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BRIEFCOMMUNICATION – BREAST ONCOLOGY

Great Debate: Does Breast-Conserving Surgery with Radiotherapy Offer Better Survival than Mastectomy in Early-Stage Breast Cancer?

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Advances in breast cancer treatment have resulted in the concomitant rise in survivorship and a greater focus on quality of life after breast cancer. Patients are increasingly afforded the opportunity to live not only longer but better. Long gone are the days where the Halsted radical mastectomy was thought to be the only option to treat all stages of breast cancer. Therapy is now individualized to best meet the needs of the patient in a shared decision-making approach, creating opportunities to tailor treatment to patient preferences. Additionally, thanks to improvements in screening and breast imaging, breast cancer is being detected at a smaller size and earlier stage, allowing patients to have more surgical options.

Here, we explore both sides of the major branchpoint in the surgical pathway in the treatment of early-stage breast cancer—breast-conservation surgery (BCS) with radiotherapy versus mastectomy. Several early randomized controlled trials demonstrated no survival difference between these two surgical options for patients with early-stage breast cancer. Subsequent research has supported the notion that BCS with radiation provides adequate local control, improves quality of life, and perhaps even enhances long-term survival, but does this evidence support that all eligible patients with early-stage breast cancer should be recommended BCS as the surgical treatment of choice? In what situations might a patient opt for a mastectomy instead? We review evidence to support both sides with respect to both survival endpoints and quality-of-life outcomes. We highlight salient points for each surgical option as well as the central importance of shared decision making.

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LOCAL CONTROL

Surgery as a locoregional treatment modality must first be effective in providing local control. We review the evidence that compares BCS with mastectomy for long-term locoregional outcomes (Table 1).

Evidence Favoring Breast-Conservation Surgery (BCS)

Low local recurrence rates for patients with early-stage breast cancer treated with BCS and adjuvant radiation have been well-established and shown to be durable with extensive follow-up.[1,2] In fact, recurrence rates are sufficiently low with BCS and adjuvant endocrine therapy alone, such that radiation has been safely omitted in certain circumstances, such as in women older than 65–70 years of age with early-stage estrogen receptor-positive breast cancer and no high-risk features.[3,4] Although ipsilateral cancer recurrences rates were higher with BCS in a 20-year follow-up of a randomized controlled study of BCS versus radical mastectomy, the majority of these were noted to appear in different quadrants of the breast, which suggests an intrinsic risk to keeping the breast rather than a failure of the local therapy for the initial cancer.[5] Additionally, repeat BCS after ipsilateral breast tumor recurrence (IBTR) has been shown to be a viable approach, further supporting BCS with radiation as an attractive initial treatment option.[6] Finally, BCS has recently emerged as an effective surgical strategery for

TABLE 1 Studies comparing local recurrence rates for patients undergoing BCS versus mastectomy

Study	Year published	Years of diagnosis	No. of patients	Type of study	Local recurrence	Data notes
Veronesi et al.[5]	2002	1973–1980	701	RCT	Higher for BCS	20-year follow-up of the Milan trial, majority of new recurrences in different quadrants
Maishman et al.[8]	2017	2000–2008	3000	Prospective	Higher for BCS	Women 18–40 years of age in the POSH prospective cohort
Davey et al.[11]	2021	Unknown	3807	Systematic review and meta-analysis	Higher for BCS	Women with BRCA mutations from 23 studies
Nguyen et al.[9]	2021	2001–2012	428	Retrospective	Higher for BCS	Two institutional databases
Shubeck et al.[12]	2022	2006–2015	395	Retrospective	Equivalent	Women with BRCA mutations from a single institution

BCS Breast-conservation surgery, *RCT* Randomized controlled trial

multiple ipsilateral breast cancers (MIBCs) with two to three foci of disease following the results of the ACOSOG Z11102 (Alliance) clinical trial.[7] These findings highlight that BCS is effective in an increasing number of clinical situations and should be the recommendation of choice for early-stage breast cancer.

Evidence Favoring Mastectomy

Age at diagnosis is one of the largest risk factors for local recurrence. A large prospective cohort study of over 3000 women under age 40 years reported a significant local recurrence rate of 6.8% over a median follow-up of 7.8 years compared with only 2.7% for mastectomy ($p < 0.001$).[8] Another study of 428 women under the age of 40 years revealed that the 10-year cumulative incidence of recurrence was 2.5-fold higher in those who had undergone BCS. Although this study did not reach statistical significance, the cumulative incidence curve for local recurrence continues to increase over time in the BCS group but plateaued at 6 years in the mastectomy group.[9] Both studies suggest that the disparity in local recurrence between groups continues to rise over time, a fact that considerably impacts younger patients with longer life expectancy. In a recently published study of pooled data from patients of all ages enrolled in the legacy Alliance for Clinical Trials in Oncology study, local recurrence was found to be 4.6% at 5 years (95% confidence interval [CI] 4.5–5.4%), which was still higher than mastectomy rates even with shorter follow-up. Recurrence was even higher in triple-negative subtypes, at 7.1% (95% CI 5.4–9.3%).[10] These sources suggest that the possibility of higher local recurrence rates after BCS should be considered, especially in younger patients or those with high-risk tumor biology.

Another population in which mastectomy may be advantageous over BCS includes patients with an hereditary high risk for breast cancer, such as in BRCA mutations. A systematic review that included 2200 patients with BRCA1 mutations and 1212 patients with BRCA1 mutations found the incidence of locoregional recurrence for the BCS and mastectomy groups at 5 years was 14.7% vs. 4.8%, 15.5% vs. 4.7% at 10 years, and 27.5% vs. 6.2% at 15-years (all $p < 0.001$).[11] Another study conducted at Memorial Sloan Kettering utilizing an institutional database did not corroborate this increased locoregional recurrence rate but did find an estimated 10-year risk of developing contralateral breast cancer of 14% in women who did not undergo bilateral mastectomy.[12] Taken together, evidence suggests that for women with high-risk genetics, such as those with BRCA mutations, who do not wish to follow high-risk surveillance or have concerns regarding risks of locoregional recurrence or contralateral breast cancer development, bilateral mastectomy may be preferable.

Regarding MIBC foci, despite the aforementioned evidence suggesting that BCS is oncologically safe for up to three foci of disease, care should be taken not to apply this concept too broadly. The ACOSOG Z11102 clinical trial excluded tumors >5 cm in their largest dimension based on preoperative imaging. Furthermore, the sample size of human epidermal growth factor receptor 2-positive (HER2+) and triple-negative disease in this study was extremely small, limiting generalizability to these subtypes. The vast majority of patients in the study were also imaged by preoperative magnetic resonance imaging (MRI) and exploratory analysis, demonstrating a significantly higher local recurrence rate of 22.6% in patients without MRI compared with 1.7% in patients with MRI ($p = 0.002$).[7] This suggests that caution should be exercised in proceeding with lumpectomy in MIBC for patients who have not undergone MRI. Additionally, significant intratumoral heterogeneity may exist and patients whose stage and tumor cell burden are difficult to fully characterize would be better served with

a mastectomy.[13] Finally, it cannot be overlooked that a large proportion of local control afforded by BCS is attributable to adjuvant breast radiation, which may make BCS a poor choice for individuals with contraindications to radiation therapy. On the other hand, for those who are candidates for radiation, this treatment comes at the cost of risk of secondary malignancies, which can be especially pertinent for younger patients.[14]

QUALITY OF LIFE

Support for BCS is based on the possibility that patients may experience better quality-of-life outcomes with BCS compared with those who undergo mastectomy. Numerous studies have evaluated this question for both short- and longer-term outcomes.

Evidence Favoring BCS

BCS has the potential for improved cosmetic satisfaction and lower surgical complication rates, which strongly contribute to an improved quality of life for patients. A survey of 1215 patients who had received BCS with radiation or mastectomy and reconstruction without radiation for early-stage breast cancer found that the former reported higher psychosocial and sexual well-being scores.[15] It follows that the option of BCS would be particularly advantageous in those who desired reconstruction after mastectomy but would be poor reconstruction candidates.[16] Additionally, with the evolution of oncoplastic BCS techniques, the ability to resect more generous margins without compromising aesthetic outcome continues to improve.[17] Clearly, cosmetic techniques have been improving in tandem with the ability to obtain more accurate margin assessment.

Oncoplastic BCS has been shown to not only be non-inferior to mastectomy from a cost perspective but has also been associated with lower complication rates.[18,19] An analysis of the National Surgery Quality Improvement Program (NSQIP) database for patients who underwent partial or complete mastectomy between 2009 and 2012 revealed that early postoperative complications such as infection (0.4% for BCS vs. 1.9% for mastectomy; odds ratio [OR] 4.1, 95% CI 3.1–7.5) and bleeding (0.05% for BCS vs. 0.2% for mastectomy; OR 4.6, 95% CI 1.3–16.0) were significantly lower in patients receiving BCS compared with those undergoing mastectomy with implant reconstruction, despite higher pre-existing risk factors in the BCS group.[20] Among all reconstruction types in a multicenter analysis of 2343 patients, the 2-year complication rate was 32.9% and the odds of complications were especially high for autologous reconstruction.[21] Additionally, the larger surgical resection required for mastectomy increases the risk of collateral nerve damage, contributing to post-mastectomy pain syndrome (PMPS), which affects 20–68% of patients worldwide.[22,23] PMPS lasts for at least 6 months but can persist for years.[24] This certainly contributes to decreased quality of life and can serve as an unpleasant reminder of the disease and treatment process.[25]

Evidence Favoring Mastectomy

Although BCS is frequently regarded as superior to mastectomy for achieving a cosmetic postoperative result and a less painful procedure, these outcomes are not necessarily reflected in the opinions of breast cancer survivors. An anonymous survivorship survey using an internet-based tool querying a convenience sampling of 354 patients after BCS found that reports of ‘excellent’ (27% of respondents) or ‘good’ (44% of respondents) cosmesis was lower than expected. Respondents also reported high rates of postoperative chronic pain, numbness, or tingling (35%), changes in the texture or color of irradiated skin (48%), and loss of flexibility in the irradiated area 30%).[26] In a prospective multicenter cohort study seeking to create a predictive model for persistent pain after breast surgery, mastectomy was not found to be an independent predictive variable.[27] These findings are further corroborated in a case-controlled cross-sectional study using the validated BREAST-Q questionnaire, which found increased reports of asymmetry and chest wall discomfort without improvements in psychosocial well-being compared with mastectomy.[28] For patients who seek to pursue mastectomy with reconstruction, there are improved options for implant and autologous-based reconstruction that can be tailored to their specific circumstances and wishes.

It is also important to consider that cosmesis may be perceived to have less impact on quality of life from a patient perspective compared with the provider perspective.[29,30] In fact, some patients may be of the opinion or at a stage in life in which cosmesis is a relatively minor consideration. BCS also requires continued surveillance of the ipsilateral breast, and it is known that fewer than half of the patients adhere to recommended cancer surveillance guidelines.[31] Indeed, the psychological benefit to some patients who choose to undergo mastectomy to avoid long-term imaging surveillance may be underappreciated by physicians.

Long-Term Survival

Perhaps contrary to expectations, recent studies have suggested that overall survival is not compromised but may in fact be better with BCS compared with mastectomy. While the interpretation of some studies may be limited by the observational nature of the data, they are nevertheless

provocative and may lead to novel biologic hypotheses about the systemic impact of surgical interventions.

Evidence Favoring BCS

Several non-randomized studies have reported survival benefits favoring BCS over mastectomy (Table 2). Retrospective analyses of large groups from the Surveillance, Epidemiology, and End Results (SEER) cancer registry have consistently found that BCS was associated with greater overall and disease-specific survival in patients with early-stage breast cancer.[32,33] Similar findings were consistent in multiple studies of more aggressive cancer subtypes, including early metaplastic breast cancer, HER2+ breast cancer, and triple-negative breast cancer.[34–37] A Swedish cohort study utilizing a prospectively collected national dataset found that overall survival and disease-specific survival were higher in the BCS and radiation cohort even when adjusted for comorbidities and socioeconomic status.[38] A study of the California Cancer Registry found improved disease-specific survival for patients undergoing BCS even with adjustments for year at diagnosis, age, race, socioeconomic status, tumor size and grade, and proportion of positive axillary nodes.[39] Although more recent studies have been observational by necessity, even when controlling for confounders, the conclusion that BCS with radiation affords improved survival over mastectomy has been reproducible.

Evidence Favoring Mastectomy

Six landmark randomized trials have been conducted supporting the lack of survival difference between BCS and mastectomy. The Milan Trial, initiated by the Milan Cancer institute in 1973, was the first randomized trial to examine outcomes after a radical mastectomy compared with BCS (quadrantectomy).[5] This was followed in 1976 by the NSABP B-06 trial comparing total mastectomy with BCS (segmental mastectomy) with or without radiation.[2] Both trials demonstrated no survival difference. Following this, the National Cancer Institute (NCI) conducted another randomized trial comparing mastectomy and BCS plus radiation inclusive of up to 5 cm tumors. Even with expanded size criteria, this trial contributed additional confirmation of the survival equivalence between these two surgical modalities.[40] Finally, the Institute-Gustave Roussy (IGR) trial out of France, the Danish Breast Cancer Cooperative Group (DBCG) trial, and the European Organisation for Research and Treatment of Cancer trial (EORTC 1081) all reported

TABLE 2 Studies comparing long-term survival for patients undergoing BCS versus mastectomy

Study	Year published	Years of diagnosis	No. of patients	Type of study	Survival	Data notes
Sarrazin et al.[42]	1989	1972–1980	179	RCT	Equivalent	Institut Gustave-Roussy (IGR) Trial
Lichter et al.[40]	1992	1979–1987	237	RCT	Equivalent	National Cancer Institute (NCI) trial
Blichert-Toft et al.[41]	1992	1983–1989	1153	RCT	Equivalent	Danish Breast Cancer Cooperative Group (DBCG)
Veronesi et al.[5]	2002	1973–1980	701	RCT	Equivalent	20-year follow-up of the Milan trial
Fisher et al.[2]	2002	1976–1984	1851	RCT	Equivalent	20-year follow-up of the NSABP B06 trial
Litiere et al.[43]	2012	1980–1986	902	RCT	Equivalent	20-year follow-up of the EORTC 10801 trial
Hwang et al.[39]	2013	1990–2004	112,154	Retrospective	Favor BCS	California Cancer Registry
De Boniface et al.[38]	2021	2008–2017	489,986	Prospective	Favor BCS	National Breast Cancer Quality Register
Zhang et al.[34]	2021	2001–2016	2412	Retrospective	Favor BCS	SEER Database
Macfie et al.[37]	2021	2002–2011	4876	Retrospective	Favor BCS	Studied early triple-negative breast cancer from a single-center database
Ji et al.[32]	2022	2010–2015	99,790	Propensity-score matching	Favor BCS	SEER database
Zhan et al.[35]	2023	2010–2015	20,277	Propensity-score matching	Favor BCS	SEER database queried for early HER2+ breast cancer

BCS Breast-conservation surgery, *RCT* Randomized controlled trial, *SEER* Surveillance, Epidemiology, and End Results, *HER2+* Human epidermal growth factor receptor 2-positive

similar findings when comparing mastectomy and BCS.[41–43] The caveat to these definitive studies is that they were all conducted prior to the advent of much of our modern treatment modalities, such as more effective chemotherapy regimens and targeted immunotherapy; thus, they may not be reflective of the current treatment landscape for early breast cancer.

Although there is more contemporary evidence to suggest improved survival with BCS, most of these data are from retrospective studies and are not prospectively randomized studies.[39] Retrospective studies are intrinsically prone to bias but it is no longer ethical to pursue randomized trials comparing mastectomy and BCS. Despite attempts to control for confounding variables, it is not possible to fully control for the more favorable conditions that may lead to treatment bias for those women opting for breast conservation. Additionally, the survival benefits conferred by BCS may be largely driven by radiation and systemic treatment rather than surgery itself. It is challenging to separate out the factors that may lead an individual to be both more likely to undergo BCS and be compliant with adjuvant treatment. Thus, although intriguing, it cannot be confidently stated that BCS with radiation truly improves survival over mastectomy.

Role of Shared Decision Making

Despite the discussion above, the patient's personal values and treatment preferences remain the most important consideration in the choice of BCS or mastectomy for a patient who is an oncologically suitable candidate for BCS. Unfortunately, a national survey of 487 women treated with BCS or mastectomy concluded that only around half of patients felt 'completely informed' about the decision they were making.[44] In the absence of germline mutations, bilateral mastectomy for early breast cancer is a drastic choice with no demonstrated survival benefit, yet the rate of bilateral mastectomy rose for several years between 2008 and 2013.[45,46] This may have been a response to media influences or fear of recurrence but it is difficult to entirely understand the underlying cause of these trends. Nevertheless, it is important to note that there are certainly well-informed women who opt for mastectomy as a matter of preference. Reasons for this could include the wish to reduce the risk of breast cancer as much as possible, to avoid radiation, or due to low personal importance regarding conserving breast tissue.[47] Regardless of the underlying reason, this choice should be respected.[48]

For surgeons, it is challenging to completely avoid personal bias, and it has been shown that surgical opinion varies geographically, by treatment setting, and by surgeon training.[47,49] Therefore, it is important to recognize any potential personal bias and attempt to guide the patient with appropriate education to make the best decisions for themselves. The concept of 'shared decision making' is frequently discussed but often not well-defined. An early reference described four key elements: (1) at a minimum, both the physician and patient be involved; (2) both share information with each other; (3) both take steps towards agreement on the treatment; and (4) both agree to implement the preferred treatment.[50] More recently, interactive tools and protocols have been developed to enhance health literacy and have been shown to improve patients' ability to make decisions that reflect their values.[51,52] Such materials offer the opportunity to ensure that patients can make an informed choice so that regardless of the choice for BCS or mastectomy, that decision was the right one for them.

CONCLUSION

As breast imaging, locoregional interventions, and systemic therapies have improved, less invasive surgical options have emerged and have been evaluated for the treatment of early breast cancer. BCS with radiation has become so effective in terms of local control, quality of life, and overall survival that the argument could be made that this should be the preferred recommendation for all women with early-stage breast cancer. However, one must avoid sweeping generalizations when there are certainly circumstances in which mastectomy may in fact be the best option. This could include multicentric breast cancer, hereditary breast cancer, treatment of patients who have contraindications to radiation, and those who would benefit from the ability to reduce or forgo surveillance, among other specific circumstances. Above all, consideration of the entire patient and an informed shared decision-making approach will best serve our patients with early-stage breast cancer.

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