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AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2026

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Introduction

Optimal management of breast cancer (BC) requires a multidisciplinary approach. The interdisciplinary AGO Breast Committee annually issues updated, evidence-based recommendations on prevention, diagnosis, and treatment. The update process follows a predefined methodological framework, including systematic review of relevant recent publications and structured assessment according to the Oxford Levels of Evidence (LoE). The strength of recommendation is determined using the Oxford Grades of Recommendation (GR) in conjunction with the AGO grading system. The most recent update for early and metastatic BC was released in March 2026. This manuscript summarizes the updated recommendations for early BC.

Options for Primary Prevention and Lifestyle Factors

The active changing of modifiable lifestyle factors is an important aspect and would lead to the primary prevention of more than a third of postmenopausal BCs [1]. Maintaining normal weight (BMI at 18.5–25 kg/m^2) is highly recommended in postmenopausal women, while in this regard no benefit was seen in the premenopausal situation [2]. However, the prevention, screening, and treatment of diabetes mellitus type II are highly effective independent of the menopausal status for the reduction of BC incidence and mortality. In this context, the use of metformin as an oral antidiabetic is not preventive (HR 0.87; CI, 0.69–1.10) but safe without inducing an increased BC risk [3]. Healthy nutrition is gaining increasing evidence in primary cancer prevention and highly recommended [4]. In a prospective cohort study after adjustments for confounders, ultra-processed food consumption was associated with an increased BC incidence (HR: 1.16; 95% CI, 1.01–1.34, p = 0.04) and this effect was even stronger in women >65 years (HR: 1.41, 95% CI, 1.12–1.78), alcohol drinkers (HR: 1.18, 95% CI, 1.02–1.37), and those with a family history of BC (HR: 1.45, 95% CI, 1.00–1.95) [5].

BC Risk, Genetics, and Prevention

Testing for BC risk genes can inform about a possible medical and/or surgical therapy for patients but also direct prevention and early detection for healthy individuals. In the therapeutic setting, genetic germline testing for *BRCA1, BRCA2* can inform about a possible therapy with PARP inhibitors (according to the label) in the early and advanced BC setting (LoE 1a/A/AGO++). Additionally *PALB2*

mutations open the possibility for a PARP inhibitor therapy in the metastatic setting (LoE 2b/B/AGO+). This therapeutic testing is independent of BC risk factors or mutation probabilities. Different from that in the preventive setting, certain criteria need to be met to test for a panel of BC risk genes. Panels include, for example, but are not restricted to genes like *ATM, BARD1, BRIP1, CDH1, CHEK2, PALB2, RAD51C, RAD51D, PTEN, TP53, STK11* (LoE 1b/B/AGO+). Criteria for testing aim to describe populations with mutation frequencies over 10%: germline testing should be offered to patients under 70 years with a triple-negative breast cancer (TNBC), to patients under 80 years with an ovarian cancer diagnosis as well to a male BC patient (LoE 2b/B/AGO++) [6]. Further criteria for testing in the context of preventive counseling in Germany are provided under https://www.krebsgesellschaft.de/unsere-themen/zertifizierung/erhebungsboegen-und dokumente from the German Cancer Society. Additionally to the genetic testing, healthy women should be provided with a risk assessment regardless of the outcome of the testing for the panel of BC risk genes. For this purpose of risk prediction, validated software tools should be used like CanRisk (https://www.canrisk.org/) (AGO++). The risk calculation is based on nongenetic risk factors, high-risk genes, and can also include the effect of a large group of low-risk genes in the form of a polygenic risk score (LoE 2b/B/AGO+) [7, 8]. Women with an increased risk of BC are offered a multimodal intensified surveillance/follow-up program including MRI (AGO++). The examinations are offered to mutation carriers in BC risk genes, healthy women up to the age of 50 without evidence of a mutation with a calculated BC risk of 5% or larger in 10 years (AGO++), and BC patients who fulfill the criteria for a genetic germline examination of the GC-HBOC and have developed BC before their 46th birthday. Both intensified surveillance/follow-up program and risk-reducing unilateral or bilateral mastectomy can represent an individual prevention strategy, but should not be offered without the presence of clearly defined genetic risk factors (LoE 2a/B/AGO−).

Early Detection and Diagnosis

Regarding the screening of asymptomatic women, participation in the national mammography screening program is recommended. The question of whether risk-adapted screening can be more effective was investigated by the randomized WISDOM trial [9]. A total of 14,160 women undergoing annual mammography were compared to 14,212 women undergoing a risk-adapted approach based on individual risk calculated by age, ethnicity, previous biopsies, breast density, and genetic testing with the Polygenic Risk Score. The endpoint was the rate of stage ≥IIB BC. Non-inferiority was demonstrated (risk-based: 30.0 [95% CI, 16.3–43.8] versus annual: 48.0 [95% CI, 30.1–65.5] per 100,000 person-years; rate difference: −18.0 per 100,000 person-years [95% CI, −40.2 to 4.1]). Due to differing circumstances – established screening with an invitation system in Germany, no routine MRI in case of high density, differences in quality assurance, availability of genetic testing, and health economic aspects – the applicability to Germany is limited. Therefore, this approach is recommended by the AGO e.V. with +/− (LoE 1b/B). For high-risk patients, participation in the intensified early detection program is recommended. Another exciting topic is the integration of artificial intelligence for carcinoma detection. While the data for replacing the second reader with artificial intelligence are currently not considered sufficient (LoE 1b/B/AGO+/−), two studies have presented an improved detection when AI is added for double reading (LoE 1b/B/AGO+) [10, 11]. The use of artificial intelligence to reduce the workload in the context of standard double reading (LoE 2b/B/AGO+) as well as an additional instrument for deciding on the need for further assessment by MRI is promising (LoE 1b/B/AGO+/−). While breast self-examination may increase breast awareness, it is no longer recommended as a screening tool (LoE 1a/B/AGO−). In women with average risk for developing BC, ultrasound alone is not recommended as a screening tool (LoE 5/D/AGO−−). However, screening ultrasound is a valid option for those with dense breasts (ACR C/D; LoE 2a/B/AGO++). In women with very dense breasts (ACR D), breast MRI can be used as additional imaging in case of a negative mammogram (LoE 1b/B/AGO+). The recommended workup in symptomatic patients includes clinical examination (LoE 3b/B/AGO++), mammography (LoE 1b/A/AGO++), and ultrasound (LoE 2b/B/AGO++). It may include tomosynthesis, contrast-enhanced mammography, and/or breast MRI in selected patients (AGO+). If indicated, minimally invasive biopsy should be performed (LoE 1b/A/AGO++). Regarding staging of the breast and axilla, there were no changes of recommendations except of a minor upgrade of the use of PET-based imaging of the axilla (LoE 2b/B/AGO+/−).

Pathology

The term TNBC is commonly used to indicate a group of highly aggressive, ER-/PR-/HER2-negative BCs, but it has also been applied in a more general sense to specify any ER-/PR-/HER2-negative BC. However, it should be emphasized that there is no single tumor entity associated with TNBC, but rather a heterogeneous group of tumor types with widely different histologies and clinical behavior. More recently, the term *TNBC-like carcinoma* has been introduced to indicate BC having similar histologic and immunohistologic features like otherwise typical, aggressive TNBC, but with low hormone-

Table 1. Spectrum of TNBCs and TNBC-like malignancies

High-risk TNBC and TNBC-like tumor subtypes	Classic TNBC, high grade (NST) TNBC-like, high grade (NST) Metaplastic Ca, high grade (spindle-cell, matrix-producing, squamous, myoepithelial Ca)
TNBC and TNBC-like subtypes with divergent behavior	Ca with apocrine differentiation (NST, ILC, others), intermediate or high proliferation Metaplastic Ca, intermediate risk, intermediate or high proliferation Secretory Ca and high-grade salivary-type TNBC (such as solid-basal adenoid-cystic Ca)
TNBC and TNBC-like subtypes with low risk	Ca with apocrine differentiation (NST, ILC, others) and low proliferation Slowly proliferating, rare, and salivary-type TNBC (such as classical adenoid-cystic Ca) Metaplastic Ca, low grade (fibromatosis-like or adenosquamous Ca)

receptor (HR-)positive status [12]. Therefore, the definition of triple-negative tumor status has become subject to discussion. For clinical purposes, the spectrum of TNBC can be classified according to its clinical behavior and subclassified according to histologic tumor types (Table 1). Another emerging topic in diagnostic breast pathology is the use of techniques that integrate artificial intelligence [13]. Artificial intelligence in diagnostic breast pathology is now routinely used as a decision support tool for specific tasks such as biomarker scoring and metastasis detection. Especially artificial intelligence-assisted HER2/ER/PR/Ki-67 scoring on digital slides is close to being considered established [14]. Second, algorithms for the detection of lymph node metastases on whole-slide images have reached very high sensitivity and are increasingly integrated as screening tools in digital workflows [15]. Third, the use of large language models (LLMs) can be an aid for accessing databases such as NCBI PubMed, but should be used with great caution, because LLMs tend to hallucinate and may generate false evidence and grossly misleading conclusions, especially when confronted with very specialized queries. ESMO has recently published guidance for both artificial intelligence generated biomarker scoring and LLMs to introduce quality criteria before their clinical implementation [16].

Prognostic and Predictive Factors

Prognosis and treatment decisions in early BC [17] are primarily driven by locoregional tumor burden and tumor biology, including ER, PR, HER2, and Ki-67. Additional to the classification defining the subtypes (HR-positive/HER2-negative, HER2-positive, and TNBC), these factors allow risk stratification into low- and high-risk groups of patients to determine treatment recommendation. An ER expression of 1–9% (ER-low) indicates loss of ER function, so endocrine therapy is questionable. Treatment decision-making for or against chemotherapy is crucial for patient with HR-positive/HER2-negative eBC. Gene expression signatures, like MammaPrint and Oncotype DX (LoE 1b/B/+), or EndoPredict and Prosigna (LoE 2b/B/+), can guide decision-making process. All genomic assays should be performed on untreated tumor tissue. In case of prior endocrine induction therapy on core biopsy specimens, Ki-67 is a proliferation marker indicating treatment responsiveness including pathologic complete response (pCR) rates after neoadjuvant chemotherapy (LoE 2b/B/AGO+) [18]. Furthermore, it is used to measure endocrine treatment response by changes in Ki-67 expression after a short 2–4 weeks preoperative endocrine induction treatment (LoE 1a/B/AGO+). A lack of Ki-67 reduction indicates resistance. A postendocrine Ki-67 decrease to <10% with an RS 0–25 suggests excellent survival without chemotherapy as demonstrated by the explorative analysis of the ADAPT trial [19]. As a treatment decision aid, postendocrine Ki-67 in combination with gene expression signatures is still under investigation in the ADAPTcycle trial, which compares chemotherapy versus endocrine therapy plus ribociclib in HR-positive/HER2-negative patients. For HER2-positive disease, the HER2DX test can estimate the benefit of neoadjuvant trastuzumab with or without pertuzumab (LoE 2b/B/AGO+/−), using pCR and risk scores to identify suitable candidates for dual HER2 blockade with a taxane [20]. If chemotherapy is indicated, it should be given neoadjuvantly. Key marker of response to neoadjuvant systemic treatment is the pCR in breast and lymph node tissue. In case of non-pCR, the CPS-EG (LoE 2b/B/AGO+) and the Residual Cancer Burden (RCB) scores (LoE 2a/B/AGO+) help guide subsequent treatments – such as identifying HR-positive/HER2-negative patients who may benefit from olaparib after neoadjuvant chemotherapy and *gBRCA* mutation [21, 22]. In this way, these tools ensure more personalized and precise treatment decisions.

Lesions of Uncertain Malignant Potential (B3)

In recent years, the published evidence underpinning recommendations for the management of clinically occult high-risk lesions has broadened considerably, generally leading to a more conservative approach, although management still depends on lesion type [23, 24]. Notably, results from the COMET trial were published only recently and indicate a low upgrade risk for atypical ductal hyperplasia (ADH) in the trial cohort [25]. However, these findings should be interpreted with caution, given the substantially higher upgrade risk observed after long-term follow-up of ADH [23]. Several factors associated with a lower risk of upgrade in ADH have been proposed to identify a subgroup of patients suitable for active surveillance [26]. Nevertheless, in view of conflicting evidence, AGO recommendations for the management of ADH have remained unchanged, and robust criteria for identifying low-risk ADH have yet to be established. In contrast to ADH, high-risk lesions of lobular intraepithelial neoplasia/lobular carcinoma in situ (LCIS) can be reliably identified histologically in core needle or vacuum-assisted biopsies. This includes nonclassical LCIS (pleomorphic and florid subtypes), which should be managed by surgical excision [24], with florid LCIS showing an upgrade rate to invasive lobular carcinoma of up to 50% [27]. A systematic review assessing upgrade risk in intraductal papilloma without atypia reported a 1.4% upgrade rate to invasive carcinoma, while 16.4% were upgraded to atypical or high-risk lesions [28]. Accordingly, AGO recommendations advocating open biopsy for papillomas have remained unchanged. Other B3 lesions associated with a lower risk of upgrade on surgical excision include flat epithelial atypia and radial sclerosing lesions (radial scar). Clinical management of these entities requires careful clinicopathologic correlation. Factors such as the presence of a mass lesion, radiologic-pathologic discordance, prior biopsies, lesion size, and specific histologic features should be considered when deciding for or against open biopsy [24].

Ductal Carcinoma in situ

DCIS is a not life-threatening preinvasive lesion that is considered to be a precursor of invasive BC. It represents an extremely heterogeneous group of lesions with variable potential for progression to invasive disease, in which not all DCIS will progress to invasion [29]. Most DCIS cases are detected within the mammography screening. In addition to mammography, which is the main diagnostic tool, pretherapeutic assessment in DCIS should also include breast and axillary ultrasound, especially to rule out an accompanying invasive solid part and lymph node involvement (LoE 4/C/AGO++). Breast MRIs might be helpful for assessment of the extension and planning surgical procedure in DCIS (LoE 1a/B/AGO+/−) but can lead to overestimations of the extension of the DCIS and by that to surgical overtreatment. Complete surgical excision remains the standard of care (LoE 1a/A/AGO++). All guidelines recommend clear margins of 2 mm for DCIS lesions except below the skin and above the muscle. SNLB might be recommended in rare cases if the surgical procedure is not allowing an SLN in case of an upstaging to invasive cancer (e.g., cases of kind of mastectomy for large DCIS lesions, LoE 3a/C/AGO+/−). Preferably "delayed sentinel" should be performed after mastectomy in DCIS grade 2 and >20 mm, DCIS grade 3 or DCIS with palpable lesion (LoE 3b/C/AGO+) (Kang E, 2025. #29) [30].

Radiotherapy is commonly recommended after BCS of DCIS (LoE 1a/A/AGO+), whereas systemic endocrine treatment (tamoxifen [TAM] 20 mg for 5 years or 5 mg for 3 years or anastrozol) is only recommended as an option (LoE 1a-b/A-B/AGO+/−) [31]. Omission of adjuvant RT for low-risk situation (<2.5 cm, G1/2, age >50 J., ASR >2 mm) is an option (LoE 1b/B/AGO+/−). Preferred radiotherapy procedures are moderately hypofractionated radiotherapy (40–42.5 Gy in 15–16 fract.) (LoE 1b/B/AGO+) and conventionally fractionated radiotherapy (50 Gy in 25 fract.) (LoE 1a/A/AGO+) [32, 33]. Radiotherapy boost to the tumor bed in DCIS may be applied in case of risk factors (LoE 2b/B/AGO+/−) but is associated with a significantly increased rate of fibrosis. Independent of DCIS grade, adjuvant endocrine treatment and irradiation have no impact on survival (LoE 1a). Radiotherapy reduces the risk of ipsilateral (invasive and noninvasive) recurrences by 50%. The number needed to treat with radiotherapy (for ipsilateral breast recurrence) is 9. Adjuvant endocrine treatment has a moderate effect on ipsilateral invasive (HR 0.79; 95% CI, 0.62–1.01) and DCIS (HR 0.75; 95% CI, 0.61–0.92) recurrences and on contralateral invasive (RR 0.57; 95% CI, 0.39–0.83) and noninvasive cancer (RR 0.50; 95% CI, 0.28–0.87) (endocrine therapy, LoE 1a). The number needed to treat to prevent any breast event is 15 (13 without RT and 17 with RT) [34]. A recently presented combined analysis from two prospective trials on radiotherapy has shown a substantial effect from TAM on invasive relapse (HR = 0.49, 95% CI: 0.28–0.84, 15-year risk 19% vs. 11.4%) if no radiotherapy was performed in patients with low-risk DCIS (size ≤2.5 cm, grade 1–2, margin ≥3 mm) [35]. Additionally to established prognostic factors (size, differentiation, margin, histological type), the Oncotype DX DCIS Score [36] and DCISionRT [37] might be useful as prognostic factors for an ipsilateral recurrence after first diagnosis of a DCIS (LoE 2b). The Oncotype DCIS Score is a multigene assay

that has been independently validated in a prospective clinical trial and a population-based cohort. The score helps identify a subset of women >50 years old with unifocal disease that carries <10% risk of any local recurrence after breast-conserving surgery alone. DCISionRT provides information regarding the recommendations to add or omit RT. In the COMET trial, women with low-risk DCIS (>40 years, HR+, G1 or 2) randomized to active monitoring every 6 months with mammography of the affected side did not have a higher rate of invasive cancer at 2 years compared with those randomized to guideline-concordant care – median follow-up 36.9 months (the 2-year Kaplan-Meier cumulative rate of ipsilateral invasive cancer was 5.9% in the guideline-concordant care group vs. 4.2% in the active monitoring group) (LoE 2a/B/AGO–) [38].

Oncological Aspects of BC Surgery

BC therapy should begin within 8 weeks of confirmed diagnosis and be planned by multidisciplinary conferences (AGO++). Surgery is an essential element of multimodal care for early BC [17], and breast surgeons must have strong skills in both diagnosis and cancer management (AGO++). Breast-conserving surgery [39] followed by radiotherapy provides overall survival outcomes that are at least comparable to those achieved with mastectomy (LoE 1a/A). For non-palpable BCs, lesion localization with wire guidance and/or intraoperative ultrasound is strongly recommended (LoE 1a/A/AGO++) [40, 41] and probe-guided techniques such as Magseed™ may be used (LoE 1b/A/AGO+). Invasive BCs should be removed with clear margins, defined as "no ink on tumor" (LoE 2a/A/++). Re-excisions are recommended if invasive or noninvasive tumor cells are reaching the margin (LoE 2a/B/++). In case of a non-palpable lesion, the adequate resection volume should be confirmed by intraoperative specimen imaging (radiography or ultrasound) (LoE 2b/B/++). In the setting of primary systemic therapy, the tumor bed should be marked early in the course of treatment.

Three randomized trials have shown non-inferiority of SLNB omission in low-risk BC patients compared to SLNB. This relates to patients ≥50 years with cT1 cN0 tumors, G1 and G2 and ER pos, HER2-negative disease, who undergo BCS and whole breast irradiation (WBI) [42–44]. Since SLNB is a diagnostic procedure and some patients might benefit even in the low-risk group, AGO strongly recommends to discuss SLNB omission in a multidisciplinary tumor board (LoE 5/D/++). If no therapeutic consequence is expected, SLNB should be omitted in appropriate patients (LoE 1b/B/++). SLNB remains a standard of care for all other patients with clinically uninvolved lymph nodes (cN0) (LoE 1b/A/++). Different tracers can be used for SLN mapping, including technetium (LoE 1a/A/AGO++), indocyanine green (LoE 2a/B/AGO+), and superparamagnetic iron oxide (LoE 2a/B/AGO+). Major changes have been endorsed regarding recommendations for axillary surgery in patients with node-positive disease before neoadjuvant chemotherapy who convert to clinically node-negative status (cN+ → ycN0). In cases with 1–3 suspicious lymph nodes at the time of diagnosis, targeted axillary dissection (TAD) is recommended as the surgical staging technique of choice (AGO++) [45]. In addition, SLNB and targeted lymph node biopsy are acceptable alternatives (AGO+), whereas primary ALND has been downgraded to AGO+/–. In patients initially presenting with 4 or more suspicious lymph nodes, TAD is graded as AGO+. TAD may also be performed in patients with occult BC (AXCUP; LoE 3b/C/AGO+). In patients with inflammatory BC, the decision to perform TAD should be made on a case-by-case basis (LoE 3b/C/AGO+/–). Regarding marking techniques for the target lymph node, the highest detection rates are achieved when markers suitable for probe-guided detection are placed before NACT (LoE 2b/B/AGO+) [46]. Participation in the international AXSANA/EUBREAST-03 study is recommended.

Oncoplastic and Reconstructive Surgery

Oncoplastic surgery enables the oncologically safe excisions of larger lesions in the breast while preserving a favorable aesthetic and cosmetic outcome. In addition to a variety of techniques and skin/soft-tissue flaps, pedicled chest wall perforator flaps are increasingly used, especially for partial breast reconstruction, such as the Li-CAP, Mi-CAP, or Ai-CAP flap (LoE 2a/B). If the patient requires mastectomy, the patient's preference for an aesthetic flat closure rather than reconstruction should be respected when discussing a possible reconstruction. If the patient wishes to have the breast reconstructed, heterologous reconstruction with implants and autologous reconstruction using pedicled or free flaps are recommended (LoE 2a/B/AGO+), depending on individual tumor characteristics and patient preferences. Breast reconstruction is associated with a range of possible complications. If implant-based reconstruction is performed in the context of planned radiotherapy, hypofractionated radiotherapy is associated with a lower rate of capsular contracture (LoE 2a/B) [47]. Regarding antibiotic prophylaxis, despite a meta-analysis suggesting prolonged antibiotics >24 h (LoE 2a/B/AGO+/–), a 24-h antibiotic course remains the standard for breast reconstruction (LoE 1a/A/AGO+). For the prevention of postoperative seromas and hematomas, the evidence regarding the use of tranexamic acid has become more

robust. Topical, intravenous, and oral tranexamic acid administration can significantly reduce postoperative seromas and hematomas (1–3 g for 1–5 days; administered IV within the first 24 h, then orally or topically in saline) (LoE 2a/B/AGO+) [48]. Another preventive option for seromas is the administration of 100 mg hydrocortisone IV immediately before surgery or 80 mg methylprednisolone locally (for 24 h in the wound cavity with clamped drainage) or 100–125 mg IV 1 h preoperatively (LoE 2a/B/AGO+/−) [49]. There are still no high-quality prospective randomized studies comparing the use of synthetic meshes versus acellular dermal matrices (ADMs) in implant reconstruction (AGO+/−). However, it is increasingly evident that the complication rate is lower with synthetic meshes compared to ADMs, as ADMs are associated with significantly more major complications [50]. The consensus on endoscopic/robotic nipple-sparing mastectomy (LoE 2b/B/AGO+/−) by Ryu and colleagues [51] places this increasingly used technique in a clinical context. For example, nodal-negative tumors ≤2 cm with a tumor-to-skin distance >5 mm to the cup C can be effectively operated on via an endoscopic approach. Finally, the use of negative pressure wound therapy after mastectomy, reconstruction, and oncoplastic surgery to prevent wound-healing disorders, mastectomy flap necrosis, infections, and seroma – especially in patients with BMI >30 – should be considered (LoE 2b/B/AGO+/−) [52].

Systemic Treatment of eBC-HR+/HER2-BC

For HR+/HER2-BC patients, it is important to distinguish those who require both chemotherapy and endocrine therapy from those who can be adequately treated with endocrine therapy alone. For a subset of patients, clinicopathological factors alone are insufficient for making this decision. In these cases, gene expression profiling should be performed. Additionally, a Ki-67 reevaluation after a short-term preoperative endocrine treatment (2–4 weeks) may provide additional information to guide optimal treatment [19]. If chemotherapy is indicated, the preferred regimen for either adjuvant or neoadjuvant chemotherapy is a dose-dense anthracycline/taxane-based chemotherapy (LoE 1a/A/AGO++). Endocrine therapy consists of initial treatment (years 1–5) and, in patients at increased risk, extended adjuvant therapy (years 6–10+). For premenopausal women at low risk of recurrence, therapy with TAM for 5 years is recommended (LoE 1a/A/AGO++). For those at high risk of recurrence, GnRHa plus TAM or an aromatase inhibitor (AI) should be used (LoE 1a/A/AGO++). For postmenopausal patients, initial adjuvant endocrine therapy should include an aromatase inhibitor (AI) (LoE 1a/A/AGO++). Extended adjuvant therapy can be recommended for pre- and postmenopausal patients at increased risk of recurrence. Patients at increased risk of recurrence who fulfill the inclusion and exclusion criteria of the monarchE and/or NATALEE trial should receive in addition a CDK 4/6i with either abemaciclib (LoE 1b/B/AGO++) or ribociclib (LoE 1b/B/+). The monarchE trial included patients with stage II and III HR+/HER2-BC at high risk of BC recurrence (≥4 positive axillary lymph nodes or 1–3 positive axillary lymph nodes and either grade 3, tumor size ≥5 cm). Abemaciclib (150 mg) was administered for 2 years. Endocrine treatment included TAM+/−GnRHa or nonsteroidal AI +/−GnRHa. After a median follow-up of 76.2 months, an overall survival benefit could be demonstrated for the first time. The 7-year OS was 86.8% in the abemaciclib group versus 85% in the control group (HR 0.842; 95% CI, 0.722–0.981; p = 0.0273) [53]. The inclusion criteria of the NATALEE trial were much broader including all patients with axillary lymph node metastases and a group of patients with no nodal involvement but additional risk factors. Ribociclib (400 mg) was given for 3 years. Endocrine treatment included AI +/− GnRHa. In an updated analysis of the NATALEE trial, the addition of ribociclib to endocrine therapy demonstrated a significant 5-year iDFS benefit (HR, 0.749; 95% CI, 0.628–0.892; $p < 0.0001$) with absolute improvements of 4.5%. The survival data are still immature [54]. For HR+/HER2− patients with germline BRCA1/2 mutations and high risk of recurrence (adjuvant ≥4 lymph nodes or neoadjuvant non-pCR with CPS-EG ≥3), 1 year of olaparib in combination with endocrine therapy is recommended [55].

Systemic Treatment of eBC-HER2+

In patients with HER2-positive early BC [17], neoadjuvant systemic therapy with anti-HER2-directed treatment is the preferred approach. For tumors larger than 2 cm and/or node-positive disease, anthracycline-free regimens consisting of a taxane and carboplatin in combination with trastuzumab and pertuzumab (LoE 1b/A/AGO++) are commonly used. Alternatively, the classical sequential regimen of AC/EC (every 3 weeks or dose-dense every 2 weeks with G-CSF support), followed by a taxane, remains an evidence-based option (LoE 1a/A/AGO++). More recently, carboplatin-free neoadjuvant regimens have been evaluated in combination with trastuzumab and pertuzumab. These include six cycles of a taxane alone [56] or four cycles of trastuzumab-deruxtecan followed by four cycles of docetaxel [57] (LoE 1b/B/+/−). In the phase III *neoCarph* trial, patients received six cycles of a taxane – either weekly paclitaxel for 18 weeks or docetaxel or nab-paclitaxel every 3 weeks – with or without carboplatin. pCR rates were 64.1% in the carboplatin-free arm compared with 65.9% in the carboplatin-containing arm

[56]. In the *DESTINY-Breast11* trial, patients received four cycles of trastuzumab-deruxtecan followed by four cycles of docetaxel with dual blockade compared with six cycles of docetaxel and carboplatin with dual blockade. pCR rates of 67% were achieved [57]. Patients with HER2-positive disease who do not achieve a pCR should receive 14 cycles of T-DM1 as adjuvant therapy (LoE 1b/B/AGO+) [58]. With a median follow-up of 8.4 years, T-DM1 sustained an improvement in invasive disease-free survival over trastuzumab. Seven-year overall survival was 89.1% with T-DM1 and 84.4% with trastuzumab. In patients with high-risk, residual invasive HER2-positive BC, 14 cycles of trastuzumab-deruxtecan significantly improved invasive 3-year disease-free survival rate compared with T-DM1 (92.4% vs. 83.7%) in high-risk patients with either inoperable disease at diagnosis (cT4 od >cN2) or node-positive disease after neoadjuvant chemotherapy (ypN+) (LoE 1b/B/AGO+) [59]. Interstitial lung disease is an important identified risk of trastuzumab-deruxtecan and requires appropriate surveillance and management. For tumors <2 cm and node-negative disease, adjuvant therapy with weekly paclitaxel for 12 cycles plus trastuzumab for 12 months represents an effective anthracycline-free option (LoE 2b/B/AGO++). Trastuzumab should be completed for a total duration of 12 months (LoE 1a/A/++). In patients with node-positive disease, the addition of adjuvant pertuzumab to trastuzumab and chemotherapy is recommended (LoE 1b/B/AGO+).

Systemic Treatment of eBC-TNBC

TNBC represents one of the preferred indications for neoadjuvant systemic therapy. While the backbone chemotherapy regimens have not fundamentally changed, data emerging over the past year have further emphasized the role of carboplatin, particularly in patients who do not qualify for the KEYNOTE-522 regimen. Neoadjuvant chemotherapy is recommended for tumors ≥10 mm (≥cT1c), supported by LoE 2b/B and an AGO++. In smaller tumors, a more individualized approach is warranted. In cT1b disease, both neoadjuvant and adjuvant chemotherapies may be considered (LoE 2b/B, AGO+), whereas in cT1a tumors adjuvant chemotherapy remains optional and should be carefully weighed against the risk of overtreatment (LoE 2b/B, AGO+/−). For patients with TNBC ≥cT2 or cN+ disease without an indication for pembrolizumab (e.g., due to adjuvant treatment or contraindications), treatment options include either a carboplatin-containing regimen or a dose-dense anthracycline/taxane-based regimen (LoE 1b/B, AGO++). Over recent years, the evidence supporting the addition of carboplatin has strengthened, demonstrating higher pathological response rates and improved survival outcomes when combined with weekly paclitaxel followed by dose-dense EC or AC (or administered in reverse sequence) [60–63]. This strategy is therefore supported by high-level evidence (LoE 1b/B, AGO++) and especially applicable for premenopausal women. In patients with T1N0 disease who do not receive carboplatin, dose-dense EC for 4 cycles followed by 12× weekly paclitaxel remains the standard of care (LoE 1b/B, AGO++). Alternatively, selected patients may receive paclitaxel + carboplatin for up to 18 weeks (LoE 2b/B, AGO++). Patients with tumors >2 cm or cN+ should receive pembrolizumab in addition to neoadjuvant paclitaxel/carboplatin followed by anthracycline-based chemotherapy, with continuation of pembrolizumab in the adjuvant setting for a total of 9 cycles irrespective of pathological response, in accordance with the KEYNOTE-522 regimen. This strategy has demonstrated a significant 5-year OS benefit for patients receiving pembrolizumab [64]. These recommendations have remained unchanged. At present, there is no indication for immune checkpoint inhibitor therapy in the purely adjuvant setting without prior neoadjuvant exposure. Capecitabine remains an important postneoadjuvant treatment option, particularly for patients who did not receive immune checkpoint inhibition, supported by strong evidence (LoE 1a/A, AGO++) [65]. Finally, in patients with a germline BRCA1/2 mutation, postneoadjuvant treatment with olaparib is recommended in TNBC with residual disease as well as in patients with stage II or higher disease, based on a demonstrated overall survival benefit of the OlympiA trial (LoE 1a/A, AGO++) [55].

Adjuvant Radiotherapy

Following breast-conserving surgery [39], WBI with moderate hypofractionation is the standard of care (LoE 1a, grade A, AGO++). Based on 10-year FAST-FORWARD results (ESTRO 2025), ultra-hypofractionated WBI may be considered in selected patients, but with a lower recommendation level (LoE 1b, grade B, AGO+) (LoE 1b, grade B, AGO+) [66, 67].

A tumor bed boost is recommended for patients ≤50 years (LoE 1b, grade B, AGO++) and for patients >50 years with risk factors (tumor size >3 cm, grade 3, HER2-positive or triple-negative subtype, or extensive intraductal component) (LoE 2b, grade B, AGO+). Simultaneous integrated boost is non-inferior to sequential boost with moderate hypofractionation (LoE 1b, grade B, AGO++). Boost irradiation may be omitted in patients >50 years with pathological complete response after neoadjuvant chemotherapy (LoE 5, grade D, AGO+). Partial breast irradiation is an alternative to WBI in low-risk disease (age ≥50 years, tumor <3 cm, pN0, ER/PgR-positive, HER2-negative, grade 1–2, L0, R0, non-lobular histology, no known BRCA mutation). Following publication of the SUPREMO trial and

updated ASTRO-ASCO-SSO guidelines, PMRT indications were refined [68, 69]. PMRT may be omitted in selected low-risk patients (pT1–2, one to two positive lymph nodes, ER/PR-positive, HER2-negative, grade 1–2, L0, age >50 years) after axillary lymph node dissection (LoE 1b, grade B, AGO–). Shared decision-making (SDM) is advised for patients aged 40–50 years, while PMRT remains indicated for ≥4 positive lymph nodes or pT4 tumors or pT3 tumors with additional risk factors (LoE 1a, grade A, AGO++). Moderate hypofractionation is the standard of care for PMRT with or without reconstruction and for regional nodal irradiation (LoE 1a–1b, grade A-B, AGO++) [70]. Ultra-hypofractionation may be considered for PMRT without reconstruction (LoE 1b, grade B, AGO+). Irradiation of the internal mammary chain may be considered in selected patients despite left-sided tumors, even with increased cardiac risk or concomitant HER2-targeted therapy (LoE 2b, grade A, AGO+/–). In patients with one to two positive sentinel lymph nodes, irradiation of axillary levels I–IV is recommended instead of axillary dissection (LoE 1b, grade B, AGO+). Trastuzumab-deruxtecan may be administered concomitantly with radiotherapy (LoE 2b, grade B, AGO+).

BC: Special Situations

In principle, treatment recommendations for older patients are based on those for younger patients (AGO++), but are adapted to take into account biological, physical, psychological, and treatment-related aspects as well as the results of a geriatric assessment. For people with disabilities, cancer screening, prevention, and treatment measures should be repeatedly weighed with regard to their practical feasibility for the individual patient and the expected benefit (AGO++). This process should take place within the framework of informed decision-making, taking into account the specific medical conditions as well as the individual abilities and needs of the patients (AGO++). Social networks, family members, and/or legal guardians should be involved in the decision-making process (AGO++). Transgender individuals should be informed about signs and symptoms of BC (AGO++). The indication for genetic counseling follows the same criteria as for cisgender individuals (whose gender identity corresponds to the sex assigned at birth) (AGO++). BC screening should be offered to transgender women after more than 5 years of gender-affirming hormone therapy (AGO++). If transgender men opt for mastectomy, age-appropriate BC screening should be performed prior to surgery. The removed breast tissue should undergo complete histopathological examination (LoE 3/A/++). For men, no specific BC screening or early detection exists due to the low incidence. Systemic therapy for men with BC is generally analogous to that for women (AGO++). For the treatment of males with HR+ BC, TAM is standard (LoE 2b/B/AGO++). Aromatase inhibitors must be administered in combination with GnRH agonists (LoE 4/C/AGO+). The diagnosis of inflammatory BC should be aided by using standardized scores (AGO++) [71]. The use of TAD might be considered in patients with cN1 who have clinically negative nodes (ycN0) after neoadjuvant therapy (LoE 3b/C/+/–) [72]. This also applies for patients with axillary cancer of unknown primary who have a clinical complete response to neoadjuvant therapy (LoE 3b/B/+) [73]. For radiotherapy-associated angiosarcoma, there is increasing evidence that multimodality treatment with chemotherapy (LoE 3a/C/+) and radiotherapy (in case of risk factors; LoE 2b/B/+) delivered either pre- or post-operatively improves outcomes. In patients with metaplastic BC, adjuvant systemic therapy should be administered according to biologic subtype (LoE 3b/C/+).

Locoregional Recurrence

A locoregional recurrence (LRR) is defined as the reappearance of BC in the ipsilateral breast, chest wall, or regional lymphatic drainage areas after primary curative treatment. The occurrence of an LRR is associated with an increased risk of distant metastasis (AGO: ++, LoE: 2b). Before initiating therapy, complete staging should be performed to exclude distant metastasis. Recommended investigations include CT of the chest, abdomen, and pelvis, as well as bone scintigraphy (AGO: ++, LoE: 2a) [74]. In selected cases, whole-body MRI or 18F-FDG PET-CT may be used (AGO: +, LoE: 2b). In cases of resectable ipsilateral LRR or a second primary BC, complete surgical resection (R0) should be pursued (AGO: ++, LoE: 2a) [74–76]. The decision must take into account the type of primary surgery and any prior radiotherapy. After second breast-conserving surgery (LoE 3b/C/++) or after resection of a chest wall recurrence (LoE 2b/B/+) without prior radiotherapy, it should be administered. In cases with in-breast tumor recurrence after breast-conserving therapy and favorable prognostic factors, second breast-conserving surgery with re-irradiation as partial breast irradiation should be considered (LoE 2B/B/+) [74, 75, 77]. Re-irradiation after resection of chest wall recurrences with prior radiotherapy may be considered (LoE 3B/B/+ [R1] or +/– [R0]). In case of re-irradiation, adding regional hyperthermia can be considered (LoE 2a/B/+/–). Following complete resection of an LRR, systemic therapy should be considered, as it may reduce the risk of further recurrence (AGO: ++, LoE: 2b). The choice of therapy depends on tumor subtype, prior treatments, and the

recurrence-free interval. In primarily unresectable LRRs, systemic therapy should be initiated with the aim of achieving secondary resectability (AGO: ++, LoE: 2b). In cM0 situations, definitive local therapy may additionally be considered. Even in metastatic disease (cM1), locoregional therapy can be useful for symptom control (AGO: +, LoE: 3). LRR represents a prognostically relevant situation that requires consistent, guideline-based, and interdisciplinary management. A combination of surgical, systemic, and radiotherapeutic treatment should be individually determined based on resectability, tumor biology, and prior therapy.

Osteooncology

Bone-modifying agents, including bisphosphonates and denosumab, remain essential components in the management of bone metastases from BC, effectively reducing skeletal-related events, hypercalcemia, and bone pain (LoE 1a, GR A, AGO++). Extended dosing intervals for zoledronic acid (every 12 weeks) have demonstrated non-inferiority compared with standard 4-weekly administration and may therefore be considered in clinically stable patients (LoE 1a, GR A, AGO++). Denosumab represents an effective alternative to bisphosphonates, particularly in patients with renal impairment, and has shown superiority in delaying time to first skeletal-related event (LoE 1a, GR A, AGO++) [78]. However, recent population-based real-world data indicate a higher incidence and earlier onset of medication-related osteonecrosis of the jaw under denosumab compared with bisphosphonates, especially in patients treated with denosumab alone or sequentially after bisphosphonates [79]. These findings emphasize the importance of stringent dental prevention strategies and careful individual risk-benefit assessment (LoE 2a, GR A, AGO++).

Radiotherapy remains a cornerstone in the treatment of painful bone metastases, spinal instability, or impending fracture (LoE 1a, GR A, AGO++). Fractionation should be individualized according to prognosis, symptoms, and anatomical location. Re-irradiation may be considered in selected patients with recurrent pain (LoE 1b, GR B, AGO++).

Surgical intervention should be considered in patients with metastatic spinal disease presenting with spinal cord compression, progressive neurological deficits, pathological fractures, or mechanical instability (LoE 2b, GR C, AGO++). In this context, direct decompressive surgical resection followed by radiotherapy has been shown to improve ambulation and neurological outcome compared with radiotherapy alone [80]. Decompressive laminectomy combined with radiotherapy is therefore recommended when indicated.

In cancer treatment-induced bone loss and osteoporosis, both antiresorptive and osteoanabolic therapies are effective in fracture prevention [81]. In early BC, adjuvant bisphosphonates are recommended for postmenopausal patients or those receiving ovarian function suppression, due to their demonstrated benefit in reducing bone recurrence and improving survival (LoE 1a, GR A, AGO+).

Complementary Therapy and Survivorship

Physical exercise and training (moderate endurance training three times weekly combined with strength training on machines twice weekly) have positive effects on quality of life, cardiorespiratory fitness, physical performance, sleep, pain, depression, lymphedema, fatigue, etc. (LoE 1a/A/AGO++) [82]. There is evidence that mind-body interventions such as Mindfulness-Based Stress Reduction (LoE 1a/A/+), Yoga (LoE 1b/A/+), or Tai Chi/Qi Gong (LoE 2a/B/+/−) among others improve quality of life as well as fatigue, etc., in BC patients. Acupuncture is effective in improving side effects of BC treatment such as pain (cancer- and aromatase inhibitor-induced), nausea and vomiting (chemotherapy-induced), and fatigue (LoE 1b/B/AGO+). Acupuncture can assist in alleviating sleep problems, cognitive dysfunction (LoE 2b/C/AGO+/−), and polyneuropathy (LoE 2b/B/AGO+/−). Short-term fasting during 3-week chemotherapy cycles reported lower toxicity, reduced fatigue, and improved quality of life in BC patients (LoE 2b/B/AGO+/−) [83]. Extreme fasting or diets should not be recommended to patients (LoE 2a/B/−−); instead, a fiber-rich diet should be pursued (LoE 2a/B/AGO+). Some small RCT studies have shown that melatonin might have beneficial effects in reducing fatigue and depression symptoms, improving sleep quality and cognition for patients (LoE 2b/B/AGO+/−).

Gynecological Issues, Pregnancy, and Reproduction

Hormone replacement therapy is contraindicated in patients with BC (LoE 1a/B/AGO−). However, for vaginal estrogen therapy (with estriol, E3 0.03 mg) a mortality reduction was found (HR, 0.77; 95% CI, 0.63–0.94) [84]. Based on these positive data, including oncological endpoints, the recent AGO's recommendation is clearly positive for the first time (LoE 2b/B/AGO+) [84]. An alternative to treat menopausal symptoms is neurokinin receptor antagonists. Elinzanetant (Lynkuet™, NK1-/NK3-R) is approved in the EU for the treatment of moderate to severe vasomotor symptoms (also known as hot flashes) associated with

menopause or caused by adjuvant endocrine therapy related to BC (LoE 1b/A/AGO+) [85]. In contrast, fezolinetant is not specifically approved for BC and should be used with caution due to its hepatotoxicity (LoE 5/D/AGO+/−).

Counseling on fertility preservation should be offered to all patients wishing to retain their fertility (AGO++). Fertility preservation using ovarian stimulation is not associated with short-term detrimental impact on cancer prognosis [86]. Therefore, assisted reproduction (including hormonal ovarian stimulation) can be performed after BC regardless of BRCA status without worsening the prognosis (LoE 2b[a]/B/AGO+) [87]. BC prognosis during pregnancy is not deteriorated, if adequate treatment is chosen (LoE 3a). Anthracyclines or taxanes after the first trimester can be safely administered (LoE 2b/2a/AGO++), platinum compounds, and G-CSF can be considered (LoE 4/C/AGO+/−). The use of MTX, endocrine therapy, CDK4/6 inhibitors, anti-HER2 drugs, checkpoint inhibitors, bisphosphonates, or denosumab is strictly contraindicated (AGO−−). Before pregnancy planning, the specific washout periods must be taken into account [88].

BC Follow-Up

The goal of follow-up for BC patients is to detect curable locally recurrent disease (LoE 1a/B/AGO++), to detect contralateral BC, and to detect symptomatic metastatic disease (LoE 3b/C/AGO+). So far, there is no evidence that intensified surveillance with additional imaging or early detection of circulating tumor cells or cfDNA and subsequent treatment lead to a better prognosis or can prevent metastatic disease (LoE 2a/D/−) [89]. The AGO recommends the participation in follow-up studies (e.g., SURVIVE study). Follow-up examinations in asymptomatic patients should not include tumor marker measurements and imaging of any kind beyond breast imaging.

Monitoring after cardiotoxic therapy should follow recommendations according to Guideline of EHA, ESTRO, and ICOS [90] and the German S3 Guidelines for supportive care [91]. Lifestyle modifications such as nicotine stop, reduction of alcohol intake below 6 gr per day, moderate physical activities (minimum 150 min per week), weight change (to obtain normal BMI) might have an influence on both quality of life and BC prognosis.

For the detection of curable events, physical examination with annual mammography and additional ultrasound is recommended. However, recent data of a non-inferiority trial including 5,235 women suggest that for patients aged 60 years or older with low-risk disease (pT1, pN0, G1-2 ER/PgR+HER2−), and relapse free at 3 years post-diagnosis less frequent mammograms (2-yearly after conservation surgery; 3-yearly after a mastectomy) were non-inferior compared with annual mammograms for BC-specific survival, recurrence-free interval, and overall survival. Therefore for these patients with low risk of relapse (local and systemic), less frequent mammograms should be considered [92].

Health Literacy and Communication

Health literacy is a decisive determinant of outcome quality in BC care. The AGO recommendations emphasize communication as an evidence-based clinical intervention rather than an auxiliary skill. In line with this, the guideline assigns high recommendation grades to structured, patient-centered communication strategies that enhance comprehension, autonomy, and adherence.

The AGO underscores that health literacy is shaped by the interaction between patient abilities and the communicative environment created by healthcare professionals. Clear, jargon-free language, teach-back techniques, and the use of validated decision aids receive "AGO+" recommendation for improving understanding and reducing decisional conflict. These measures are particularly relevant in complex therapeutic settings such as adjuvant systemic therapy or genetic counseling, where patients must integrate probabilistic information into personal value frameworks.

SDM is highlighted as a core component of modern oncologic care [93]. SDM in preference-sensitive decisions is supported by robust evidence demonstrating improved satisfaction, reduced anxiety, and better alignment between treatment choices and patient priorities [94]. Communication training for multidisciplinary teams is recommended reflecting consistent but less extensive evidence for its impact on patient-reported outcomes.

Digital health literacy emerges as a new focal point in the 2025 update. Given the proliferation of online information and misinformation, the AGO recommends (**grade B**) proactive guidance toward high-quality digital resources and systematic assessment of patients' digital competencies [95]. This approach aims to mitigate disparities that disproportionately affect vulnerable populations.

Overall, the AGO 2026 framework positions communication as a therapeutic modality with measurable clinical relevance. Strengthening health literacy through structured, empathetic, and evidence-based communication contributes to improved patient empowerment, treatment adherence, and long-term quality of life – central goals of contemporary BC care.

Conclusion

The recommendations of the AGO Breast Committee presented here reflect the recent rapid advances in diagnostic and therapeutic options for early BC.

Conflict of Interest Statement

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