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Triple-negative breast cancer: 2025 consensus guidelines

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ABSTRACT

Objective: To disseminate the clinical guidelines established at the 2025 São Paulo Breast Diseases Symposium regarding the management of early triple-negative breast cancer (TNBC). **Methods:** The symposium convened 110 panelists, predominantly mastologists from São Paulo (101 mastologists, of which 94 from São Paulo and 7 from other regions: 1 from Bahia [Northeast], 2 from Rio Grande do Sul [South], 1 from Minas Gerais, 2 from Goiânia [central region], and 1 from Fortaleza [Northeast]), plus 6 oncologists, 2 pathologists, and 1 radiotherapist (all from São Paulo). Four priority topics were presented in evidence-based lectures, followed by technical discussions and anonymous electronic voting by all panelists. Consensus was defined as ≥75% agreement. **Results:** Voting showed 40% support for T1cN0 as the cutoff for upfront surgery, 16% for T2N0, but no consensus was reached. Consensus was achieved for using tumor-infiltrating lymphocytes (TILs) as an adjunct biomarker to guide initial systemic treatment (83%) and for sentinel lymph node biopsy (SLNB) as standard following neoadjuvant chemotherapy (NACT) (78%). Post-mastectomy radiotherapy was recommended even after pathological complete response (pCR) by 72%, though without consensus. **Conclusions:** The 2025 São Paulo Breast Diseases Symposium established guidelines for early TNBC management. Consensus was achieved for using TILs as an adjunct biomarker (83%) and SLNB as standard post-NACT (78%), while upfront surgery cutoff (40% for T1cN0) and radiotherapy omission post-pCR (72%) did not reach consensus, reflecting heterogeneous practices and the need for individualized approaches and further research.

KEYWORDS: triple-negative breast cancer; upfront surgery; tumor-infiltrating lymphocytes; sentinel lymph node biopsy; neoadjuvant chemotherapy; post-mastectomy radiotherapy.

INTRODUCTION

Triple-negative breast cancer (TNBC) is an aggressive and heterogeneous subtype characterized by the absence of estrogen receptor, progesterone receptor, and HER2 expression, limiting targeted therapy options and making chemotherapy the cornerstone of systemic treatment[1,2]. The 2025 São Paulo Breast Diseases Symposium, held on April 15–16, 2025, convened 110 panelists — predominantly mastologists from São Paulo (101 mastologists, of which 94 from São Paulo and 7 from other regions: 1 from Bahia [Northeast], 2 from Rio Grande do Sul [South], 1 from Minas Gerais, 2 from Goiânia [central region], and 1 from Fortaleza [Northeast]), plus 6 oncologists, 2 pathologists, and 1 radiotherapist (all from São Paulo) — to establish evidence-based clinical guidelines for four critical areas in early TNBC management: the cutoff for upfront surgery, the use of tumor-infiltrating lymphocytes (TILs) to guide therapy, the omission of sentinel

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lymph node biopsy (SLNB) following neoadjuvant chemotherapy (NACT), and the omission of post-mastectomy radiotherapy in cases of pathological complete response (pCR). These decisions integrate clinical factors (tumor size and nodal status), biological factors (molecular profile and BRCA1/2 mutations), and immunological factors (TILs levels) to optimize overall survival (OS), disease-free survival (DFS), and the feasibility of breast-conserving surgery[3-18]. The symposium's consensus process aimed to standardize TNBC management in Brazil, influence clinical decision-making, and address gaps in the literature.

METHODS

Panelists for the 2025 São Paulo Breast Diseases Symposium were selected through nominations by the organizing committee and national breast cancer societies, based on criteria including at least 10 years of clinical experience in breast diseases, significant academic contributions (e.g., peer-reviewed publications), or leadership roles in relevant professional organizations. This ensured multidisciplinary expertise and some regional representativeness, though the group was predominantly from São Paulo. The two-day event, held April 15–16, 2025, in São Paulo, Brazil, included 110 panelists: 101 mastologists (92%) and 9 other specialists (8%; 6 oncologists, 2 pathologists, and 1 radiotherapist). The symposium acknowledged 94 panelists and organizers (listed in Acknowledgments), with an additional 13 co-authors contributing to the manuscript preparation, together comprising 107 of the 110 panelists.

Plenary sessions addressed four thematic axes:

1. Definition of the cutoff for upfront surgery in early TNBC.
2. Use of TILs to guide initial systemic therapy.
3. Omission of SLNB following NACT.
4. Omission of post-mastectomy radiotherapy in patients with pCR.

Each topic was introduced with a 10-min evidence-based lecture reviewing the literature, followed by a 50-min technical debate among panelists, discussants, and speakers. Anonymous electronic voting was conducted by all 110 panelists, with consensus defined as ≥75% agreement. Results were tabulated descriptively and drafted as clinical guidelines. The event's significance lies in its multidisciplinary composition, fostering collaboration to standardize TNBC management practices in Brazil and address gaps in the literature.

RESULTS

The voting outcomes for the four topics are summarized below and in Table 1, which differentiates areas of consensus (≥75% agreement) from non-consensus.

1. Cutoff for Upfront Surgery in TNBC Voting Results (Panelists):
   - T1aN0 (≤5 mm): 9%
   - T1bN0 (6–10 mm): 36%
   - T1cN0 (11–20 mm): 40%
   - T2N0 (>20 mm): 16%.
2. Use of Tumor-Infiltrating Lymphocytes (TILs) to Guide Initial Systemic Treatment in TNBC Voting Results (Panelists):
   - Yes: 83%
   - No: 17%.
3. Omission of Sentinel Lymph Node Biopsy in cN0 TNBC After Neoadjuvant Chemotherapy Voting Results (Panelists):
   - Yes (omit): 22%
   - No (perform): 78%.
4. Omission of Radiotherapy in TNBC with pCR After Neoadjuvant Chemotherapy Voting Results (Panelists):
   - Yes (omit): 28%
   - No (perform): 72%.

DISCUSSION

Cutoff for Upfront Surgery in TNBC The highest support was for T1cN0 (40%) as the cutoff for upfront surgery, followed by T1bN0 (36%), but no option reached consensus (≥75%), indicating heterogeneous practices among panelists. This variability aligns with current evidence, where the decision to pursue upfront surgery versus NACT depends on tumor size, nodal status, and biological factors. NACT is supported for its ability to induce pCR (37–64% depending on regimen), a prognostic marker associated with

Table 1. Summary of voting results and consensus status.

Topic	Voting results	Consensus achieved?
Cutoff for upfront surgery	T1aN0 (≤5 mm): 9% T1bN0 (6–10 mm): 36% T1cN0 (11–20 mm): 40% T2N0 (>20 mm): 16%	No
Use of TILs as an adjunct biomarker for initial systemic treatment	Yes: 83% No: 17%	Yes (83%)
Omission of SLNB post-NACT in cN0 TNBC	Yes (omit): 22% No (perform): 78%	Yes (78% for performing SLNB)
Omission of post-mastectomy radiotherapy post-pCR	Yes (omit): 28% No (perform): 72%	No

TILs: tumor-infiltrating lymphocytes; SLNB: sentinel lymph node biopsy; NACT: neoadjuvant chemotherapy; TNBC: triple-negative breast cancer.

improved DFS and OS[3-8]. The National Surgical Adjuvant Breast and Bowel Project (NSABP) B-18 trial demonstrated that NACT increases breast-conserving surgery rates without compromising survival[1]. The NSABP B-27 protocol confirmed pCR's association with reduced recurrence[8]. A large meta-analysis by Spring et al., including 27,985 patients, demonstrated a strong association between pathologic complete response (pCR) after neoadjuvant chemotherapy and improved long-term outcomes in TNBC[3]. For small tumors (T1a/T1b, ≤1 cm), Fasano et al. found no OS benefit from adjuvant chemotherapy in T1a/T1bN0 TNBC, but an 18% OS gain in T1cN0 (11–20 mm)[5]. Less aggressive histologies (e.g., adenoid cystic, medullary) are suitable for upfront surgery due to indolent behavior[11]. The CREATE-X trial supported adjuvant capecitabine for non-pCR cases, and OlympiA showed olaparib's benefit in BRCA1/2-mutated non-pCR cases, with limited impact in T1a/T1bN0[4,7]. The Keynote-522 trial demonstrated pembrolizumab's benefit in T2N0 or T1N+ tumors, increasing pCR and OS[6].

This lack of consensus reflects challenges in balancing surgical and systemic approaches, particularly for T1cN0 tumors, and aligns with National Comprehensive Cancer Network (NCCN) guidelines, which recommend individualized decisions based on tumor size and biology[9]. In contrast, European Society for Medical Oncology (ESMO) guidelines lean toward NACT for T1c or larger tumors to assess response and enable breast conservation[10]. The symposium's findings underscore the need for Brazilian clinicians to refine upfront surgery criteria through further research, potentially increasing breast conservation rates.

Practical recommendations:

- Tumors ≤5 mm (T1aN0): Upfront surgery is preferred; chemotherapy may be omitted.
- Tumors 6–10 mm (T1bN0): Consider NACT if risk factors (e.g., lymphovascular invasion, grade 3, basal subtype, BRCA mutations) are present.
- Tumors 11–20 mm (T1cN0): Upfront surgery may be acceptable, but NACT should be considered, especially in young patients or those with BRCA mutations.
- Tumors >20 mm (T2N0): NACT is preferred to assess response, enable breast-conserving surgery, and access complementary therapies for residual disease.

Use of TILs to Guide Initial Systemic Treatment in TNBC Consensus was reached for using TILs as an adjunct biomarker (83%). High TIL levels correlate with better outcomes in TNBC. A meta-analysis by Loi et al. (2,148 patients) showed that each 10% increase in TILs reduces recurrence and mortality (HR 0.84–0.87)[14]. Helal et al. reported higher pCR rates with TILs ≥30% in stage II–III TNBC (OR 3.08)[15]. Leon-Ferre et al. demonstrated that high tumor-infiltrating lymphocyte levels are strongly associated with improved outcomes in early-stage triple-negative breast cancer, supporting the biological relevance of the host immune response[16]. Conversely, De Boo et al. identified a higher recurrence risk in patients <40 years with low TILs and lymphovascular invasion[17]. Standardized TILs quantification is critical for clinical application[18].

This consensus aligns with emerging evidence supporting TILs' prognostic value[13-19]. NCCN guidelines include TILs as a potential biomarker but do not mandate their use, while ESMO emphasizes their role in research settings[9,10]. The strong support suggests a shift toward incorporating immunological factors in TNBC management, encouraging Brazilian centers to adopt TILs assessment for treatment personalization, provided standardized protocols and training are implemented.

Practical recommendations:

- Assess TILs in initial biopsies with standardized quantification[18].
- Consider upfront surgery for tumors <2 cm, cN0, and TILs ≥30% in selected scenarios.
- Maintain NACT for T2–T3 or low TILs and/or lymphovascular invasion.
- Explore de-escalation strategies for TILs >50% in clinical trials.

Omission of Sentinel Lymph Node Biopsy in cN0 TNBC After Neoadjuvant Chemotherapy Consensus was achieved against omission (78% for performing SLNB). Studies like SOUND and INSEMA explore omitting axillary surgery in cN0 patients, but TNBC representation is low (6% and 1.6%, respectively)[18]. NACT achieves axillary pCR in up to 64.8% of TNBC cases, with residual axillary disease as low as 0–5.6%[19-26]. However, SLNB remains the standard due to its accuracy (false-negative rate <10% when ≥3 nodes are evaluated)[22,24,26]. Clinical and imaging assessments have higher false-negative rates (up to 16%)[20].

This consensus aligns with NCCN and ESMO guidelines, which recommend SLNB for accurate staging[9,10]. The limited TNBC-specific data in trials like SOUND and INSEMA justifies caution against omission[19]. The guideline reinforces SLNB's role in Brazilian practice for accurate staging and treatment planning, though future trials may support omission in select cases.

Practical recommendations:

- SLNB should remain the standard after NACT.
- Omission is reserved for clinical trials with documented radiological pCR.
- Axillary staging is essential for defining systemic and radiotherapy treatment.

Omission of Radiotherapy in TNBC with pCR After Neoadjuvant Chemotherapy Support for performing radiotherapy reached 72% (no consensus for omission). Adjuvant radiotherapy is recommended in most TNBC cases because of the higher risk of locoregional recurrence associated with aggressive tumor biology and incomplete pathological response after neoadjuvant chemotherapy[27]. Nagar et al. reported low locoregional recurrence rates after neoadjuvant chemotherapy followed by mastectomy in patients with T3N0 breast cancer, supporting the

favorable prognosis observed in patients achieving good pathological response[28]. Preliminary NSABP B-51/RTOG 1304 results suggest radiotherapy omission may be safe in select ypT0 ypN0 cases, though unpublished[29]. For breast-conserving surgery, NCCN and ASTRO (American Society for Radiation Oncology) guidelines mandate radiotherapy[9].

The majority support for radiotherapy reflects caution, aligning with NCCN and ASTRO recommendations[9]. ESMO guidelines allow consideration of omission in select ypT0 ypN0 cases post-mastectomy but emphasize clinical trial settings[10]. The findings highlight the need for further data to guide omission in Brazilian practice.

Practical recommendations:

- Maintain radiotherapy in breast-conserving surgery and/or initial axillary disease (cN1).
- Consider omission only in ypT0 ypN0 post-total mastectomy, age >50 years, documented pCR, and clinical trial participation.
- Evaluate factors such as age, tumor grade, Ki-67, BRCA status, and pathological response.

Limitations

This symposium represents expert consensus among predominantly Brazilian specialists, primarily from São Paulo, limiting generalizability to global or diverse populations. Selection relied on nominations, which may introduce bias toward established networks. No external validation of the guidelines was performed, and quantitative analyses of potential clinical impact (e.g., survival modeling) were not conducted. Voting captured current practices but does not replace randomized trials. Future studies should address these gaps.

CONCLUSIONS

The 2025 São Paulo Breast Diseases Symposium established guidelines for early TNBC management. Consensus was achieved for using TILs as an adjunct biomarker (83%) and SLNB as standard post-NACT (78%), while upfront surgery cutoff (40% for T1cN0) and radiotherapy omission post-pCR (72%) did not reach consensus, reflecting heterogeneous practices and the need for individualized approaches and further research.

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AUTHORS' CONTRIBUTION

ECP: Conceptualization, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. FB: Conceptualization, Investigation, Methodology, Validation, Writing – review & editing. MM: Conceptualization, Methodology, Supervision, Validation, Writing – review & editing. JTAN: Investigation, Methodology, Validation, Writing – review & editing. GMT: Investigation, Resources, Validation, Writing – review & editing. FB: Investigation, Methodology, Resources, Validation, Writing – review & editing. BBG: Data curation, Visualization, Writing – original draft, Writing – review & editing. DAB: Investigation, Methodology, Validation, Writing – review & editing. FZ: Investigation, Validation, Writing – review & editing. MA: Investigation, Resources, Validation, Writing – review & editing. DLG: Formal analysis, Investigation, Validation, Visualization, Writing – review & editing. SEB: Methodology, Supervision, Validation, Writing – review & editing. ATH: Conceptualization, Supervision, Validation, Writing – review & editing.

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