparing hypofractionated regimens with conventional fractionation in women who underwent surgery for breast cancer, considering oncological outcomes, acute and late toxicity, and cosmetic outcomes.

METHODS

This is an integrative literature review based on the methodological framework proposed by Whittemore and Knafl[6] and guided by the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[7]

The research question was structured according to the PICO strategy: in women with breast cancer who underwent surgery (P), does hypofractionated adjuvant radiotherapy (I), compared with conventional fractionation of 50 Gy in 25 fractions (C), yield equivalent oncological, toxicity, and cosmetic outcomes (O)? Accordingly, the population comprised patients with breast cancer who received adjuvant radiotherapy following breast-conserving surgery or mastectomy; the intervention included moderately hypofractionated or ultrahypofractionated regimens; the comparator was conventional fractionation; and the outcomes included locoregional control, overall survival, disease-free survival, acute and late toxicity, and cosmetic outcomes.

The search was conducted in the PubMed/MEDLINE database between October and December 2024, combining Medical Subject Headings (MeSH) descriptors with free-text terms according to the following strategy: (breast neoplasms OR breast cancer) AND (radiotherapy OR radiation therapy) AND (dose fractionation, radiation OR hypofractionated OR hypofractionation) AND (conventional fractionation OR standard fractionation OR whole breast irradiation). Additional searches were performed using the names of specific clinical trials and examining the reference lists of retrieved articles.

Randomized clinical trials comparing hypofractionated and conventional radiotherapy

in patients who had undergone surgery for breast cancer were included, as well as systematic reviews and meta-analyses of these trials, published in English between January 2008 and December 2024, with a minimum sample size of 50 participants. Nonrandomized studies; investigations of partial breast irradiation, neoadjuvant or palliative radiotherapy; secondary analyses that did not provide new outcomes from previously included trials; duplicate publications; conference abstracts, editorials, letters to the editor, and protocols without results; and studies involving fewer than 50 participants were excluded.

Two reviewers worked independently in two stages: screening of titles and abstracts, followed by full-text assessment of potentially eligible articles. Disagreements were resolved by consensus. Extracted data (author, year, country, study design, sample size, fractionation regimen, outcomes, and follow-up duration) were recorded using a standardized form. The findings were synthesized narratively and organized by theme, without quantitative pooling due to heterogeneity among the studies; no statistical analyses were performed.

As this was a literature review conducted exclusively using previously published and publicly available data, the study did not require review by a Research Ethics Committee.

During the preparation of this manuscript, the authors used Claude (Anthropic) for linguistic review, grammatical correction, and textual organization of the manuscript. The tool was not used for literature searching, study selection, data extraction, or interpretation of the findings. After using the tool, the authors reviewed and edited the content as necessary, ensuring the absence of plagiarism and assuming full responsibility for its content.

RESULTS

Of the 436 records initially identified, 128 were duplicates and were removed; title and abstract screening excluded a further 241 records; and an additional 55 articles were excluded following full-text assessment. Ultimately, 12 studies were included: eight randomized clinical trials and four systematic reviews or meta-analyses. Together, the randomized trials included approximately 14,000 patients treated in Europe, North America, and Asia. The characteristics of these trials are summarized in Table 1.

Table 1. Characteristics of Randomized Clinical Trials Comparing Hypofractionated and Conventional Radiotherapy in Breast Cancer, PubMed, 2008–2024.

Study	Year	N	Country	Hypofractionated Regimen	Comparator Regimen	Follow-up
START-A	2013	2,236	United Kingdom	41,6 Gy/13 fractions or 39 Gy/13 fractions (5 weeks)	50 Gy/25 fractions (5 weeks)	10 years
START-B	2013	2,215	United Kingdom	40 Gy/15 fractions (3 weeks)	50 Gy/25 fractions (5 weeks)	10 years
Ontario Clinical Oncology Group	2010	1,234	Canada	42,5 Gy/16 fractions (22 days)	50 Gy/25 fractions (35 days)	10 years
DBCG HYPO	2020	1,882	Denmark, Norway and Germany	40 Gy/15 fractions (3 weeks)	50 Gy/25 fractions (5 weeks)	9 years
Wang et al. (pós-cirurgia conservadora)	2020	734	China	43,5 Gy/15 fractions (3,5 weeks, with boost)	50 Gy/25 fractions (6 weeks, with boost)	73.5 years
Wang et al. (pós-mastectomia)	2019	820	China	43,5 Gy/15 fractions (3 weeks)	50 Gy/25 fractions (5 weeks)	58.5 months
FAST	2020	915	United Kingdom	28,5 Gy/5 weekly fractions	50 Gy/25 fractions (5 weeks)	10 years
FAST-Forward	2020	4,096	United Kingdom	26 Gy/5 frações (1 week)	40 Gy/15 fractions (3 weeks)	5 years

Note: N = number of randomized patients. In the FAST-Forward trial, the comparator arm received the moderately hypofractionated regimen of 40 Gy in 15 fractions rather than conventional fractionation of 50 Gy in 25 fractions. The studies by Wang et al. represent two distinct trials conducted by the same research group, differentiated by year and surgical setting.

Randomized Clinical Trials

The British START program provides the largest body of randomized data on this topic. In START-A (n = 2,236), two 13-fraction regimens (41.6 Gy and 39 Gy) were compared with the control regimen of 50 Gy in 25 fractions, with the same five-week treatment duration maintained across all three arms specifically to isolate the effect of fraction size. After 10 years of follow-up, locoregional recurrence did not differ between groups, and statistical modeling estimated the tumor alpha/beta ratio to be approximately 4.6 Gy. In the 39 Gy arm, late effects were comparable to, if not less frequent than, those in the control group.[2,4]

START-B (n = 2,215) also investigated shortening the overall treatment duration: 40 Gy in 15 fractions over three weeks versus the conventional regimen of 50 Gy in 25 fractions over five weeks. At 10 years, the recurrence rate was 4.3% in the hypofractionated group compared with 5.5% in the conventional group, and late effects (breast shrinkage, telangiectasia, and edema) were all less frequent in the 40 Gy arm.[3,4]

In Canada, the trial conducted by the Ontario Clinical Oncology Group (n = 1,234) randomized women with T1–2 N0 tumors to receive either 42.5 Gy in 16 fractions or the conventional regimen of 50 Gy in 25 fractions. After 10 years, the difference in local recurrence between groups was only half a percentage point (6.2% versus 6.7%), and cosmetic outcomes were equivalent in both arms.[8]

The DBCG HYPO trial (n = 1,882), conducted in Scandinavia and Germany, included patients older than 40 years who were randomized to receive either 40 Gy in 15 fractions or the conventional regimen of 50 Gy in 25 fractions. The development of breast fibrosis, the study's primary endpoint, was not increased by hypofractionation, and recurrence rates at nine years were virtually identical between groups (3% versus 3.3%).[9]

Two trials conducted in China compared the same types of fractionation. In the first (n = 734, patients who underwent breast-conserving surgery), the five-year cumulative incidence of local recurrence was 1.2% in the hypofractionated arm, which received 43.5 Gy in 15 fractions, compared with 2.0% in the conventional arm.[10] In the second (n = 820, a high-risk postmastectomy setting), recurrence rates were similar (8.3% versus 8.1%), but grade 3 skin toxicity was significantly lower in the hypofractionated group (3% versus 8%).[11]

Further reducing treatment duration, the FAST trial (n = 915) demonstrated, after 10 years of follow-up, that 28.5 Gy delivered in five weekly fractions did not worsen late effects.[12] The FAST-Forward trial (n = 4,096), with a considerably larger sample, confirmed that 26 Gy delivered in five daily fractions over one week was non-inferior to the three-week regimen used as the control.[13]

Systematic Reviews and Meta-Analyses

The four included secondary evidence syntheses are summarized in Table 2.

Table 2. Characteristics of Systematic Reviews and Meta-Analyses Comparing Hypofractionated and Conventional Radiotherapy in Breast Cancer, PubMed, 2008–2024.

Author (year)	Study design	Included stdies	Setting	Outcomes Analyzed	Conclusion
Budach et al. (2015)	Meta-analysis	4 trials, 7.095 patients	After breast-conserving surgery	Ipsilateral recurrence. Late toxicity.	Moderate hypofractionation recommended as standard
Gu et al. (2021)	Meta-analysis	14 articles, 10.941 patients	After breast-conserving surgery	Local recurrence. Recurrence-free survival. Overall survival. Cosmetic outcomes.	Hypofractionation non-inferior to conventional fractionation
Liu et al. (2020)	Meta-analysis and systematic review	25 studies, 3.871 patients	Postmastectomy	Overall survival. Disease-free survival. Recurrence. Metastasis. Acute and late toxicity.	Hypofractionation safe and effective after mastectomy
Krug et al. (2021)	Meta-analysis and systematic review	Data from the FAST and FAST-Forward trials	Early-stage breast cancer	Overall survival. Disease-free survival. Recurrence. Metastasis. Acute and late toxicity.	Moderate hypofractionation as standard; ultrahypofractionation for selected cases

The meta-analyses yielded similar findings. One pooled four of the landmark trials, involving 7,095 patients with more than 10 years of follow-up, and found no difference in ipsilateral recurrence.[14] Another included 14 publications involving 10,941 patients and likewise found no relevant differences in local recurrence (hazard ratio of 0.90), recurrence-free survival (hazard ratio of 0.96), or cosmetic outcomes (relative risk of 0.96).[15] A third meta-analysis, focusing on the postmastectomy setting, analyzed 25 studies involving 3,871 patients and reached the same conclusion, finding no differences in survival, recurrence, or toxicity.[16] Finally, a review of data from the FAST and FAST-Forward trials concluded that moderate hypofractionation remains the standard of care, with ultrahypofractionation reserved for selected patient groups.[17]

Comparative Synthesis of Outcomes

The comparison of the main outcomes between the hypofractionated and comparator arms across the twelve included studies is summarized in Table 3.

Table 3. Comparison of Outcomes Between Hypofractionated and Conventional Radiotherapy in the Included Studies, PubMed, 2008–2024.

Study	Locoregional Recurrence	Overall Survival	Acute Toxicity	Late Toxicity	Cosmetic Outcomes
START-A	No difference	No difference	Lower than or equal to control	Comparable or lower (39 Gy)	No difference
START-B	4,3% versus 5,5%	No difference	Less breast edema	Less breast shrinkage, telangiectasia, and edema	Favorable trend
Ontario Clinical Oncology Group	6,2% versus 6,7%	Comparable	Comparable	No increase at 10 years	69.8% versus 71.3% (no difference)
DBCG HYPO	3% versus 3,3%	No difference	Comparable	Induration/fibrosis: no increase	No difference
Wang et al., 2020 (after breast-conserving surgery)	1,2% versus 2,0%	No difference	Similar or lower	Comparable	Comparable
Wang et al., 2019 (postmastectomy)	8,3% versus 8,1%	No difference	Grade 3 skin toxicity: 3% versus 8%	No difference	Not assessed
FAST	No difference	Comparable	Comparable	28,5 Gy: no increase	28,5 Gy: comparable
FAST-Forward	Non-inferior	No difference	Maneageable	26 Gy: comparable at 5 years	26 Gy: comparable
Budach et al.	No difference (pooled)	Not assessed	Not assessed	Comparable or favorable	Not assessed
Gu et al.	Hazard ratio: 0.90	No difference	Not assessed	Not assessed	Relative risk: 0.96
Liu et al.	No difference (mastectomy)	No difference	Comparable	No difference	Not assessed
Krug et al.	Non-inferiority	Not assessed	Not assessed	28,5 Gy comparable to 50 Gy	Not assessed

Note: The values refer to comparisons between the hypofractionated arm and the comparator arm. In the last four studies, the results represent pooled data from multiple trials. In the FAST-Forward trial, the comparator arm received 40 Gy in 15 fractions.

DISCUSSION

All 12 studies analyzed pointed in the same direction: moderately hypofractionated regimens provided efficacy and safety comparable to those of conventional five-week fractionation. These clinical findings confirmed in practice what the linear-quadratic model had already predicted theoretically. The alpha/beta ratio for breast cancer, estimated by START-A to be approximately 4.6 Gy, demonstrated that the tumor responds to increases in fraction size similarly to late-responding normal tissues.[2,4] It was this agreement between theoretical predictions and observations in thousands of patients that largely supported the acceptance of hypofractionation by the oncology community.

The question remained whether the results of the initial trials, which predominantly included women with small tumors and negative lymph nodes, would also apply to more diverse clinical profiles. Subsequent studies helped answer this question. DBCG HYPO included Scandinavian and German patients;[9] the Chinese trials included Asian women treated with more modern systemic regimens, including high-risk postmastectomy settings;[10,11] and FAST-Forward went even further by investigating ultrahypofractionation.[13] In none of these expanded settings was hypofractionated radiotherapy inferior to the conventional regimen.

From a healthcare delivery perspective, the adoption of hypofractionated regimens has a substantial impact. Fewer treatment sessions mean less travel, fewer absences from work, lower costs for patients and healthcare institutions, and more efficient use of linear accelerators, equipment that is scarce in many radiotherapy services. This impact is likely to be greater in low- and middle-income countries, where access to radiotherapy is already limited and waiting times frequently exceed clinically acceptable intervals. The COVID-19 pandemic accelerated this transition: faced with the need to reduce exposure among patients and healthcare teams, radiotherapy services rapidly adopted ultrashort treatment regimens, even before the publication of the FAST-Forward efficacy results.[18]

Nevertheless, adoption of the new regimen was not uniform. Data from the United States covering the period from 2008 to 2013 showed that, even among patients eligible under the American Society for Radiation Oncology guidelines in effect at the time, the proportion who actually received the shorter regimen reached only approximately one-third by the end of the study period.[19] Reported reasons included institutional inertia, reimbursement models that favored longer treatments, and remaining uncertainties regarding specific patient subgroups.

The optimal approach to incorporating a tumor bed boost into a hypofractionated regimen remains unclear. The safety of ultrahypofractionation in patients requiring nodal irradiation also remains unresolved, as the FAST-Forward trial did not evaluate this setting in its primary analysis.[13] Cardiotoxicity beyond 10 years, particularly in left-sided breast tumors, requires continued surveillance. Furthermore, certain groups, such as BRCA mutation carriers, women with large breasts, and patients with connective tissue diseases, remain underrepresented in the available evidence.

Taken together, the findings support that hypofractionated radiotherapy is non-inferior to conventional fractionation in terms of tumor control, survival, toxicity, and cosmetic outcomes, both after breast-conserving surgery and following mastectomy. The regimen of 40 Gy in 15 fractions over three weeks is recommended as the reference standard for most patients

requiring adjuvant breast irradiation, with ultrahypofractionation using 26 Gy in five fractions reserved for selected low-risk patients. In healthcare systems where radiotherapy capacity is insufficient and waiting times exceed clinically acceptable intervals, shortening treatment duration increases service capacity without requiring additional equipment. Future research should quantify this potential benefit within the Brazilian public healthcare system and generate effectiveness data in Latin American populations, which are currently absent from the available evidence base.

CONCLUSIONS

Hypofractionated radiotherapy was noninferior to conventional fractionation in breast cancer in terms of tumor control, survival, toxicity, and cosmetic outcomes, both after breast-conserving surgery and after mastectomy. The 40 Gy in 15 fractions regimen should be adopted as the standard for most patients, while the 26 Gy in five fractions regimen may be used in selected low-risk cases. Shortening treatment duration improves access to radiotherapy without requiring additional equipment, which is particularly relevant within Brazil's Unified Health System (SUS). Further research is needed to investigate nodal irradiation with hypofractionation, long-term cardiotoxicity, and treatment effects in Latin American populations.

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