



Association of Breast Surgeons of India (ABSI) Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India 2021—Indian Solutions for Indian Problems

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Abstract

Several international and national consensus guidelines from professional bodies and expert panels are available for the management of breast cancers. The widely used international guidelines are from the National Comprehensive Cancer Network (NCCN), St. Gallen International Expert Consensus, and the European Society of Medical Oncology (ESMO) and the National Institute for Health and Care Excellence (NICE) of the UK. This article is an update from the Association of Breast Surgeons of India (ABSI) regarding the guidelines to manage breast cancer in India. The earlier version of the same was published in 2016. This article has been updated with the latest research work in the management of breast cancer to date and necessary changes made to the earlier version.

Keywords ABSI Guidelines 2021 · Breast cancer · Indian guidelines · Breast cancer treatment

Introduction

Breast cancer is the commonest cancer affecting women all over the world. In 2020, there were 2.3 million women diagnosed with breast cancer and 685,000 deaths globally. At the end of 2020, there were 7.8 million women alive who were

diagnosed with breast cancer in the past 5 years, making it the world's most prevalent cancer [1, 2].

Female gender is the strongest breast cancer risk factor with approximately half of breast cancers developed in women who have no identifiable breast cancer risk factor other than gender (female) and age (over 40 years) [3, 4].

Since 1980s, there has been significant improvement in breast cancer survival rates in countries with robust early detection programs combined with different modalities of treatment to eradicate invasive disease [5].

Treatment recommendations and its implementation are the hallmark for positive clinical outcomes, which have been meticulously designed utilizing vast clinical experience backed up with evidence from several clinical trials. The situation continues to evolve with newer research and treatment modalities.

In India, the incidence of breast cancer has overtaken cervical cancer to become the most common form of cancer affecting women in the country. In cities like Mumbai, Delhi, Bengaluru, Bhopal, Kolkata, Chennai, and Ahmedabad, breast cancer accounts for 25 to 32% of all female cancers, more than 1/4th of all female cancers [6].

In India, breast cancer is more prevalent in the younger age group. Compared to the West, breast cancer presents a decade earlier in India. Significantly higher proportion

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of women diagnosed with breast cancer in India are ER-negative and HER2-positive. The current reported statistics in India states that 1 in 9 Indians will develop cancer and 1 in 29 females would be diagnosed with breast cancer during their lifetime. Almost 50% of all cases are in the age group of 25–50 with more than 70% of the cases presenting in the advanced stages with poor survival and high mortality. However, over the past 5 years, the trend has shifted to more women being diagnosed in stage II rather than with advanced breast cancer. Breast conservation has become increasingly accepted as a surgical management worldwide, including in India. There has been a steady increase of breast conservation surgeries from 30 to 55% all across India [7]. The Indian Council for Medical Research published data that states the total number of new cancer cases is expected to be about 14.5 lakhs in the year 2016 with increase to 17.3 lakhs in 2020. The simplest way to breast cancer prevention is by being able to do a self-breast examination. Women should be doing this on a regular basis after they turn 30 [8]. Shift from average tumour size from 5.2 to 3.2 cm is observed among Indian patients [9, 10]. In year 2016, ABSI had published consensus statement and treatment guidelines for treatment of breast cancer in India. With the new available information, the revision to this consensus statement is now presented by the authors in this paper [11].

Objective and Scope of This Consensus Statement

Several international and national consensus guidelines from professional bodies and expert panels are available for the management of breast cancers. The widely used international guidelines are from the National Comprehensive Cancer Network (NCCN), St. Gallen International Expert Consensus [12], and the European Society of Medical Oncology (ESMO) and the National Institute for Health and Care Excellence (NICE) of the UK.

In India, in the year 2016 ICMR has published consensus document for the management of breast cancer in India. Breast cancer carries a significant economic burden and it is multiplied with a higher stage of cancer at diagnosis. Thus, earlier diagnosis of breast cancer can lower treatment costs and can improve survival rates [6].

Breast cancer is a treatable disease and chances of survival are higher if it is detected in time. Unfortunately, the delay in detection in India is an important contributor in poor survival rates. Improvement in health literacy including public awareness, continued medical education for HCWs, infrastructure for early detection, and diagnosis are important determinants for health promotion. Breast conservation has become increasingly accepted as a surgical management worldwide, including in India [7, 13].

Therefore, systematic collection of medical history, signs, and symptoms can help detect the case at preliminary stages. Moreover, public education, especially to women, is very important (Box 1). Overcoming stigma and shyness is very important. Women need to be made aware of their right for good health and access to medical treatment and to reach out the closest medical practitioner of the family for any healthcare needs. Women need to be trained for breast self-examination and primary healthcare centres across the country can play a pivotal role.

Box 1 Symptoms of breast cancer (for public awareness campaigns)

- A breast lump or thickening;
- Alteration in size, shape, or appearance of a breast;
- Dimpling, redness, pitting, or other alterations in the skin;
- Change in nipple appearance or alteration in the skin surrounding the nipple (areola); and/or
- Abnormal nipple discharge

Thus, in order to streamline the management of breast cancer, these consensus guidelines are updated in the current context. Table 1 provides the list of recommendations for easy referral. These consensus guidelines are prepared for healthcare professionals working in the cancer treatment as practical referral guidelines that can help in early detection and drawing systematic treatment plan for the patients.

Table 1 Consensus guidelines: list of recommendations from the ABSI expert panel

1	Breast cancer evaluation
2	Breast cancer screening in India
3	Surgery for DCIS
4	ICG technique
5	Surgery of the primary (early breast cancer (EBC))
6	Management of locally advanced breast cancer (LABC)
7	Surgical management of LABC
8	Management of axilla in EBC
9	Management of axilla in LABC/post-NACT patients
10	Oncoplastic surgical principles
11	Post-mastectomy reconstruction
12	Risk-reducing surgery and genetic testing
13	Adjuvant RT
14	Surgical pathology
15	Biomarkers
16	Molecular profiling of breast cancer
17	Adjuvant hormonal therapy
18	Breast cancer in young patients
19	Fertility issues in young breast cancer
20	Surgery for metastatic breast cancer
21	Concept of de-escalation of surgery
22	Survivorship

ABSI Practical Consensus Statement, Recommendations, and Guidelines for the Treatment of Breast Cancer in India from the Expert Panel 2021

Breast Cancer Evaluation

Early breast cancer may be asymptomatic and there may be absence of pain and discomfort. So, it is very important to have a proper evaluation of the breast cancer. Mandatory clinical breast examination, imaging with mammography or sonomammography, core biopsy, metastatic work-up for stage III breast cancer, and an early diagnosis enable an oncologist to provide an ideal treatment for management of breast cancer. This triple assessment is mandatory for breast cancer evaluation (Box 2).

Box 2 Triple assessment mandatory for all breast lumps

1. Clinical breast examination
2. Mammography/sonomammography
3. Core biopsy and not FNAC

Recommended Use of PET-CT Is Not Mandatory It can be used for evaluation for locally advanced and metastatic disease. However, in India CT scan with bone scan in CABC is the most preferred option. Use of PET or PET-CT is not indicated in stages I and II or operable III (T3 N1) disease.

Breast Cancer Screening in India

Low awareness and the fact that breast cancer is a ‘taboo’ issue in many parts of rural India coupled with lack of a well-organised population-based screening programme are the main reasons for high mortality rates among women in India [14]. Innovative public awareness initiatives and patient educational programmes explained in a simple and easy to understand format must be undertaken to encourage women to come forward and participate in early detection programmes and education of self-breast examination.

Celebrity breast cancer survivors should be requested to become ‘Brand Ambassadors’ for such public awareness campaigns.

Population-based screening mammography is not a viable option for India due to enormous costs, early age at diagnosis (<50 years), dense breasts in younger women compromising diagnostic accuracy, huge variation in mammographic reporting, and quality assurance issues. There is now emerging evidence to suggest that clinical breast examination (CBE) performed by trained health-care workers is a valuable alternative screening method, particularly in rural India where 70% of the population reside [15, 16].

However, screening mammography is the best available modality to detect breast cancer in early stages and opportunistic screening (where women over the age of 40 present themselves for screening mammogram) must be actively encouraged in centres which have facilities for breast imaging [15, 17–21].

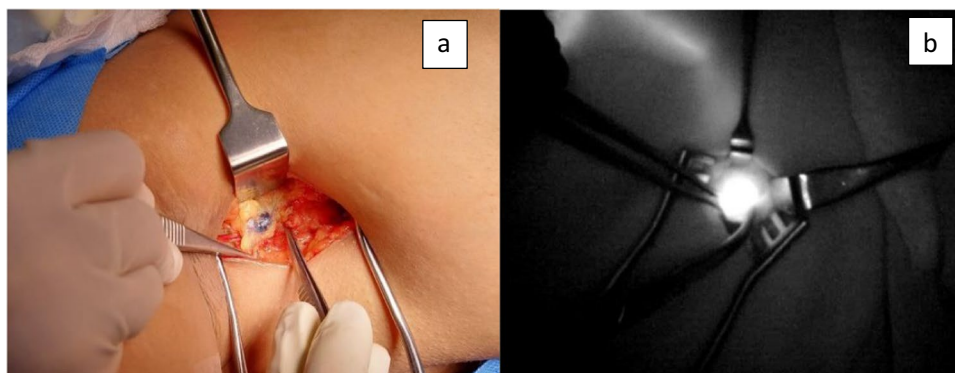
Surgery for DCIS

Recommended work-up for DCIS includes clinical assessment, bilateral mammography, and ER receptor status. Management strategies include surgery (BCS or mastectomy), radiation therapy (WBRT), and adjuvant endocrine therapy. SLNB should be considered in patients undergoing mastectomy. A 2-mm margin is desirable in patients undergoing lumpectomy and WBRT. Endocrine therapy with tamoxifen for 5 years in premenopausal and post-menopausal women and with aromatase inhibitors in post-menopausal women should be recommended in ER-positive DCIS.

ICG Technique

It is the low-cost, easily accessible technique specifically for Indian patients. ICG fluorescence imaging permits real-time visualization of lymphatics and provides an additional dimension to SLN biopsy that is safe and effective (Fig. 1).

Fig. 1 a SLNB with blue dye. b SLNB with ICG



ICG can reliably replace dual dye and be employed as a sole tracer for SLNB in early breast cancer, thus avoiding the potential drawbacks of gold standard tracer agents (i.e. licencing, availability, exposure, disposal, and costs of the radioisotope). ICG-based SLNB detection would bring about a significant change in the management of women diagnosed with early breast cancer at centres with low resources where there is no access to a nuclear medicine department.

Indian solutions for Indian problems made in the Indian ICG machine Irillic nanometre fluorescence imaging (Irillic, India) are recommended; they are low-cost ICG based on SLNB to be used without any need for nuclear medicine department [22].

Surgery of the Primary Cancer (Early Breast Cancer (EBC))

For the surgical treatment of EBC, the experts recommended no ink on invasive tumour as the minimum acceptable surgical margin, and en bloc excision for treatment of unilateral multifocal and multicentric tumours. The width of the margin that needs to be excised is independent of tumour biology, and it should not be greater after neoadjuvant therapy. During surgery, frozen section for margin assessment should be preferred if expertise and infrastructure exist; and for the situations where case margin(s) are found positive after breast conservation surgery, the experts recommended mandatory re-excision in all patients, except if skin/deep fascial margin only is positive. The researches indicated that oncoplastic surgery results in excision of larger volume of breast tissue (> 30% volume loss) and correspondingly obtains wider surgical margins as compared to conventional breast conservation surgery [23]. Where frozen section facilities are not available, cavity shaving is recommended in India [24].

Neoadjuvant chemotherapy in operable breast cancer can be offered to patients wanting breast conservation ($\geq T2$ ds, or $\geq N1$) or considered to have high-risk disease like triple-negative breast cancer. However, a patient of operable cancer showing disease progression should be taken promptly to surgery.

Management of Locally Advanced Breast Cancer (LABC)—Neoadjuvant Trastuzumab: Multimodality $\pm$ Reactant Based on MDT Approval

If neoadjuvant chemotherapy is planned, all planned chemotherapy should preferably be delivered prior to surgery. Response to NACT should be assessed clinically after every cycle of chemotherapy to check for response or if there is any disease progression. USG or mammogram should be repeated at the end of NACT schedule.

It is preferable to deliver NACT in a dose dense schedule. Sequential anthracyclines and taxanes are the preferred regimen. AC or EC for up to 4 cycles given every 14 days with growth factor support is an appropriate component of dose dense regimens. Paclitaxel (175 mg/m² every 14 days or 80/m² every week) should be considered as appropriate dose dense chemotherapy. Use of appropriate supportive drugs and care are essential for safe administration of dose dense chemotherapy. Toxicity of dose dense chemotherapy vs. 'standard frequency' is a significant limiting factor in the Indian scenario.

All patients eligible for HER2 targeted therapy should be offered trastuzumab, at least in the neoadjuvant setting, which is likely to result in better outcomes compared with no HER2 targeted therapy. Dual HER2 blockade is currently *not* cost-effective in Indian setting. Switch to TDM-1 may be considered in patients who have not undergone pathological CR after chemotherapy with trastuzumab in neoadjuvant setting. If financial constraints are not limiting, then dual anti-HER2-negative therapy is preferred.

Neoadjuvant endocrine therapy using AI inhibitors, CDK4/6 inhibitors, and phosphatidylinositol 3-kinase (PI3K) inhibitors may be considered an alternative in suitable ER-positive tumours and luminal A-type breast cancers. When NACT is used, clipping of tumour prior to initiating NACT should be done.

Surgical Management of LABC

T3 disease can be offered breast conservation post-NACT. However, recent meta-analysis of EBCTCG suggesting poorer locoregional control following neoadjuvant chemotherapy mandates that caution should be exercised in Indian patients before practising de-escalation of surgical treatment. For cT4 disease post-NACT BCS should be offered only under a well-defined multi-disciplinary breast cancer service. Patients with inoperable disease showing disease progression on NACT can be offered additional systemic therapy, palliative mastectomy, or palliative breast irradiation for better disease control. For T4 lesion LABC, breast conservation surgery is not a standard of care.

Management of Axilla in EBC

For the management of axilla in EBC, USG-guided FNAC for preoperative staging of axilla before SLNB/ALND and SLNB should be considered in clinically node-negative axilla that can be performed in resource-constrained setup using blue dye in countries like India; the acceptable false negative rate for SLNB can vary from 5 to 10%. For SLN assessment, routine molecular analysis was not recommended, and completion of ALND is not mandatory after identification of micro-metastasis in SLN but it should

be mandatory if macro-metastasis is identified in SLN. In current Indian scenario, the SLNB is now increasingly being considered the favoured method to treat low-volume axilla, and various studies have proved its significance [25].

Indocyanine green is emerging as an alternative to blue dye and radiocolloid method of SLNB to overcome the constraint of availability of nuclear medicine facility. Low axillary sampling may be an alternative to sentinel lymph node biopsy in resource-constrained settings.

Management of Axilla in LABC/Post-NACT Patients

For the management of axilla in LABC/post-NACT patients, SLNB can be performed after NACT for the patients planned to be treated with NACT. In pre-NACT clinically and radiologically node negative patients, it is safe and appropriate to do SNB post chemotherapy. Three or more nodes should be sampled for SLNB to be considered adequate. In post-NACT setting, targeted axillary dissection (TAD) or picking of a clipped node is an ideal option to decrease the false negative rates and should be done in context of research setting. In cN1 (1–3 nodes) which become cN0 on imaging after NACT, SLNB is not recommended.

Oncoplastic Surgical Principles

After BCS, if the volume loss is 20%, then oncoplastic procedure should be considered. Central tumours are not contraindications to breast conservation surgery. If the volume loss is 20–40% and > 40%, oncoplastic reconstruction surgeries must be considered.

Post-mastectomy Reconstruction

Post-mastectomy breast reconstruction is preferred to be immediately performed. As per the researches, breast reconstruction after resection of breast cancers is helpful in increasing the psychosocial functioning and quality of life among the treated patients [26].

Risk-Reducing Surgery and Genetic Testing

Prophylactic bilateral mastectomy and prophylactic bilateral salpingo-oophorectomy can be performed for risk reduction in BRCA-positive women. However, studies have suggested that total mastectomy provides the greatest breast cancer risk reduction due to removal of more breast tissue [27]. Thorough genetic counselling should be performed with at least BRCA1 and BRCA2 for whole family screening being recommended [28].

These surgeries are highly effective as bilateral prophylactic mastectomy has been shown to reduce the risk of breast cancer by at least 95% in women who have a deleterious mutation in the BRCA1 gene or the BRCA2 gene [29–32], while bilateral prophylactic salpingo-oophorectomy has been shown to reduce the risk of breast cancer by approximately 50% in women who have high risk of developing the disease [27].

Genetic Testing

In India, we have rapid advancements in the field of genetic testing/counselling, and therefore, more oncologists are expected to include genetic testing/counselling as part of the clinical practice. Despite the heterogeneity in the country, genetic testing addresses two important aspects: identifying deleterious germline mutations in families with predisposition to cancers, followed by predictive genetic testing in these high-risk families; and identifying molecular markers or signatures in the tumours for treatment and prognosis. A robust methodology/algorithm in genetic testing is extremely important for maintaining test quality. Genetic testing must be based on national accreditation programs (Box 3; Table 2). It is ideal to initiate genetic testing in a family member who is most likely to test positive for a pathogenic variant, which is usually a woman affected by early BC/OC (any age). Children should not be tested for *BRCA* before the age of 18 years. Genetic testing is important and can help identify high-risk and moderate-risk genes that are responsible for

Table 2 Genetic testing recommendations (Ref: [28, 33])

• The tumour content for somatic <i>BRCA</i> testing must be certified by a trained pathologist • DNA from the tissue sample should be extracted from a single representative block using a standardized and validated method • Known positive and negative controls should be included during testing • Somatic testing is generally recommended at 500× coverage to avoid a false negative assessment	Recommended somatic testing report: 1. Suitability of tumour sample for tumour content 2. Specific testing method used 3. Number and names of genes tested (if using a multigene panel) 4. Depth of cover age for each gene 5. Details of mutation, if detected (as per Human Genome Variation Society nomenclature) 6. Reference sequence of the gene 7. Interpretation of results with reference to therapy
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breast cancer with better management in onset, prevention, and management of hereditary breast cancer in Indian patients [33].

Box 3 Observed important genes for Indian HBOC patients.

BRCA1, BRCA2, BRIP1, TP53, ATM, PALB2

Predicted pathogenic VUS: BRCA1, BRCA2, BRIP1, ATM, RAD51C, and BARD1

Non-BRCA genes such as ATM, PALB2, and TP53 seem contributory to HBOC in the Indian population

Adjuvant RT

Radiotherapy is recommended in T1/T2 1–3 node-positive patients but can be omitted in selected patients and axillary radiation has no therapeutic role after complete ALND. APBI should be offered to a select group of early breast cancer patients, and for patients with T1 tumour and 1–2 metastatic SLNs, radiotherapy to axilla is a valid option instead of surgery in select cases. It is advised to omit the radiotherapy for elderly and low-risk patients undergoing BCS and suggested that cancer stage before the neoadjuvant therapy forms the base for radiotherapy.

After mastectomy, adjuvant treatment may include local irradiation, systemic therapy with cytotoxic chemotherapy, or endocrine therapy. The adjuvant treatment was considered useful, and a decrease was recorded in breast cancer mortality in the US and UK [34].

Adjuvant RT is routinely recommended post chemotherapy and a hypofractionated (39–42.9 Gy) schedule of whole breast irradiation has outcomes comparable to standard 50 Gray schedule and is a preferred option for those receiving RT to breast only.

Regional nodal RT is recommended for infraclavicular, supraclavicular, internal mammary and axillary nodal area considered to be at risk (more than 4 or more positive nodes, 1–3 positive nodes, and negative axilla but tumour > 5 cm). CECT/PET for detection of IMN was recommended in locally advanced cancer. A boost to the IMN should be considered if found positive/radiologically involved. Initially, for positive IMN picked up on CT/PET disappearing post systemic therapy, the IMN should be treated.

Surgical Pathology

Box 4 TNM

1. **Tumour (T):** How large is the primary tumour in the breast? What are its biomarkers?
2. **Node (N):** Has the tumour spread to the lymph nodes? If so, where, what size, and how many?
3. **Metastasis (M):** Has the cancer spread to other parts of the body?

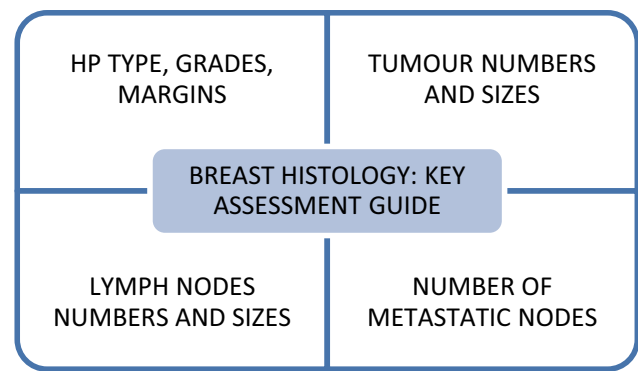


Fig. 2 Histology reporting data scheme

The experts strongly recommended that reporting of breast histology must be mandatory in practice which should include HP type, grade, margins, tumour numbers and size, lymph nodes, numbers, sizes, and number of metastatic nodes (Fig. 2). Mandatory pre-surgery pathology must include core biopsy, IHC4, ER, PR, HER2-NEGATIVE, and Ki-67, in all patients. The TNM as per AJCC 8th edition (Box 4) must be performed and documented [35].

Biomarkers

The experts recommended that IHC for ER, PR, and HER2neu should be tested in breast pathology as a minimum biomarker. For selected patients, IHC for ER, PR, HER2neu, and Ki67 may also be tested.

Molecular Profiling of Breast Cancer

For the molecular profiling of breast cancer, multigene signature testing in luminal B is the right approach to decide the ideal adjuvant treatment and oncoType Dx testing is strongly recommended for node-negative, ER/PR-positive, and HER2-negative patients. In Indian patients, CAN-ASSIST BREAST ONCOSCAN assist in IHC-based monomorphic tests is preferred [36].

Adjuvant Hormonal Therapy

For the use of adjuvant hormone therapy, the ideal duration for adjuvant hormonal therapy in premenopausal ER/PR+ patients is 10 years and in high-risk patients, ovarian suppression as adjuvant therapy should be considered in addition to tamoxifen or chemotherapy. Some post-menopausal breast cancer patients may or may not be adequately treated with tamoxifen alone. AI in post-menopausal breast cancer patients should be started upfront in all patients and should be used for 5 years.

Table 3 Consensus guidelines: list of recommendations at glance

1 Breast cancer evaluation	• Mandatory triple assessment: proper clinical examination, imaging, core biopsy, and metastatic work-up for stage III breast cancer • Recommended use of PET-CT for locally advanced and metastatic disease
2 Breast cancer screening in India	• To improve cancer awareness and attempts to decimate stigma, fear, and gender inequality • To encourage and impart training for breast cancer self-examination) • To improve health infrastructure for early detection
3 Surgery for DCIS	• Clinical assessment, bilateral mammography, and ER receptor status necessary • Management strategies such as surgery (BCS or mastectomy), radiation therapy (WBRT), and adjuvant endocrine therapy to be considered • SLNB should be considered in patients undergoing mastectomy
4 ICG technique	• It is the low-cost, easily accessible technique specifically for Indian patients • ICG fluorescence imaging permits real-time visualization of lymphatics and provides an additional dimension to SLN biopsy that is safe and effective • Indian solutions for Indian problems made in India ICG machines (IEILYC NM) are recommended; they are low-cost ICG based on SLNB to be used without any need for nuclear medicine department
5 Surgery of the primary (early breast cancer (EBC))	• No ink on invasive tumour as the minimum acceptable surgical margin is recommended • En bloc excision for treatment of unilateral multifocal and multicentric tumours advised • Neoadjuvant chemotherapy in operable breast cancer can be offered to patients wanting breast conservation
6 Management of locally advanced breast cancer (LABC)	• Any neoadjuvant chemotherapy planned should preferably be delivered prior to surgery • Neoadjuvant endocrine therapy using AI inhibitors, CDK4/6 inhibitors, and phosphatidylinositol 3-kinase (PI3K) inhibitors may be considered an alternative in suitable ER-positive tumours
7 Surgical management of LABC	• Offer NABT BCS only under a well-defined multi-disciplinary breast cancer service with all specifications • Ensure tumour marking prior to initiation or immediately after the first cycle of NACT
8 Management of axilla in EBC	• Mandatory USG-guided FNAC for preoperative staging of axilla before SLNB/ALND • SLNB should be considered in clinically node-negative axilla • Blue dye and indocyanine green can be considered in the Indian settings • Beware of the false negative rate (5–10%) for SLNB that can be confounding
9 Management of axilla in LABC/post-NACT patients	• SLNB should be performed after NACT for the patients planned to be treated with NACT • Three or more nodes should be sampled for SLNB to be considered adequate
10 Oncoplastic surgical principles	• If the volume loss after BCS is 20%, then oncoplastic procedure should be considered including central tumours
11 Post-mastectomy reconstruction	• It is an important aspect to provide emotional support and quality of life to the patients and should be performed immediately post-mastectomy reconstruction surgery
12 Risk-reducing surgery and genetic testing	• Total mastectomy provides the greatest breast cancer risk reduction • Prophylactic bilateral mastectomy and prophylactic bilateral salpingo-oophorectomy can be performed for risk reduction in BRCA-positive women • Genetic testing answers two important aspects: 1. Identifying deleterious germline mutations in families with predisposition to cancers, followed by predictive genetic testing in these high-risk families 2. Identifying molecular markers or signatures in the tumours for treatment and prognosis • Genetic testing is important and can help identify high-risk and moderate-risk genes that are responsible for breast cancer • Offers better management in onset, prevention, and management of hereditary breast cancer in Indian patients

Table 3 (continued)

13 Adjuvant RT	• This is routinely recommended post chemotherapy • Preferred option for those receiving RT to breast only • Regional nodal RT is recommended for infraclavicular, supraclavicular, internal mammary and axillary nodes
14 Surgical pathology	• CECT/PET for detection of IMN was recommended in locally advanced cancer • Histopathology report must include HP type, grade, margins, tumour numbers and size, lymph nodes, numbers, sizes, and number of metastatic nodes
15 Biomarkers	• Reporting of percentage positive staining (> 1% is cutoff) of ER/PR and some semi-quantitative method for HER2 disease should be reported to factor in ER-low and HER2-low tumours while making treatment decisions
16 Molecular profiling of breast cancer	• For molecular profiling of breast cancer, multigene signature testing is not the right approach to decide the ideal adjuvant • Treatment and oncotype Dx testing are strongly recommended for node-negative, ER/PR-positive, and HER2neu-negative patients
17 Adjuvant hormonal therapy	• Ideal duration for adjuvant hormonal therapy in premenopausal ER/PR + patients is 10 years and in high-risk patients, ovarian suppression as adjuvant therapy should be considered in addition to tamoxifen or chemotherapy • AI in post-menopausal breast cancer patients should be started upfront in all patients and should be used for 5 years
18 Breast cancer in young patients	• Ovarian suppression should be offered to most high-risk premenopausal patients with ER + breast cancer who remain premenopausal • Surgical oophorectomy is safe and can be considered
19 Fertility issues in young breast cancer	• Pregnancy is not a contraindication for breast cancer surgery as well as oncology • Supportive treatment can be offered in the 2nd and 3rd trimesters of pregnancy • The patient management needs team approach with the surgeon, medical oncologist, and obstetrics and gynaecology specialists with complete communication with the patient and the family
20 Surgery for metastatic breast cancer	• This therapeutic option is applicable for de novo metastatic breast cancer having a good performance status, oligometastatic disease, no (or limited) visceral involvement, and luminal or HER2-positive biology, after initial response to first-line systemic therapies
21 Concept of de-escalation of surgery	• De-escalation of surgery is based on clinical situation • Surgeries must be targeted for breast conservation based on tumour stage and its biology as well as predicted prognosis
22 Survivorship	• Survivorship care should be added as part of care continuum • Patient should be well-equipped with information on a treatment summary, follow-up care plan, self-management, and health promotion practices as well as must be offered emotional support and all possible help to improve QoL

Tamoxifen is found effective in premenopausal and post-menopausal women with hormone-sensitive (ER-positive) breast cancer [37]. Although tamoxifen's use is associated with post-menopausal symptoms such as hot flashes and vaginal discharge [38], its overall risk–benefit ratio is considered favourable for patients, and it should be offered as adjuvant treatment to women with hormone-sensitive breast cancer [39].

Breast Cancer in Young Patients

For breast cancer in young patients, it is recommended to test the BRCA1 and BRCA2 mutations in women < 40 years of age, and it is highly recommended to offer the fertility preservation to women < 40 years of age. The patients under 40 years of age comprise about 5% of the overall breast

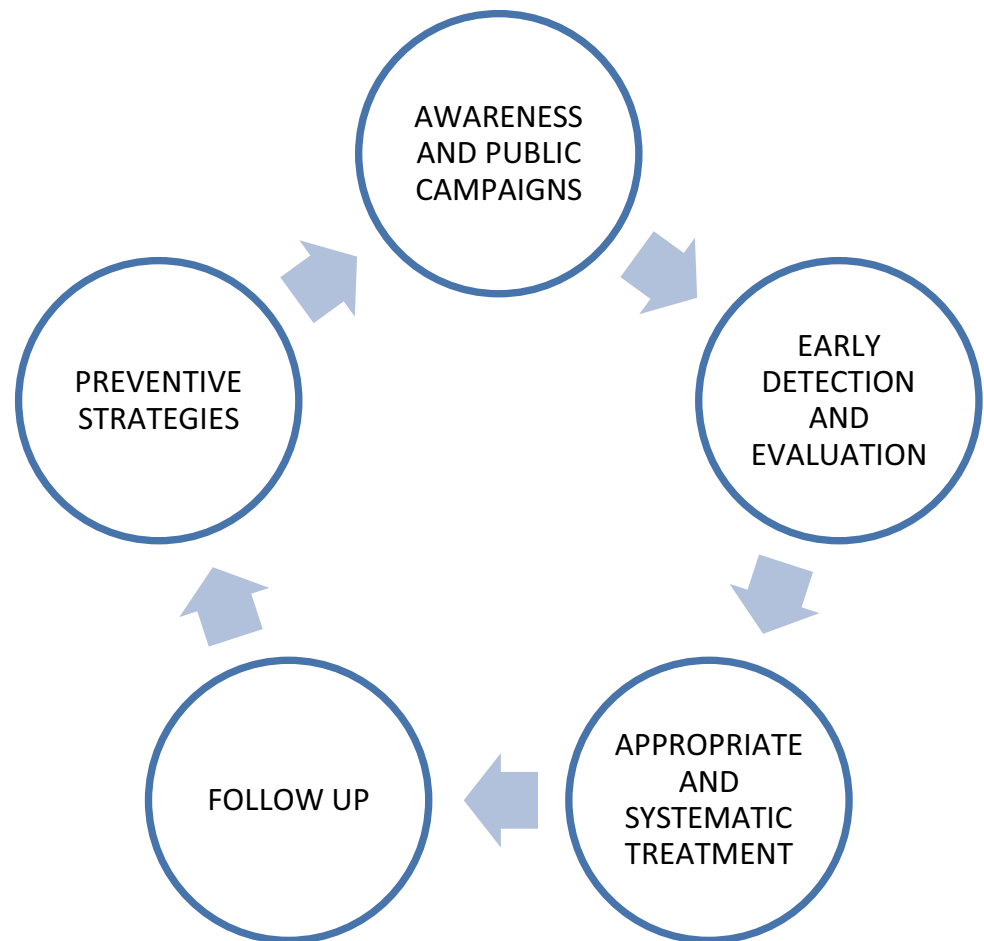
cancer population, so it is very important to diagnose the disease at early stage [40] and an improved survival with early detection is a valid argument for careful screening among young patients [41].

Ovarian suppression should be offered to most high-risk premenopausal patients with ER + breast cancer who remain premenopausal. Surgical oophorectomy is a safe and cost-effective method of ovarian suppression in Indian women. Tumours with weak ER- and/or PR-positive staining (Allred 3–5) are less likely to benefit from the addition of ovarian suppression.

Fertility Issues in Young Breast Cancer

Pregnancy is not a contraindication for breast cancer surgery as well as oncology and supportive treatment that can

Fig. 3 Integrated approach to achieve early detection and treatment



be offered in the 2nd and 3rd trimesters of pregnancy. The patient management needs team approach with the surgeon, medical oncologist, and obstetrics and gynaecology specialists with complete communication with the patient and the family. The benefit-risk ratio must be systematically evaluated, and optimum treatment modalities must be adopted [42, 43].

Surgery for Metastatic Breast Cancer: Not Standard of Care

Breast surgery of the primary tumour may be considered a therapeutic option in patients with de novo metastatic breast cancer having a good performance status, oligometastatic disease, no (or limited) visceral involvement, and luminal or HER2-positive biology, after initial response to first-line systemic therapies.

The surgery for primary tumour should be done in patients with oligometastatic breast cancer with good response to chemotherapy in an appropriately selected subgroup of patients such as young and hormone-positive patients and good response to systemic treatment. Surgery

can be considered in patients who have a complete radiological response at the primary site. Surgery for metastatic breast cancer is not a standard of care but can be considered the only option ahead with discussions with the patient and the immediate family. Surgery in the patients with stage IV breast cancer could be an option of improving at least the quality of life along with the possible avoidance of local complications due to progression. These decisions must be undertaken with proper counselling with the patient and the legal family member [13].

Concept of De-escalation of Surgery

De-escalation of surgery is based on clinical situation. Surgeries must be targeted for breast conservation based on tumour stage and its biology as well as predicted prognosis. Several interventions to reduce surgical morbidity must be undertaken. The preference for neoadjuvant therapy in HER2-positive and triple-negative, stage II and III breast cancer must be considered. For women with higher risk tumours, adjuvant endocrine treatment to include ovarian suppression in premenopausal women and extended therapy

for post-menopausal women are recommended. Treatment must be individualised based on the tumour characteristics, patient comorbidities, and preferences as well as prudent considerations with regard to the treatment cost and access to medical care.

Survivorship

Survivorship care should be added as part of care continuum. Patient should be given a treatment summary and follow-up care plan at the time of completion of primary treatment. Information about self-management and health promotion practices should be made available to survivors. A simple screening checklist can be used to screen for late and long-term effects such as emotional distress, fatigue, arm shoulder problems, premature menopause-related issues, body image, and sexuality issues and appropriate referrals should be made to address them.

Conclusion

These revised consensus guidelines are based on the existing evidences, current practices in India, and international data and recommended the consensus guidelines which are the perfect blend of the evidences, clinical expertise, and real-life preferences (Table 3). The consensus guidelines emphasise the need of mandatory core biopsy, metastatic work-up for stage III breast cancer, triple assessment, and clinical breast examination for diagnosis and screening of breast cancer in India. The guidelines highlight the recommendations for surgical treatment of EBC, LABC, management of LABC, use of NACT, and management of axilla in EBC and LABC. Oncoplastic surgical principles are recommended for every breast cancer surgeon. Surgery for DCIS is recommended in these revised guidelines. Management of locally advanced breast cancer (LABC) is revised with recommended use of neoadjuvant chemotherapy prior to the surgery. Surgery for metastatic breast cancer, managing de-escalation, and survivorship are the additional recommendations in this version. This recommendation also takes into consideration the important aspects of early screening, use of ICG technique that is easily manageable without a nuclear medicine department, importance of genetic testing, and management of fertility issues among young patients of reproductive age.

This revision is based on the real-world evidences and optimum treatment options suitable for Indian patients. The collection of the information and gathering experiences are a continuous and dynamic process, and therefore, these recommendations must be used and updated periodically based on the new insights and additional knowledge updated time to time. The aim of these consensus

guidelines is to find and define the Indian solutions for Indian problems. It is very important that all HCWs and HCPs along with patient groups should work together towards public awareness campaigns that enable early detection and systematic treatment (Fig. 3).

The economic burden of investigations and treatment is huge, and with lack of financial support for medical treatment, it is essential that appropriateness of clinical practice with systematic approach shall be helpful for patients. We need to recognise the social issues and attitude towards healthcare for female gender in the country and as a healthcare professional need to mobilise the awareness campaigns for early, effective, and economical healthcare treatment. These guidelines are revised as a simple effective approach to achieve this objective. The expert panel is hopeful that the fraternity shall find it useful in day-to-day practice.

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Declarations

Conflict of Interest The authors declare no competing interests.

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