

# Not Too Little, Not Too Much: Optimizing More Versus Less Locoregional Treatment for Older Patients With Breast Cancer

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## Overview

Although undertreatment of older women with aggressive breast cancers has been a concern for years, there is increasing recognition that some older women are overtreated, receiving therapies unlikely to improve survival or reduce morbidity. De-escalation of surgery may include breast-conserving surgery over mastectomy for appropriate candidates and omitting or reducing extent of axillary surgery. Appropriate patients to de-escalate surgery are those with early-stage breast cancer, favorable tumor characteristics, are clinically node-negative, and who may have other major health issues. De-escalation of radiation includes reducing treatment course length through hypofractionation and ultrahypofractionation regimens, reducing treatment volumes through partial breast irradiation, omission of radiation for select patients, and reducing radiation dose to normal tissues. Shared decision making, which aims to facilitate patients making decisions concordant with their values, can guide health care providers and patients through complicated decisions optimizing breast cancer care.

Over 77,000 women age 70 years or older in the United States are diagnosed with breast cancer annually. As the population ages, this figure will rise.<sup>1</sup> Women age 70 years or older account for 31% of diagnosed breast cancers, and given widespread mammography use in older women, the majority are diagnosed with stage I, estrogen receptor–positive (ER+)/human epidermal growth factor receptor 2–negative (HER2–) tumors.<sup>2</sup> Although undertreatment of older women with aggressive breast cancers has been a concern for years, there is increasing recognition that some older women with stage I, ER+, HER2– breast cancers are overtreated, receiving therapies unlikely to improve survival or reduce morbidity.

Studies have found that omitting radiation therapy after breast-conserving surgery and/or omitting axillary surgery in women age 70 years or older with stage I, ER+/HER2– breast cancer does not affect their survival when taking endocrine therapy.<sup>3–6</sup> While radiation therapy after lumpectomy may reduce local recurrence, the absolute risk reduction is <10% and takes years to achieve.<sup>3,5</sup> Thus, women age 70 years or older with stage I, ER+/HER2– face decisions regarding de-escalation or omission of parts of their locoregional therapy. More than 70% of women age 70 years or older with breast cancer undergo axillary surgery and receive radiation therapy.<sup>7–11</sup> Is this appropriate treatment or overtreatment? In thinking about patients who are best suited for de-escalation of axillary surgery or radiation therapy, this management

pathway assumes compliance with endocrine therapy. Unfortunately, studies have demonstrated close to one-third of patients will have early discontinuation of endocrine therapy.<sup>12–14</sup> For older patients who are of higher risk for early endocrine therapy cessation, radiation gains importance in decreasing risk of locoregional recurrence.

As breast cancer care makes advances, individualized therapy should consider unique patient preferences, risk factors, and overall goals of care. These take precedence over uniform, generalized recommendations. There can be significant physician and patient discomfort with deviating from traditional treatment paradigms and when recommending de-escalation of locoregional care for the older patient with breast cancer. What is considered de-escalation? When is it appropriate? And how do we think about de-escalation of locoregional breast cancer care in the context of ongoing clinical trials and advances in therapies and technologies? The ensuing discussion will initially review de-escalation of surgery and radiation therapy and afterward provide an overview of the importance of shared decision making (SDM) in the care of older patients with breast cancer (Table 1).

## SURGERY

De-escalation of surgery for patients with breast cancer refers to reducing the extent or invasiveness of surgical procedures while maintaining optimal clinical outcomes. The goal of de-escalation is to minimize the

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## PRACTICAL APPLICATIONS

- Consider de-escalation of surgery for those patients with early-stage breast cancer, favorable tumor characteristics, are clinically node-negative, and who may have other major health issues.
- De-escalation of surgery entails decreasing the extent of surgery including offering breast conservation therapy over mastectomy for appropriate candidates, incorporating oncoplastic surgery techniques to increase patient eligibility for lumpectomy, and omitting or reducing extent of axillary surgery.
- De-escalation of radiation includes reducing treatment course length through hypofractionation and ultrahypofractionation regimens, reducing treatment volumes through partial breast irradiation, omission of radiation, and reducing radiation dose to normal tissues.
- Shared decision making, which aims to facilitate patients making decisions concordant with their values, can guide health care providers and patients through complicated decisions optimizing breast cancer care.

impact of surgery on a patient's physical and emotional well-being, without compromising the effectiveness of treatment.

De-escalation of surgery may be appropriate for patients who meet the following criteria:

1. Early-stage breast cancer: Patients with small, localized tumors are typically good candidates for breast-conserving surgery over mastectomy.
2. Favorable tumor characteristics: Patients whose tumors are hormone receptor-positive and HER2- may be good candidates for de-escalation of surgery. These tumors tend to be less aggressive and have a lower risk of recurrence, which may allow for less-invasive surgical procedures.
3. Clinically node-negative: Patients whose cancer has not spread to regional lymph nodes may be candidates for de-escalation of axillary surgery.
4. Other health issues: Patients who have other health issues may be more susceptible to complications from surgery, and de-escalation may be appropriate to reduce the risk of surgical complications and to balance the risks and benefits of breast cancer care.

Surgery for breast cancer may be de-escalated for the older patient in thinking about the appropriate extent of surgery in the breast and axilla. First, this can include removal of less breast tissue. The survival rates for patients with breast

cancer who undergo lumpectomy versus mastectomy depend on the stage and aggressiveness of the cancer as well as the individual patient's overall health and other medical conditions. There is no significant difference in long-term survival rates between patients who undergo lumpectomy and those who undergo mastectomy for early-stage breast cancer. Lumpectomy with radiation therapy has been shown to be just as effective as mastectomy for treating early-stage breast cancer while allowing for breast preservation. Long-term follow-up of NSABP-06 found no significant difference in overall survival (OS) among women who underwent mastectomy and those who underwent lumpectomy with or without postoperative breast irradiation.<sup>15</sup> Additionally, for locally recurrent breast cancer after previous breast-conserving surgery, standard treatment historically has been mastectomy. However, there may be a role for repeat breast lumpectomy with radiation as studied in Radiation Therapy Oncology Group (RTOG) 1014 for select patients.<sup>16</sup> Furthermore, the Cancer and Leukemia Group B (CALGB) 9343 and PRIME II trials have demonstrated that patients who have early, low grade ER+ cancers can do well with surgery alone without adjuvant radiation.<sup>3,4</sup>

An older patient may also be able to consider oncoplastic reconstructive surgery after breast lumpectomy instead of mastectomy with postmastectomy reconstruction to de-escalate the extent of surgery in certain circumstances. Oncoplastic surgery involves combining breast cancer surgery with plastic surgery techniques to reshape and reconstruct the breast tissue, which can improve cosmetic outcomes while maintaining optimal clinical outcomes and allowing a greater proportion of patients to have breast conservation. Oncoplastic surgery may be used to achieve a more natural-looking breast shape after breast-conserving surgery. For example, in cases where a significant amount of breast tissue needs to be removed, oncoplastic techniques

**TABLE 1.** Recommendations for Clinical Practice in Locoregional Treatment of Older Patients With Breast Cancer

De-escalation of surgery	Offer breast conservation therapy over mastectomy for appropriate candidates Incorporate oncoplastic surgery techniques to increase patient eligibility for lumpectomy Omit or reduce extent of axillary surgery Consider whether appropriate to repeat breast conserving therapy for local recurrence
De-escalation of radiation	Reduce treatment course length with hypofractionation and ultrahypofractionation regimens Reduce treatment volumes through partial breast irradiation Consider appropriate patients for omission of radiation Reduce radiation dose to normal tissues
Shared decision making	Facilitates patients making decisions concordant with their values Guides health care providers and patients through complicated decisions

can be used to reshape the remaining tissue to maintain symmetry and contour. Oncoplastic surgery can minimize scarring and reduce the risk of complications in older patients with other medical conditions that may affect wound healing or increase the risk of infection. It can be a valuable option for older patients with breast cancer who desire both cancer removal and a good cosmetic outcome without necessitating a mastectomy. The specific techniques used depend on the patient's individual circumstances, including the size and location of the tumor, the amount of breast tissue to be removed, and the patient's overall health and preferences.

In addition to thinking about de-escalating the extent of surgery in the breast, de-escalation of surgery in the axilla is similarly important. In older patients with breast cancer, the omission of axillary surgery may be considered as a treatment option, particularly for those with early-stage disease and low risk of lymph node involvement. This is because axillary surgery, either in the form of sentinel lymph node biopsy (SLNB) or axillary lymph node dissection, can be associated with certain risks and complications, including lymphedema, numbness, and shoulder dysfunction. Several studies from Europe and North America have demonstrated no difference in breast cancer-specific mortality between undergoing axillary surgery versus no axillary surgery.<sup>17-20</sup> Furthermore, the International Breast Cancer Study Group trial 10-93 found that quality of life was significantly better in the group that avoided axillary surgery, and disease-free survival (DFS) and OS were similar for patients in the two arms of the trial.<sup>6</sup> The Society of Surgical Oncology's Choosing Wisely campaign now recommends that surgeons do not to routinely use sentinel lymph node surgery in women older than 70 years who have hormone receptor-positive breast cancer given this does not increase the risk of locoregional recurrence and has no adverse impact on mortality.<sup>21,22</sup>

De-escalation of surgery for breast cancer may be appropriate for certain patients with low-risk disease, where reducing the extent or invasiveness of surgical procedures can still maintain optimal clinical outcomes. However, the decision to de-escalate surgery should be made on a case-by-case basis, factoring in stage and grade of the tumor, the patient's age and overall health, and the presence of any comorbidities. The decision to de-escalate surgery is recommended to be made in consultation with a multidisciplinary team of breast cancer experts, including surgeons, medical oncologists, and radiation oncologists, who can help determine the optimal treatment plan for each patient on the basis of their individual circumstances.

## RADIATION

Radiation therapy remains an integral component of breast conservation therapy for the majority of patients with early-

stage invasive breast cancer.<sup>23-26</sup> In addition, regional nodal irradiation (RNI) improves cancer control outcomes for patients with axillary lymph node-positive or high-risk node-negative breast cancer.<sup>27-29</sup> However, our improved understanding of breast cancer biologic subtypes coupled with advances in diagnostic and therapeutic modalities has led to the recognition that there are likely subsets of patients who derive little benefit from adjuvant radiation therapy. De-escalation strategies include the following:

### Reducing Radiation Treatment Course Length

Hypofractionation (HF) courses of whole breast irradiation (WBI) are now the standard of care. The data support HF courses for many patients undergoing RNI and postmastectomy radiation therapy (PMRT) as well. This reduces the treatment burden from 5 to 6.5 weeks down to 3 weeks or even less with ultrahypofractionation. HF refers to increasing the daily fraction size of radiation while simultaneously reducing the total number of fractions delivered and the total radiation dose delivered. Hypofractionated regimens are attractive in situations in which the radiosensitivity of the tumor cells is similar to the radiosensitivity of the surrounding normal tissues such that a higher dose per fraction can be delivered to obtain tumor control but a lower total dose delivered to reduce normal tissue toxicity.<sup>30</sup> The seminal UK START A and START B trials as well as the Canadian HF trial established that HF regimens result in similar cancer control outcomes with the same or reduced acute and late toxicities compared with conventionally fractionated radiation regimen.<sup>31-36</sup> The United Kingdom moved on with testing results of an ultrahypofractionated WBI regimen of 26 or 27 Gy in five once daily fractions (5.2 or 5.4 Gy/fraction) compared with HF WBI of 40 Gy in 15 fractions in the FAST-Forward trial in a group of women with fairly low-risk breast cancer (median age 60 years; 81% HR+/HER2-; median tumor size, 1.6 cm; 81% pN0; <25% received chemotherapy).<sup>37</sup> The United Kingdom has led to large studies investigating ultrahypofractionation, in which radiation is delivered to the whole breast in a total of five fractions. The UK FAST study randomly assigned women with early-stage breast cancer (pT1-2 pN0) to conventionally fractionated WBI (50 Gy/25 F) or to one of two experimental arms of either 30 Gy/5 F given once per week or 28.5 Gy/5 F given once per week such that all regimens were delivered over a total of 5 weeks (no tumor bed boost in any arm). The 10-year risk of ipsilateral breast events were similarly low across all groups (0.7% 50 Gy/25 F v 1.4% 30 Gy/5 F v 1.7% 28.5 Gy/5 F), but there were significantly worse normal tissue effects (eg, photographic changes in the breast, induration, edema) for 30 v 50 Gy but not for 28.5 v 50 Gy. Therefore, for patients with significant comorbidities or socioeconomic factors that preclude daily treatment, the 28.5 Gy in five fractions once per week is an acceptable alternative to conventionally fractionated WBI.<sup>37</sup>

The 26 Gy in five fraction regimen was much more tolerable, although there were still significantly higher rates of certain side effects, such as breast swelling, when compared with 40 Gy in 15 fractions. In addition, for patients requiring a tumor bed boost, this was delivered sequentially with an additional five to eight fractions, thereby increasing the course from 1 week to 2-2.5 weeks. Recent data from the Radiation Therapy Oncology Group 1005 study demonstrated that HF WBI of 40 Gy in 15 fractions with a concomitant boost to the tumor bed to a dose of 48 Gy in 15 fractions resulted in equivalent local control with similar acute toxicity, late toxicity, and cosmesis compared with WBI delivered with a sequential boost.<sup>38</sup> Thus, the RTOG 1005 regimen, which is delivered in 3 weeks, is an excellent option for high-risk patients requiring tumor bed boost.

HF regimens have also been used to deliver RNI and PMRT. In the START A and START B clinical trials, 8.3% and 14.6% of patients received hypofractionated PMRT.<sup>31,32</sup> In addition, Wang et al<sup>39</sup> performed a randomized non-inferiority trial of HF PMRT (43.5 Gy in 15 fractions) compared with PMRT delivered as 50 Gy in 25 fractions in 810 patients with T3-4 and/or N2-N3 breast cancer and found noninferior local-regional control with HF PMRT. A recent meta-analysis of 25 trials involving almost 4,000 patients comparing efficacy and toxicity of hypofractionated versus conventionally fractionated PMRT showed no differences in local-regional recurrence, DFS, OS, or in any early or late toxicities between the groups.<sup>40</sup> The results of two recently completed randomized studies specifically comparing HF PMRT with conventionally fractionated PMRT in the reconstruction setting are highly anticipated.

### Reducing Radiation Treatment Volumes

**Partial breast irradiation.** Most in-breast tumor occurrences are located within 1 cm of the original tumor bed.<sup>41,42</sup> This has led to numerous clinical trials comparing partial breast irradiation (PBI), which targets the tumor bed region with a margin of 1-2 cm, with WBI. All forms of PBI use HF, although some regimens are delivered twice per day with moderately large fractions (3.4-3.85 Gy  $\times$  10 fractions), while some are delivered daily with standard HF (2.67 Gy  $\times$  15 fractions) and others are given every other day with large fraction sizes (6 Gy per fraction  $\times$  five fractions). Intraoperative radiation therapy delivers a single large dose (20-21 Gy) to the tumor bed with either low-dose photons or high-energy electrons.

The key APBI studies are summarized in Table 2. PBI should be considered as an alternative to WBI in the appropriate patient population, specifically patients who are 50 years or older with stage I, lymph node-negative (pT1 pN0), ER+/HER2- breast cancers. Across all techniques and fractionation schedules, it seems as though 10-year in-

breast tumor recurrences are 2% or less when PBI (or WBI) is used in this patient population. Although there are no randomized studies that compare one PBI technique with another, it does seem that once daily PBI (30 Gy in five fractions given every other day or 40 Gy in 15 fractions given daily) is associated with low rates of acute and late toxicities and extremely high rates of favorable cosmesis.

### Omission of Radiation Therapy

**Biomarker-guided omission of radiation in hormone-sensitive breast cancer.** While data support omission of radiation therapy in patients with ER+/HER2- breast cancer treated with lumpectomy and adjuvant endocrine therapy on the basis of age through the CALGB 9343 and PRIME II studies, recent focus has shifted to the use of genomic and immunohistochemistry-based biomarkers to help make these decisions with numerous ongoing prospective trials.<sup>3,4</sup> The recently reported LUMINA study was a single-arm prospective study that evaluated omission of radiation therapy in women age 55 years or older with grade 1-2 tumors that were  $\leq$  2 cm in size, surgical margins  $\geq$  1 mm, lymph node-negative, and had a low proliferative index (Ki67  $\leq$  13.25%) and found that the 5-year risk of local-regional recurrence in the 727 patients enrolled was extremely low at 2.3%.<sup>44</sup>

**Omission of radiation in HER2-positive breast cancer.** Much of the de-escalation of radiation therapy has been focused on patients with ER+/HER2- disease. HER2+ breast cancers represent approximately 10%-15% of all breast cancers, and systemic therapy studies have demonstrated that patients with small node-negative tumors (pT1N0) have exceedingly low rates of local-regional and distant recurrences with de-escalation of systemic therapy.<sup>45,46</sup> For example, in the APT trial, patients who received lumpectomy with radiation therapy had <1% rate of in-breast recurrences.<sup>47</sup> This observation has led to a phase III randomized trial of postlumpectomy radiation versus omission of radiation in patients with pT1N0 HER2+ breast cancer treated with lumpectomy + axillary surgery and adjuvant chemotherapy with HER2-targeted therapy.

### Reducing Radiation Dose to Normal Tissues

The entire field has shifted from a 2D anatomic landmark-based approach to design radiation fields toward 3D computed tomography (CT)-based radiation planning with improved delivery techniques such as 3DCRT using multileaf collimators to design fields,<sup>48-50</sup> prone breast radiation therapy,<sup>51-56</sup> inverse planned intensity-modulated radiation therapy, and volumetric modulated arc radiotherapy (RT), all of which have resulted in reduced treatment toxicities.<sup>57,58</sup> Respiratory gating with use of deep inspiration breath hold (DIBH) and improved image guidance during treatment delivery including real-time on-board

**TABLE 2.** Key Studies of De-Escalation Using HF and Ultrahypofractionation for Whole Breast Irradiation

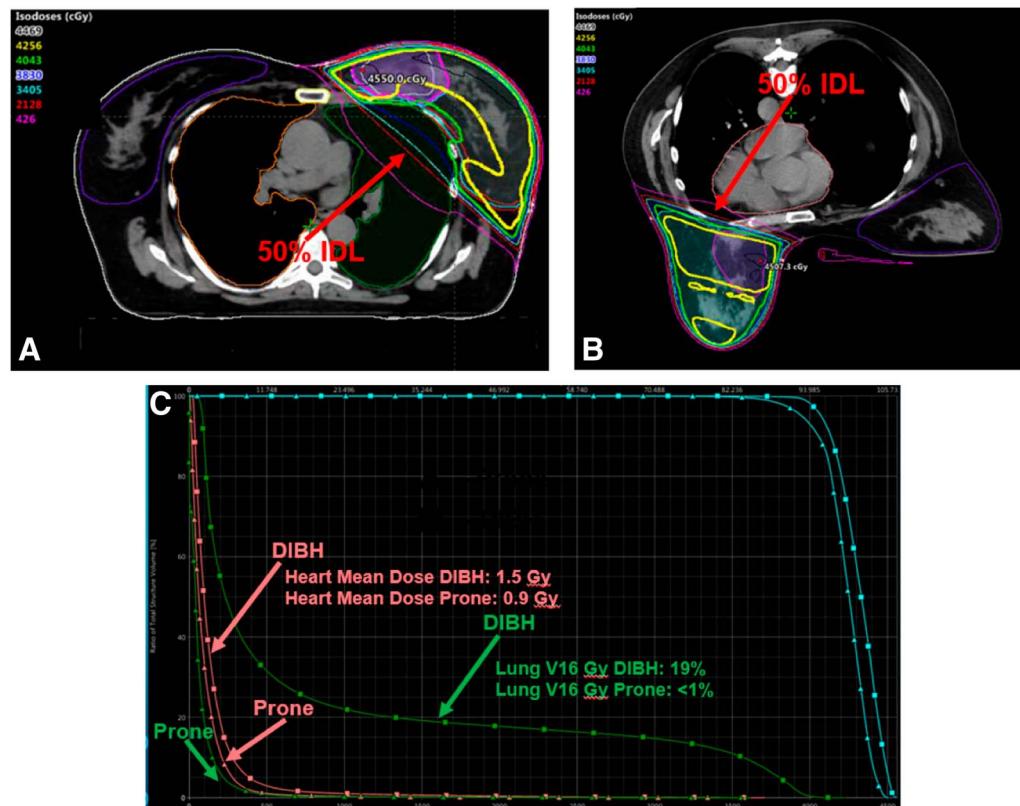
Trial	Study Duration	N	Follow-Up (years)	XRT Dose	LR (%)
Whelan (OCOG) <sup>16</sup>	1993-1996	1,234	12	CF: 50 Gy/25 F	6.7
				HF: 42.56 Gy/16 F	6.2
START-A <sup>12</sup>	1999-2002	2,236	9.3	CF: 50 Gy/25 F/5 w	6.7
				HF: 41.6 Gy/13 F/5 w	5.6
				HF: 39 Gy/13 F/5 w	8.1
START-B <sup>11</sup>	1999-2001	2,215	10	CF: 50 Gy/25 F	5.2
				HF: 40 Gy/15 F	3.8
HYPO <sup>43</sup>	2009-2014	1,854	9	CF: 50 Gy/25 F	3.3
				HF: 40 Gy/15 F	3.0
FAST-Forward <sup>17</sup>	2011-2014	4,096	5.9	HF: 40 Gy/15 F	2.1
				UHF: 27 Gy/5 F	1.7
				UHF: 26 Gy/5 F	1.4

Abbreviations: CF, conventional fractionation; HF, hypofractionation; LR, local recurrence; N, number of patients; OCOG, Ontario Clinical Oncology Group; XRT, radiation.

imaging with cone beam CT capabilities further aid the field of radiation oncology to improve targeting and reduce radiation to normal tissue during treatment delivery.<sup>43,59,60</sup>

In Figure 1, a patient with a medially located lumpectomy cavity in the left breast underwent simulation in both the prone position and the supine position with use of DIBH

because of concerns that the location of the lumpectomy cavity may result in a higher dose to the heart in the prone position. However, in this case in which contours for the target volumes (breast and lumpectomy cavity) and OARs were in place, the prone radiation plan resulted in lower mean heart dose (0.9 v 1.5 Gy) and substantially lower



**FIG 1.** Individualizing radiation treatment technique. (A) This panel demonstrates radiation in the supine position with DIBH. (B) Same patient in the prone position. The 50% IDL is highlighted in the red arrow while the yellow and green curves represent the 100% and 95% IDL, respectively. (C) This panel demonstrates the dose-volume histogram. Curves with squares represent the DIBH radiation plan, and the curves with triangles are the prone radiation plan. DIBH, deep inspiration breath hold; IDL, isodose line.

volume of lung receiving  $\geq 16$  Gy (<1% prone v 19% DIBH) without compromising target volume coverage. This is an example of how RT approaches can be individualized to the patient and how modern radiation techniques and planning approaches can enable us to adequately cover our targets and reduce dose to normal tissues.

## SDM

SDM, which aims to facilitate patients making decisions concordant with their values, can help to guide health care providers and patients through complicated decisions. It requires patients and providers to work together to select tests and treatments, with each party bringing different expertise to the decision-making process. Patients are responsible for sharing preferences while providers are responsible for informing patients of their treatment options and integrating relevant evidence-based information into the conversation.<sup>61</sup> SDM is particularly useful in the setting of multiple treatment options, when there is uncertainty regarding the evidence supporting a treatment or its outcomes, when there are both advantages and disadvantages that patients must weigh and when the decision is high impact as is the case for breast cancer treatment decision making for older women.<sup>61</sup> However, existing research demonstrates gaps in effective SDM with these women. Older women with breast cancer often report unmet informational needs, feel ill-prepared to communicate their preferences to their physicians, and feel uncomfortable asking their surgeons questions.<sup>61</sup> Furthermore, older women report being less likely to be given treatment choices, to engage in treatment decisions, and/or to be satisfied with treatment outcomes than younger women.<sup>62</sup> Many also have low knowledge of breast cancer survival and recurrence rates.<sup>63</sup> Yet, older women are increasingly interested in taking more active roles in treatment decisions, reporting that they would value educational materials to better understand their treatment options and to know what questions to ask.<sup>64</sup>

Decision aids (DAs) are educational tools that provide detailed, current information to guide patients through a deliberative process. Rather than replacing patient-physician interaction, they are intended to supplement the conversation.<sup>65</sup> They have been found to perform better than usual care with respect to improving patients' knowledge about risk perception and treatment outcomes, incorporating patients' preferences and values, and encouraging users to take a more active role in decision making without increasing anxiety. DAs also improve patient satisfaction with the decision-making process, possibly improving patient quality of life.<sup>65</sup>

A 2016 systematic review identified 23 individual breast cancer treatment DAs.<sup>66</sup> For this chapter, a literature review was performed for patient DAs for women with invasive breast cancer. Studies included were published since 2010

and included women age 65 years or older in the testing of the DA. Table 3 presents the 18 DAs identified. Six of the DAs focused on women age older than 65 years, two of which discussed RT and were only studied in Canadian women who had already chosen to undergo RT.<sup>74,78</sup> These DAs need to be tested among women facing this treatment decision. Another DA focused on SDM around cessation of surveillance mammography among women age 75 or older and encouraged older women to consider their tumor characteristics and life expectancy when deciding when to cease surveillance mammography.<sup>80</sup> Another study aimed to provide older women with information on their prognosis with and without breast cancer and with and without comorbidities.<sup>73</sup> Wyld et al<sup>79</sup> developed the Age Gap Decision Tool. This tool was developed for women age 70-99 years in the United Kingdom diagnosed with primary operable invasive breast cancer (T1-3, N0-1, M0). It considered a woman's age, tumor size, grade, ER and HER2 status, comorbidities and frailty to provide information on a woman's 2-year and 5-year OS, chance of breast cancer death, and chance of death from other causes if she is treated with (1) surgery plus endocrine therapy versus primary endocrine therapy and (2) surgery plus chemotherapy versus surgery alone. In a large cluster, RCT that included 1,339 women seen at 46 different breast units, use of the tool was associated with women having increased knowledge about treatments, more SDM, and with more women receiving primary endocrine therapy and fewer receiving chemotherapy (Table 2).<sup>79</sup>

Since there is a complex interplay between treatments that older women should consider when deciding on treatment, Schonberg et al<sup>85</sup> developed and pilot-tested a comprehensive DA for women age 70 or older with stage I, ER+/HER2- breast cancer. This DA was designed with low literacy principles, iteratively revised, and is on the preferred medium (paper) of older women. The DA encompasses surgical decisions (breast surgery and axillary surgery), the decision to proceed with RT, and endocrine therapy options. It also incorporates competing health issues into the decision process. In addition to the standard components of DAs, such as describing the health condition and the positive and negative features of treatment choices, the DA also includes a question prompt list since question prompt lists have been shown to increase patient knowledge, self-efficacy, identification of treatment preferences, and participation in decision making, especially among patients with cancer.<sup>86</sup> In a pilot pretest/post-test trial of 33 women, the DA improved women's knowledge of their treatment options and 97% would recommend it; the DA is available in the appendix of the article.<sup>72</sup>

Although DAs have been repeatedly shown to increase patient knowledge and reduce decisional conflict, successful integration requires engaging physicians in the process.

**TABLE 3.** Patient DAs for Older Women With Invasive Breast Cancer: Studies That Included Women Age Older Than 65 Years in Testing and Were Published Since 2010<sup>a</sup>

Reference	Participants	Decision	Methods	Results
Ager et al <sup>67</sup>	23 Australian women with history of stage I or II breast cancer; mean age, 58.6 (range, 43-67 years)	Contralateral prophylactic mastectomy	In-person interviews	The DA was found to be acceptable
Durand et al <sup>68</sup> (images of the DA in the article)	16 surgeons, 616 US women with stage I-IIIA breast cancer; mean age, 59.7 ( $\pm 12.5$ years)	Mastectomy v BCS	Three-arm RCT (Option Grid Text, Picture Option Grid [pictures + text], and usual care) with surgeon-level random assignment	Patients in Picture Option Grid arm had higher knowledge, improved decision process, lower decision regret, and more SDM compared with usual care. Patients in Option Grid text arm had higher decision process, better coordination of care, and more SDM compared with usual care arm
Freedman et al <sup>80</sup> (DA in the appendix)	21 US breast cancer survivors; median age, 78 (range, 75-92 years); 21 oncologists	Surveillance mammography	Observational cohort study of patients and survey of oncologists	Nearly all patients and clinicians would recommend the guide to others. Both previsit and postvisit patients reported strong intentions for surveillance mammography
Harwood et al <sup>69</sup> (images of the DA in the article)	Part 1: 28 Australian women with history of stage I/II breast cancer; mean age, 55 (range, 32-76 years) Part 2: Eight Australian women newly diagnosed with stage I/II breast cancer; mean age, 55 (range, 34-75 years)	Mastectomy v BCS; axillary dissection v sentinel node biopsy	Part 1: Qualitative Part 2: Observational cohort study	Part 1: Positive feedback on the DA Part 2: Too small but possible reduction in decisional conflict and possibly improved decisional satisfaction, knowledge, and choice
Hawley et al <sup>70</sup> (iCanDecide)	537 US women with stage I/II breast cancer; mean age 57 ( $\pm 11$ years; range, 21-84)	Locoregional and systemic treatment decision making	RCT: iCanDecide interactive and tailored website v iCanDecide static website <sup>6</sup>	Tailored DA associated with high-quality decisions and greater knowledge compared with nontailored DA. No differences in values-concordant treatment decisions by arm
Ke et al <sup>82</sup> (screenshots of the DA in the appendix)	15 Singaporean women with breast cancer who completed primary treatment (age range, 46-67 years); eight health care professionals	Breast cancer survivorship	Mixed methods	All patients found the final DA easy to navigate with sufficient interactivity
Lam et al <sup>71</sup>	276 Cantonese-speaking or Mandarin-speaking Chinese women in Hong Kong with stage 0-III breast cancer; mean age DA arm, 56.8 $\pm$ 10.8 years (mean age of controls, 54.6 $\pm$ 10.1 years)	BCS and RT, mastectomy, mastectomy and reconstruction	RCT: DA (take-home booklet) v standard information booklet (control condition)	Receipt of DA led to significantly lower decisional conflict scores, lower decision regret, and lower depression scores
Minami et al <sup>72</sup> (DA available in the appendix)	33 US women age 70 or older, with stage I, ER+, HER2- breast cancer; mean age, 74.7 $\pm$ 3.8 years	Mastectomy v BCS; lymph node surgery, RT, endocrine therapy	Pretest-post-test trial	Nearly all participants strongly agreed that the DA was helpful and that it prepared them for treatment decision making. Knowledge significantly improved after receiving the DA
Mühlbauer et al <sup>73</sup> (SPUPEO DA; images of DA in the article)	Part 1: 20 German women with history of early-stage ER+, HER2- breast cancer; mean age, 60 (range, 32-77 years) Part 2: 86 German women with history of early-stage ER+, HER2- breast cancer; mean age, 51 (range, 27-76 years)	Displayed age-based noncancer prognosis stratified by history of breast cancer and also by comorbidity for women 65-84 years	Part 1: focus groups Part 2: online survey	The DA was found to be helpful, informative, and interesting

(Continued on following page)

**TABLE 3.** Patient DAs for Older Women With Invasive Breast Cancer: Studies That Included Women Age Older Than 65 Years in Testing and Were Published Since 2010<sup>a</sup> (Continued)

Reference	Participants	Decision	Methods	Results
Neve et al <sup>74</sup> (images of the DA in the appendix)	40 Canadian women undergoing or had undergone whole breast RT with stage I/II ER+, HER2-, breast cancer; median age 72 (range, 65-86 years)	Adjuvant RT including WBRT, APBI, and omission of RT	Pretest-post-test trial	Decisional conflict decreased after using the DA, and nearly all stated the DA was useful for future patients
Raphael et al <sup>83</sup> . (BRASA DA)	Dutch women with T0-T3, N0, or N1 breast cancer facing a choice about RT; control group mean age 60.4 (±11.3 years), intervention group mean age, 62.8 (±12.6 years)	RT (boost/no boost, chest was RT, low-risk breast cancer)	Preintervention and postintervention trial	Knowledge increased with receipt of the DA, and fewer chose additional RT. There was no change in decisional conflict with DA
Savelberg et al <sup>81</sup> (images of the DA in the appendix)	84 Dutch women with stage I/II breast cancer; mean age, 61.1 (±9.9 years)	Surgical treatment	Observational cohort study	SDM was high as measured by CollaboRATE; 67% of patients used the DA at home
Sivell et al <sup>75</sup> (Bresdex)	62 women from the United Kingdom with stage I/II breast cancer; mean age, 53.3 (range, 29-80 years)	Designed to support surgical decision making	Observational cohort study	After receiving the DA, readiness to make a decision increased. There was no significant improvement in knowledge
Ter Stege et al <sup>84</sup> (borstreconstructie keuzehulp)	17 Dutch women with a history of making a decision about breast reconstruction (mean age, 51.3 [range 31-77 years]) and 40 health care professionals	Breast reconstruction after mastectomy	Semistructured qualitative interview with patients, survey of health care professionals	The DA was perceived to be informative, helpful, and easy to use
Tucholka et al <sup>76</sup>	227 US women with stage 0-III breast cancer; median age, 59 (range, 27-80 years)	Considering breast surgery	RCT: standard cancer websites ( <a href="http://breastcancer.org">breastcancer.org</a> ) v health dialog DA	Receipt of the DA was associated with higher knowledge; both arms found the interventions helpful
Vodermaier et al <sup>77</sup>	111 German women with stage I-III ER+ breast cancer; mean age, 55.2 (±11.0 years)	Surgical and systemic treatment	RCT: a 20-minute decision board intervention plus an information brochure v usual care	Receipt of the DA was associated with less decisional conflict; no effect on anxiety, depressive symptoms, or quality of life
Wong et al <sup>78</sup> (images of the DA in the article)	Part 1: 16 Canadian women with stage I, ER+/PR+ breast cancer completed WBRT; median age, 77 (range, 71-84 years) Part 2: 36 Canadian women with stage I, ER+/PR+ breast cancer receiving WBRT; median age, 75 (range, 66-95 years)	Adjuvant radiation therapy	Part 1: qualitative Part 2: pretest-post-test study	All women thought the DA was helpful and informative. Patients experienced less decisional conflict and were more knowledgeable after using the DA
Wyld et al <sup>79</sup> (Age Gap Decision Tool)	1,339 UK women with T1-3, N0-1, M0, breast cancer; mean age, 78 (±6 years; range, 70-99)	Surgery plus ET v PET; surgery v surgery plus chemotherapy	Cluster RCT of two DAs (surgery and ET v PET; chemotherapy v no chemotherapy) v usual care; 46 breast units were randomly assigned	Use of DAs increased knowledge, facilitated SDM, and increased use of PET and decreased use of chemotherapy; no effect on global quality of life

Abbreviations: APBI, accelerated partial breast irradiation; BCS, breast-conserving surgery; DA, decision aid; ER+, estrogen receptor-positive; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; PET, primary endocrine therapy; PR+, progesterone receptor-positive; RCT, randomized controlled trial; RT, radiotherapy; SDM, shared decision making; WBRT, whole breast radiotherapy.

<sup>a</sup>If the age range of patients in the study was not reported, studies were included where the mean age plus the standard deviation was 65 years or older.

Qualitative studies have found that trust in one's surgeon is a key factor influencing older women's breast cancer treatment decisions,<sup>63</sup> but surgeons may overestimate older women's recurrence risk and the benefits of radiation therapy after breast-conserving surgery,<sup>87</sup> that surgeons may lack familiarity with recommendations to omit SLNB and the data supporting this recommendation, and that surgeons may lack the skills to engage older women in SDM.<sup>88</sup> Physicians in general tend to underestimate patient desire to participate in treatment decisions, especially for older adults, and are often incorrect when they attempt to infer patient treatment preferences.<sup>89,90</sup>

There thus remains much work to be done on SDM improvement with older patients with breast cancer. Physicians need training in SDM and DA use overall, but specific to this population is the need for tactful integration of patient health and life expectancy into treatment conversations. The relative risks and benefits of treatment (or omission of treatment), and the concepts of overtreatment and undertreatment in this patient population, require broaching the topic of remaining life expectancy.<sup>91</sup> Since the benefits of breast cancer treatments (ie, reduction of breast cancer morbidity and/or mortality) may take years to achieve, it is necessary to estimate if an older women is likely to live long enough on the basis of her overall health to have a chance of benefitting. The ePrognosis website provides risk calculators to help clinicians estimate older adults' mortality within the next 14 years (eg, the Lee-Schonberg index). Patients with a >50% risk of mortality during a specific time (eg, 10 years) are estimated to have a life expectancy less than that time since life expectancy is the median survival of a population.

Using the Lee-Schonberg index as a brief method for geriatric assessment, Mott et al<sup>92</sup> developed and pilot-tested a strategy for oncologists for de-escalating radiation therapy after breast-conserving surgery and for omitting SLNB. Their strategy considers whether a patient is a minimizer (tends to prefer a wait and see approach) versus a maximizer (tends to prefer taking action), estimates patients' health and overall prognosis using the Lee-Schonberg index, and provides tailored scripts for clinicians to explain why radiation therapy after breast-conserving surgery and SLNB may not be beneficial. The 22 oncologists (15 surgeons/ eight radiation oncologists) who tested this strategy found it useful, particularly the assessment of patients' 10-year prognosis; however, some were concerned with patients seeing their overall prognosis while others felt it helped foster communication. Evidence-based strategies for oncologists to incorporate discussion of patient overall health and life expectancy in treatment decisions are much needed.

SDM around breast cancer treatment may also be challenging because these decisions often involve the

preferences and values of patient family members in addition to those of patients themselves. An analysis of physician notes of patients older than 80 years diagnosed with breast cancer found that 71% had a family member present during consultation and that treatment decision making often occurred collaboratively between older women, their families, and physicians.<sup>93</sup> Clinicians may want to assess patient preferences for family involvement in decision making, welcome and involve family involvement when appropriate, and recognize that family involvement in the decision-making process may start before the initial visit and continue afterward.<sup>94</sup>

This discussion of SDM has focused on treatment decisions faced by older women with low-risk breast cancers; however, older women with more aggressive breast cancers also face many breast cancer treatment decisions (eg, chemotherapy, immunotherapy), and the approach to SDM should be similar. High-quality SDM for breast cancer treatment decisions in older women must consider the lag time to benefit from each treatment, whether the patient has adequate remaining life expectancy to have a chance of benefiting from the treatment, how the patients value the potential benefits and risks of each treatment, and the patient's preferences. The lag time to benefit is the time between when a treatment is given and the time to when improvement in breast cancer survival would be expected based on data from clinical trials.<sup>95</sup> If the patient's life expectancy because of their other health conditions is shorter than the lag time to benefit from the treatment, the patient will be very unlikely to benefit from the treatment. A formal geriatric assessment may also help inform oncologists and older women of their likelihood of benefiting from treatment and may inform SDM.<sup>96</sup>

The complexity of treatment options set by the current breast cancer literature requires physicians to be skilled in SDM communication. To engage older women in SDM, Mulley and Sepucha recommend a multistep approach that includes (1) inviting a patient to participate; (2) presenting the treatment options; (3) the benefits and harms of each treatment, (4) eliciting patient priorities, concerns, or decisional needs; (5) facilitating deliberation with involvement of trusted others; and (6) then implementing the shared decision.<sup>97</sup> The Agency for Healthcare Research and Quality has published example language for clinicians to use for these conversations.<sup>98</sup> For example, to invite patients to participate, a clinician may say "I want to go over all the options so we can find a path that works for you" and to elicit patients' values and preferences, a clinician may say "As you think about your options, what's important to you?" To facilitate deliberation, a clinician may ask older women to describe their understanding of their treatment options and to encourage these patients to take time to consider their options and to consult trusted family or friends.

While preferred decisional roles can run the gamut from passive to active in older patients with breast cancer,<sup>99</sup> nearly all older women regardless of their preferred decision-making role want treatment decisions to incorporate their values and preferences. Therefore, physicians need the

skills to facilitate high-quality decisions. As the oncologic community continues to work toward tailored individualized breast cancer care, effective, feasible, sustainable interventions aimed at improving SDM in older adults are much needed.

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