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Hypofractionated whole and partial breast irradiation: Brazilian Society of Radiotherapy (SBRT) consensus

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ABSTRACT

Background: Breast cancer is the most common cancer in women worldwide, with 73,610 new cases expected annually in Brazil between 2023 and 2025. Post-operative radiation therapy (PORT) is a critical component of treatment, and recent advances have allowed for shorter treatment times that can help overcome shortages in low- and middle-income countries. The Brazilian Society of Radiotherapy (SBRT) updated its consensus on hypofractionated whole-breast radiotherapy and included recommendations for partial breast irradiation.

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Materials and methods: The SBRT convened a national panel of experts to develop updated recommendations. Using a modified Delphi method, the panel reached a consensus through structured rounds of voting. Recommendations were categorized based on the strength of available evidence.

Results: The consensus supports hypofractionation, which offers shorter, cost-effective treatment schedules, and partial breast irradiation (PBI), which targets high-risk areas while sparing healthy tissue. Despite high-quality evidence, adopting these techniques has been inconsistent. The panel's recommendations provide evidence-based guidance to clinicians, tailored to the Brazilian context, emphasizing safety and efficacy.

Conclusion: The updated SBRT consensus presents hypofractionation and PBI as practical alternatives to conventional radiation therapy, offering improved access and reduced costs. These recommendations aim to guide clinicians in adopting these approaches and help address barriers to access.

Keywords: breast cancer; hypofractionation; partial breast irradiation; post-operative radiation therapy (PORT); radiation oncology; low- and middle-income countries; consensus guidelines; external beam radiation therapy (EBRT)

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Introduction

Breast cancer is the most common female tumor in the world [1]. In Brazil, 73,610 new breast cancer cases are expected annually in the triennium 2023–2025, corresponding to 66.54 new cases per 100,000 women [1]. Post-operative radiation therapy (PORT) is essential in breast cancer management and plays a role both after breast-conserving surgery and mastectomy [2–4].

Conventional whole-breast PORT schemes usually lasted five to six weeks (25–28 daily fractions of 1.8–2.0 Gy/fraction). However, improved understanding of radiation biology and technological advances have allowed for shorter schemes of three [5], or even one week [6, 7]. These schemes are particularly important for low and middle-income countries that still struggle to provide radiation therapy (RT) for their population [8]. A Brazilian analysis showed that moderate hypofractionation reduces treatment cost per patient by 35.9% (from 2,669.20 USD to 1,711.98 USD), and ultra-hypofractionation reduces it by 65.1% (from 2,669.20 USD to 929.81 USD) [9]. Using a realistic model that considered clinical characteristics relevant to the choice of the hypofractionation scheme, researchers showed that 72,929,315.40 USD could have been saved in 2020 by switching from conventional fractionation to hypofractionation (70% moderate and 30% ultra) [9].

In addition to fractionation advances, the observation that most invasive breast tumor recurrences occur near the index tumor has led to a change in the paradigm of treatment volume definitions [10]. Partial breast irradiation (PBI) treats the area at higher recurrence risk, sparing the surrounding healthy tissue and organs, optimizing time and costs[11]. It has been shown to be safe and effective for low-risk early-stage patients [12–14]. PBI can be delivered through intraoperative radiation therapy (IORT), brachytherapy, and external beam radiation therapy (EBRT).

Despite the high-quality evidence supporting hypofractionation and PBI, and the possible positive impact on public health, its implementation was not widespread and was larger in academical than in community centers [2]. To address this issue and to provide clinicians with recommendations tailored to the national reality, the Brazilian Society for Radiation Oncology (SBRT) published a consensus for hypofractionation [15]. However, in the last years, important trials were published, including the ones validating ultra hypofractionation. Therefore, SBRT developed an updated Consensus to guide clinicians in their practice, with a focus on EBRT techniques only.

Materials and methods

Participants

A Consensus Panel led by the co-chairs (A.A.R., G.N.M., M.S.C., and N.M.A.F.) was responsible for writing the protocol, consensus development, and drafting the manuscript. A Steering Committee

was formed, including representatives from the relevant clinical specialties (radiation oncologists, medical oncologists, and breast surgeons).

The Steering Committee identified and invited the potential Consensus Group participants, which included the Consensus Panel members and a wider body of experts. Those experts were identified by the Consensus Panel and endorsed by the Brazilian Society of Radiation Oncology (SBRT), Brazilian Society of Mastology (SBM), Brazilian Society of Surgical Oncology (SBCO), and Brazilian Society of Medical Oncology (SBOC). Invited participants were required to have at least 15 years of breast cancer clinical experience. To minimize bias and increase opinion diversity, invited participants had to represent different Brazilian realities, coming from different geographical regions and working in both public and private healthcare systems. There were 20 final participants in the Consensus Group. Only Radiation Oncologists had voting rights.

Consensus

After conducting a literature review, the Steering Committee wrote the draft recommendation, and all members reviewed it. A modified Delphi strategy was chosen to provide a structured, transparent process and obtain anonymous feedback [16]. A preliminary round was done with questionnaires circulated electronically among the Consensus Group participants.

The Steering Committee reviewed and compiled answers to the questionnaires, along with clinical considerations made by participants. The compilation was made in an anonymized fashion to ensure confidentiality. The Steering Committee met online to review the results and discuss the comments. The statements that did not reach a consensus were re-evaluated after another literature review, and a second set of statements was developed for the live meeting round.

On May 19th, 2023, during the 2023 Brazilian Breast Cancer Symposium (BBCS), a Consensus meeting was held with all the Consensus Group participants. Preliminary questionnaire results and an updated literature review were presented. Delphi rounds were done on key statements that had not reached a consensus. Several rounds with anonymous voting were done, and there were subsequent revisions. Recommendations were discussed, and the rating was approved after consensus achievement.

Analysis

Answers were rated using a 4-point Likert Scale (strongly agree — 1, agree — 2, disagree — 3, and strongly disagree — 4) to ensure that each participant would provide a specific opinion. The percent agreement, median score for each question, and overall response rate were calculated for each question. The percent agreement was calculated by summing the number of raters who indicated either agree or strongly agree divided by the total number of raters for the round, and it did not include nonresponders in the denominator [16]. The consensus was reached when at least 75% of the panel members indicated agreement (strongly agree and agree combined) or disagreement (strongly agree and strongly disagree combined). Recommendations were classified as unanimous support (100%), strong support (90–99%), and support (75–89%) [4]. The level of evidence was presented according to Grading of Recommendations Assessment, Development and Evaluation Grading of Recommendations Assessment, Development and Evaluation Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines [17].

Because there was no individual-level patient data or human-subject research in this study, it was exempted from additional ethical approval.

Results

Percentage agreement, median score, overall response rate, recommendation strength, and quality of evidence after the Delphi voting rounds are presented in Supplementary File — Tables S1 and S2. The final consensus statements are summarized in the Panel (Tab. 1).

Moderate hypofractionation

The efficacy and safety of moderate hypofractionated irradiation have been demonstrated in large randomized controlled trials (RCTs) that included ductal carcinoma in situ (DCIS) [18] and invasive breast cancer [5]. RCTs have also validated the integration of moderate hypofractionation with sequential and concurrent boost [19–23]. Overall survival, metastases-free survival, and local

Table 1. Panel

I. Moderate Hypofractionation
1. Whole breast moderate hypofractionated irradiation is safe and effective regardless of patient's age at diagnosis, breast size, pathological stage, histological subtype, invasive tumour or DCIS, margin status, boost indication (whether sequential or concurrent), oncoloplastic surgery, breast recontruction, connective tissue disease (collagenosis) or previous systemic treatment.
2. Chest wall moderate hypofractionated irradiation should be offered under the same recommendations as for the whole breast irradiation and should be the standard of care for patients with or without breast reconstruction, regardless of the time and type of reconstruction.
3. Moderate hypofractionation is safe and effective for nodal irradiation as standard of care.
II. Ultra hypofractionation
4. Whole breast ultra hypofractionated irradiation is safe and effective for patients ≥ 50 years old without breast reconstruction and without nodal irradiation indication, regardeless of breast size, molecular subtype, invasive tumour or DCIS, histological grade, margin status, oncoloplastic surgery, connective tissue disease (collagenosis), previous systemic treatment, and concurrent boost indication.
5. Chest wall ultrahypofractionated irradiation should be offered under the same recommendations as for the whole breast irradiation, and it is safe and effective for patients without breast reconstruction.
6. Chest wall ultra hypofractionated irradiation for patients with breast reconstruction and nodal ultrahypofractionation should only be offered within a clinical trial.
III. Technology
7. Moderate hypofractionation requires minimum technology (3D radiotherapy with CT scan guided planing), and 2D moderate hypofractionation can only be offered when conformal planning is unavailable
8. Ultra hypofractionation minimum technological requirement is 3D planning with CT scan guided planing and daily IGRT, and 2D ultra hypofractionation is not recommended. DIBH is strongly recommended for ultra hypofractionated irradiation of the left breast
IV. Partial breast irradiation
9. Partial breast irradiation is safe and effective for low risk patients and should follow ESTRO recommendations: patients ≥ 50 years old, with luminal-like tumors, smaller than ≤ 3 cm, without lymph vascular space invasion, non-lobular invasive carcinoma, tumor grade 1-2, low-to-intermediate grade DCIS (less than ≤ 2.5 cm, and margins ≥ 3 mm), lesions unicentric or unifocal, margins > 2 mm, node-negative, and no use of primary systemic therapy and neoadjuvant chemotherapy.
10. Clip placement on the surgical bed is required for EBRT treatment planning. In patients who underwent oncoplastic surgery, at least four surgical bed clips are required. Moderate and ultra hypofractionation are acceptable for partial breast external beam irradiation. Treatment planning requires IMRT.

DCIS — ductal carcinoma in situ; CT — computed tomography; IGRT — image-guided radiation therapy; DIBH — deep inspiration breath hold; ESTRO — European Society for Radiotherapy and Oncology; EBRT — external beam radiation therapy; IMRT — intensity-modulated radiation therapy

and loco-regional control results are similar when comparing hypofractionation and conventional fractionation [5]. In addition, acute and later toxicity are also similar, and cosmesis shows a trend towards favoring hypofractionation [5]. Despite limited data specifically targeting breast reconstruction, there is no evidence that moderate hypofractionation increases reconstruction complications [24]. In addition, there is also a trend towards decreased breast radiation toxicities with moderate hypofractionation in the studies, which raises the hypothesis that reconstruction complications might be even lower [24].

Retrospective studies have shown that hypofractionation is safe and effective for patients with breast reconstructions, and they have not found an interaction between fractionation, toxicity, reconstruction type, and timing [25, 26]. The results of the prospective randomized trial FABREC showed that fractionation was not associated with toxicity, which supports the use of hypofractionation in the set of a tissue expander or implant-based reconstruction [27, 28]. RT CHARM was another prospective RCT that showed that hypofractionation was non-inferior to conventional fractionation in reconstruction complications in patients with breast reconstruction. Autologous reconstruction had a lower complication rate than implant-only reconstruction, regardless of fractionation [29].

Ultra hypofractionation

The efficacy and safety of ultra hypofractionation have been shown in the FAST [6] and the FAST-Forward [7] trials. Both trials focused on early-stage breast cancer, and even though FAST-Forward did include T3 patients, they represented only approximately 2% of the cohort [7]. Approximately 95% of patients had ductal, lobular, or mixed histologies, and approximately 90% were

hormone receptor-positive [7]. It is important to highlight that rare histologies, such as breast sarcoma and phyllodes tumors, might not have been represented in the study, which hampers the generalization of results to those underrepresented populations. In FAST-Forward, less than 5% of patients received neoadjuvant systemic treatment, and approximately 25% received adjuvant systemic treatment [7].

The FAST [6] trial only included patients older than 50 years old. While the FAST-Forward [7] trial included patients 18 or older, those younger than 40 represented 1.4% of the cohort, and those between 40 and 49 represented 13.4%. In addition, the duration of the follow-up (10 years in the FAST trial and five years in the FAST-Forward trial) precludes conclusions on long-term toxicity. This is extremely important for younger patients who are expected to live longer and might experience those toxicities in the long term. The European Society for Radiotherapy and Oncology — Advisory Committee on Radiation Oncology Practice (ESTRO-ACROP) consensus recommends considering ultra-hypofractionation for patients under 50 years old when other specific indications are met [4].

Mastectomy patients were only included in the FAST-Forward trial, however, they represented less than 7% of patients, and less than 1% of patients underwent breast reconstruction [7]. The study thus did not have the power to evaluate the interaction between ultrahypofractionation and breast reconstruction. These trials did not include nodal fields; however, the FAST-Forward Lymphatic Radiotherapy is an ongoing trial evaluating ultra hypofractionation for nodal treatment [30]. Favorable preliminary 2–3 years follow-up results have been presented in ESTRO 2022, but the formal primary analysis is planned at five-year follow-up [31].

There were no restrictions related to breast size in the trials. The main recommendation was related to dose homogeneity, FAST restricted dose variation across the treated volume to be between — 5% and 7% of the reference isodose [6], and FAST-Forward recommended that less than 5% of the volume received ≥ 105% of the dose, less than 2% of the volume received ≥ 107% of the dose, and the global maximum dose should be less than 110% of the prescribed dose [7]. The trials also did not detail the margin status of the included patients.

FAST-Forward was the only trial that allowed boost prescription, and it was always sequential in either 5 or 8 fractions [7]. According to the authors, five-fraction synchronous boost regimens might be incorporated into the 26 Gy treatment [7].

In addition to those RCTs, a recent trial conducted during the COVID-19 pandemic also corroborated the safety and effectiveness of ultra-hypofractionation compared to moderate hypofractionation [32].

No RCT has specifically evaluated ultra hypofractionation for DCIS. However, some institutions started using it based on biological plausibility and extrapolation from other trials in which there was no difference in safety or effectiveness between invasive breast cancer and DCIS regarding fractionation [33]. The MC1635 was a phase 3 Trial comparing ultra and moderate hypofractionation after BCS that included 16% of DCIS patients [34]. Overall, both arms showed similar treatment-related toxicity and the provider scored cosmesis [34].

Partial breast irradiation

PBI using EBRT has been evaluated in three RCTs [12–14]. Recently ESTRO published a consensus with recommendations regarding PBI [4]. After reviewing this guideline during our consensus meeting, we agreed to corroborate ESTRO's recommendations and add specific technical recommendations that had not been covered in their guideline.

Technology

Whole breast radiation therapy

In the major RCTs evaluating moderate hypofractionation, RT has been performed using a 2D [35–37], 3D [18, 38], or a combination of either 2D, 3D, or intensity-modulated radiation therapy (IMRT) techniques [39]. Therefore, high-level evidence supports the use of all these options and demonstrates their safety and effectiveness. It is important to highlight, though, that analysis from the major trials evaluating field-in-field and inverse planning for breast cancer have shown a correlation between dose homogeneity and acute toxicity [2]. Thus, 3D and IMRT that allow the evaluation

and adjustments in dose homogeneity and dose in normal tissues should be preferred.

Regarding ultra-hypofractionation, FAST did not state its image guidance (image-guided radiation therapy — IGRT) method [6], while FAST-Forward recommended treatment set-up verification using electronic portal imaging (MV or kV) for each fraction [7].

Electronic portal imaging (EPID) has been shown to underestimate setup errors by up to 50% in breast cancer patients, and cone beam computed tomography (CBCT) can significantly decrease those uncertainties [40]. One of the main concerns of using CBCT is the dose to adjacent normal tissue. Doses in organs at risk can vary by 75% depending on the chosen CBCT protocol [41]. In an analysis comparing IGRT techniques for breast cancer, the heart dose with orthogonal kV images was 0.16 cGy, while with CBCT, it varied between 0.27 and 1.08 cGy. The choice of the appropriate method should consider the techniques available, the fractionation scheme chosen, and the clinical characteristics of the patient (such as reproducibility and treatment position).

In conventional fractionation, a single fraction represents 4% of the treatment, in moderate hypofractionation, each fraction represents 6%, and in ultra hypofractionation, 20%. Therefore, set-up errors in a single fraction have a higher impact in shorter treatments.

Techniques of respiratory movement management, used mainly for left breast irradiation, may be considered to improve dose distribution, especially in the heart. We do not recommend that they should always be a part of treatment, however, when available, this option should be considered and evaluated during planning.

Partial breast irradiation

For the localization of the tumor bed, the IMPORT LOW trial recommended surgical clips [12]. Still, it allowed the use of image modalities (ultrasound, magnetic resonance imaging, or computer tomography) for CTV delineation or clinical evaluation, provided the clinician was confident about the localization [12]. The RAPID trial did not require the placement of surgical clips [13]. However, it excluded patients when it was not possible to localize the surgical cavity due to the absence of surgical clips or seroma [13]. The Florence trial required an insertion of a minimum of 4 surgical clips [14].

For treatment planning, IMPORT LOW recommended forward-planned field-in-field IMRT[12], the RAPID trial allowed 3D conformal RT and IMRT [13], and the Florence trial used five step-and-shoot IMRT coplanar fields (6 MV) [14].

Regarding dose and fractionation for PBI, IMPORT LOW prescribed 40 Gy in 15 fractions [12], RAPID prescribed 38.5 Gy in 10 fractions twice a day over 5–8 days (minimum interval 6–8 h) [13], and the Florence trial prescribed 30 Gy in 5 non-consecutive once-daily fractions [14].

Evidence regarding oncoplastic surgery is scarce [42], so we opted for a more conservative approach, not considering these patients for PBI unless at least four clips have been placed.

Constraints

While trials varied in their protocols, and some protocols allowed for 2D treatments, a lot has evolved in the understanding of the relationship between dose and radiation toxicities. Suggested dose constraints based on data from RCT are presented in Table 2.

Recommendations

The final SBRT recommendations are summarized in the Panel.

Conflict of interest

The authors declare no conflict of interests.

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Author contribution

Conceptualization and study design: N.M.A.F., G.N.M., A.A.R., and M.S.C. Literature review: C.F.P.M.S., N.M.A.F., A.A.R., M.S.C., S.A.H., C.C.,

Table 2. Constraints

Trial	Start B	FAST	FAST-Forward	Florence	MDACC	ROTG SIB	Chinese Mastectomy Trial	Halfmoon
Scheme	40.05 Gy (15 × 267 cGy)	28.5-30 Gy (5 × 570-600 cGy)	26 Gy (5 × 520 cGy)	30 Gy (5 × 600 cGy)	10-12.5 Gy (4-5 × 250 cGy)	40.05 Gy (15 × 267 Gy) 48 Gy (15 × 320 Gy)	43.5 Gy (15 × 290 cGy)	40.05 Gy (15 × 267 cGy)
PTV			V95% > 90-95% V105% < 5-7% V107% < 2% Dmax < 110%	V28.5 Gy = 100% Dmax < 105% (31.5 Gy) Dmin 28 Gy		V95 % > 90% *Vboost < 20% PTV		
Ipsilateral lung	V16 Gy < 15–20% V8 < 35–40% V4 < 50–55%	V8 Gy < 15% V10 Gy < 30% (α/β = 1.7)	V30% < 15%	V10 Gy < 20%	V16 Gy < 15–20% V8 Gy < 35–40% V4 Gy < 50–55%	Dm < 10 Gy	V20 Gy < 13–25% Dm < 6.5–11 Gy	V31 Gy < 15% V26.4 Gy < 20% V17.6 Gy < 30% Dm < 13 Gy
Heart	V16–20Gy < 5% V8 Gy < 30–35% Dm < 3.2–4 Gy	V14 Gy < 5% V7 Gy < 5% V1.5 Gy < 30%	V25 Gy < 5% V5 Gy < 25%	V3 < 10%	V16–20 Gy < 5% V8 Gy < 30–35% Dm < 3.2–4 Gy	Dm < 5 Gy Dmax < 40 Gy	Dm < 0.5–1.5 Gy	V8 < 15% V6 Gy < 20% Dm < 5 Gy
Contralateral breast	NA	NA	NA	V15 Gy < 50% (uninvolved breast) Dmax < 1 Gy (contralateral breast)	NA	Dmax < 300 cGy (acceptable Dmax < 330 cGy)	NA	NA

PTV — planning target volume; NA — not available

H.A.C., G.R.M.G., P.H.R.Z., C.R.S.H.W.F., W.J.A.J., A.B.B.B., F.M.O., J.T.P., L.D.F., A.C., R.F.J., A.M., C.A.A.R., R.L., G.N.M. Consensus recommendation development: N.M.A.F., A.A.R., M.S.C., S.A.H., C.C., H.A.C., G.R.M.G., P.H.R.Z., C.R.S.H.W.F., W.J.A.J., A.B.B.B., F.M.O., J.T.P., L.D.F., A.C., R.F.J., A.M., C.A.A.R., R.L., G.N.M. Manuscript preparation: C.F.P.M.S., N.M.A.F., G.N.M., S.A.H., C.C., P.H.R.Z. Manuscript review and approval: C.F.P.M.S., N.M.A.F., A.A.R., M.S.C., S.A.H., C.C., H.A.C., G.R.M.G., P.H.R.Z., C.R.S.H.W.F., W.J.A.J., A.B.B.B., F.M.O., J.T.P., L.D.F., A.C., R.F.J., A.M., C.A.A.R., R.L., G.N.M.

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