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Clinical Decision-Making in Early Breast Cancer

Charles M. Balch, M.D.,* S. Eva Singletary, M.D.,† and Kirby I. Bland, M.D.‡

From the Division of Surgery, Department of General Surgery, and the Breast Surgery Service,† The University of Texas M.D. Anderson Cancer Center, Houston, Texas, and the Department of Surgery,‡ University of Florida Medical Center, Gainesville, Florida*

Objective

This in-depth review of the multidisciplinary approach to early breast cancer treatment (in situ, stage I and II) will update the surgeon about the indications, risks, and benefits of breast surgery, radiation therapy, adjuvant chemotherapy and hormonal therapy, and the importance of breast reconstructive surgery.

Summary Background Data

Breast cancer will occur in one of eight women in the United States during their lifetime and is the second leading cause of death in women from cancer. The practice of multidisciplinary breast cancer treatment has become the standard of care for the majority of breast cancer patients. If the surgeon is to retain the primary coordinating role in breast cancer management, then he or she must fully understand all modalities of oncology therapy and know how to deploy them to benefit individual patients.

Conclusions

This article provides a framework for making clinical decisions about the appropriate combination and sequence of treatment for various presentations of early breast cancer.

Determining the most appropriate treatment plan for a patient with early breast cancer represents one of the most difficult decision-making processes in clinical medicine. The biological presentations of breast cancer are varied, the treatment options are many, and patients' differing perceptions of "quality of life" are diverse; but all of these areas have to be incorporated into an organized treatment plan.

Some surgeons have stated that there are no "wrong answers" in treating breast cancer because the therapeutic options are so diverse and many of the surgical and nonsurgical alternatives seem to produce similar survival outcomes. However, the knowledgeable and experienced surgeon treating breast cancer knows that these treatment options are, in fact, difficult to apply correctly and consistently in the individual patient setting. The optimal treatment for an individual patient should take into account the patient's physical, emotional, psychological, and rehabilitation needs.

This article provides a framework for the surgeon to understand the management of early breast cancer, to be able to participate meaningfully on a multidisciplinary team of cancer specialists, and to be able to coordinate the care of the patient, not only her surgical treatment but also a multidisciplinary approach that may require

Address reprint requests to Charles M. Balch, M.D., 1515 Holcombe Blvd., Box 112, Houston, TX 77030.
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the application of two, three, or more modalities of breast cancer treatment.

Why should the surgeon be involved in the broader issues of oncology management for the breast cancer patient? In the past, there have been few treatment options available, and surgical treatment was the mainstay of breast cancer management. The surgeon made the diagnosis and provided the first (and usually the only) treatment. However, breast cancer treatment has undergone fundamental changes. Contemporary breast cancer therapy has evolved to a point at which multidisciplinary approaches are the standard of treatment for most breast cancer patients, even those with early-stage disease. If the surgeon is to retain the primary coordinating role in breast cancer management, then he or she must fully understand all modalities of oncology therapy and know how to deploy them to benefit individual patients. This role as coordinator of therapy demands knowledge about the indications, risks, and benefits of adjuvant chemotherapy, hormonal therapy, and radiation therapy, and the importance of breast reconstructive surgery. Otherwise, the general surgeons and general surgical oncologists will be relegated to a secondary, largely technical role in the treatment of the breast cancer while other oncology specialists will assume the predominant place in coordinating the management of the breast cancer patients.

CURRENT STAGING SYSTEM

A thorough history and physical examination remain the cornerstone of breast cancer staging (primary tumor-nodal metastasis-distant metastasis). The TNM system[1] (Table 1) for staging of breast cancer should be used and recorded in the patient's medical record.

It is rare for patients with early invasive breast cancer to have clinically detectable distant metastasis at the time of initial diagnosis. The metastatic workup should therefore be judicious, consisting of a history and physical examination, chest x-ray, measurement of liver function enzymes, and bilateral mammography. Although the positive yield is low ($\leq$ 5%), an initial bone scan may serve as a useful baseline for future reference. Computed tomography (CT) scans of the brain, chest, and abdomen are not indicated in the absence of signs or symptoms suggestive of metastatic breast cancer. Currently available techniques for measuring tumor markers, such as carcinoembryonic antigen (CEA) or CA 15-3, are still not sufficiently sensitive or cost-effective to justify routine use for metastatic screening.

BREAST BIOPSY

Because the type and site of the biopsy can affect later options for treatment and reconstruction, the biopsy approach is critical in the treatment process. An algorithm that depicts biopsy and follow-up strategies is shown in Figure 1.2 The goal is to obtain the diagnosis with the least disturbance of the breast tissue. A large biopsy scar or a poorly executed biopsy with inadequate or unknown surgical margins can adversely affect the results of subsequent surgical resection, radiation therapy, and/or breast reconstruction.[3] Breast tissue distortion resulting from inadequate hemostasis may obscure such key diagnostic and staging parameters as the size of the tumor and significant skin changes, as well as risk the dissemination of tumor cells within the breast.

In our practice, a fine-needle aspiration biopsy (FNA) is the simplest, quickest, and most cost-effective approach to establish the breast cancer diagnosis in patients with a palpable mass. Even for nonpalpable le-

Table 1. TNM BREAST CANCER CLASSIFICATION SYSTEM

Primary tumor (T)
- T_x Primary tumor cannot be assessed
- T_0 No evidence of primary tumor
- T_{is} Carcinoma *in situ* or Paget's disease of the nipple with no associated tumor
- T_1 Tumor 2 cm or less in greatest dimension
- T_2 Tumor more than 2 cm but not more than 5 cm in greatest dimension
- T_3 Tumor more than 5 cm in greatest dimension
- T_4 Tumor of any size with direct extension to chestwall or skin

Regional lymph node (N)
- N_x Regional lymph nodes cannot be assessed
- N_0 No regional lymph node metastasis
- N_1 Metastasis to ipsilateral axillary lymph nodes
- N_2 Metastasis to ipsilateral axillary node(s) fixed to one another or other structures
- N_3 Metastasis to ipsilateral internal mammary lymph node(s)

Distant metastases (M)
- M_x Presence of distant metastasis cannot be assessed
- M_0 No distant metastasis
- M_1 Distant metastasis (includes metastasis to supraclavicular lymph nodes)

Stage grouping

Stage 0	T_{is}	N_0	M_0
Stage I	T_1	N_0	M_0
Stage IIA	T_0	N_1	M_0
	T_1	N_1	M_0
	T_2	N_0	M_0
Stage IIB	T_2	N_1	M_0
	T_3	N_0	M_0
Stage IIIA	T_0	N_2	M_0
	T_1	N_2	M_0
	T_2	N_2	M_0
	T_3	N_1, N_2	M_0
Stage IIIB	T_4	Any N	M_0
	Any T	N_3	M_0
Stage IV	Any T	Any N	M_1

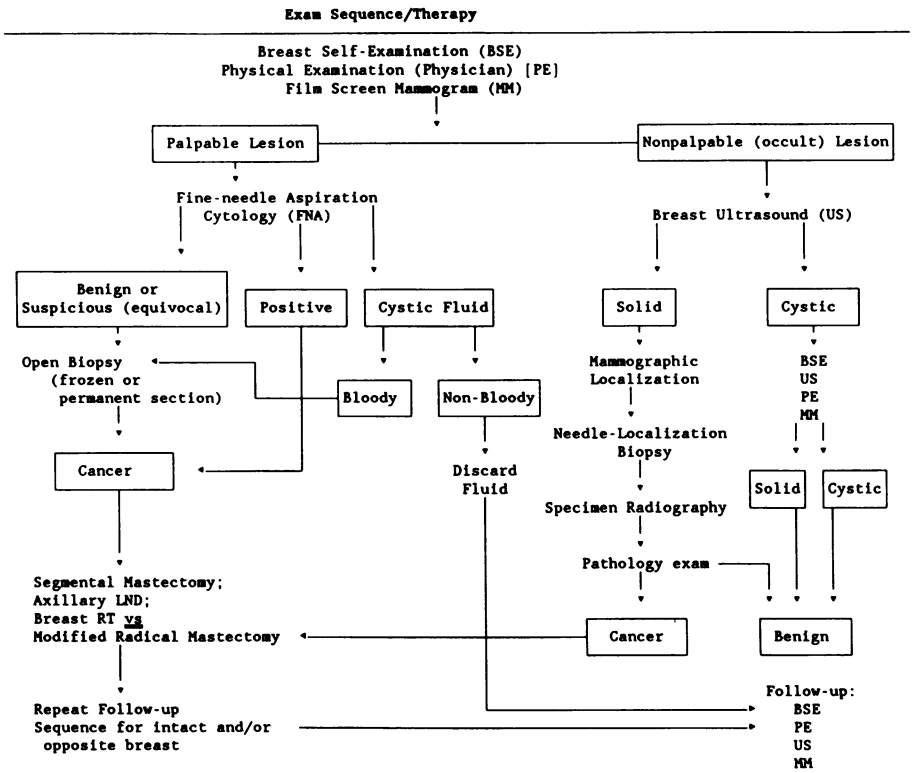

Figure 1. Decision options (algorithm) for biopsy approaches to breast abnormalities by palpation or mammography (Reprinted with permission. Bland KI, Love N. Evaluation of Common Breast Masses. Minneapolis, MN: Postgraduate Medicine McGraw-Hill Healthcare Publications, 1992).

sions, a needle biopsy with either ultrasound or stereotactic guidance can be used.[4,5] The accuracy of diagnosis is clearly dependent on the experience of the cytopathologist. In most institutions, the false-negative interpretation rate is low, approaching 10% or less. Negative or nondiagnostic FNA should be followed by an open biopsy if the breast lesion is clinically suspicious. Similarly, although a false-positive FNA is rare, the prudent surgeon should always correlate the diagnosis with clinical judgment before embarking on definitive surgery. Another limitation of FNA is the inability to distinguish cytologically between invasive and noninvasive forms of breast cancer; these variants are best identified on permanent histologic sections.[6]

An open (excisional) biopsy is indicated in patients when the FNA biopsy or core-needle biopsy is not definitive or cannot be done. We complete the procedure as a formal segmental mastectomy that combines both diagnostic and local treatment goals. For nonpalpable suspicious lesions that are apparent only on mammograms or ultrasound scans, the placement of a needle or guidewire under radiographic guidance enables the surgeon to know exactly where to perform the biopsy so as to remove only a minimal amount of normal breast tissue.

The success of needle localization depends on communication between the radiologist and surgeon and the cooperation of the patient. A three-view mammogram and any additional special views should be available before the procedure begins. The radiologist and the surgeon should confer with each other regarding the nature and the geographic location of the lesion as well as the type of needle or guidewire to be used for the localization. The guidewire of the needle is then placed in the breast by the shortest direct path to the lesion. A mammogram should be obtained after needle placement to demonstrate the orientation of the needle with respect to the lesion. If a hookwire system is not used, the needle should be sutured securely to the skin before the surgical field is prepared.

For open biopsy, a curvilinear incision that directly overlies the lesion is usually used. Although not essential, excision of a small ellipse of skin that includes the needle in continuity with its track is often helpful for placement of markers for later orientation. For a large lesion in the lower half of the breast, a radial incision may be necessary to avoid nipple distortion. A circumareolar incision for a peripherally located lesion should be avoided because it exposes more breast tissue to dissemination of tumor cells and may interfere with planning of the radiation boost field.

The breast specimen is excised en bloc and personally delivered by the surgeon to the pathology suite. A radiograph of the specimen is obtained to document that the lesion in question has been removed. The pathologist then inks the specimen circumferentially according to the surgeon's directions of the designated orientation —

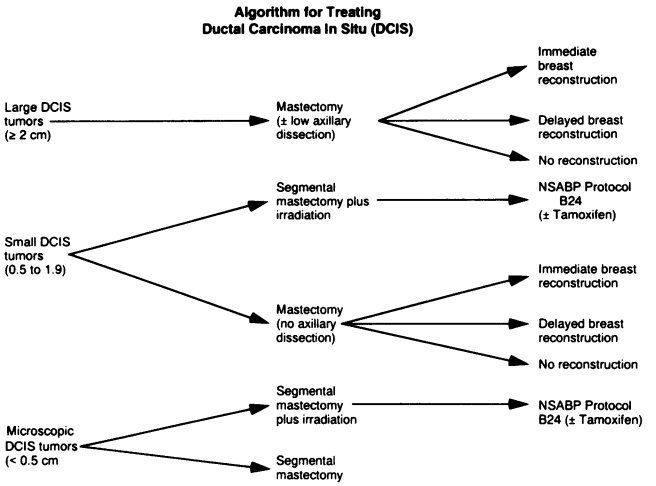

Figure 2. Treatment options for patients DCIS. Tumor size is the primary parameter for selecting treatment options. Combinations of surgery, irradiation, and hormonal therapy may be deployed in some patients.

lateral, medial, superior, inferior, and deep margins. The specimen is serially sectioned to include all margins within each section.

For a palpable mass, frozen-section examination is done to establish a diagnosis and tissue hormone receptor assays and flow cytometry analysis are done. Any margins that appear grossly close to the tumor are also checked by frozen-section examination. When no mass is palpable, or when the lesion is small with microcalcifications, the pathology examination is often deferred and the entire specimen fixed for permanent staining so as to accurately distinguish an atypical benign process from an *in situ* carcinoma. A second specimen radiograph of the sectioned tissue is often helpful to locate the lesion and can provide more information about the adequacy of the margins. If a malignancy is confirmed, radiopaque hemoclips may be used to mark the base of the biopsy site; this will assist the radiation therapist in planning the treatment field if the patient elects to have breast conservation surgery and the final margins of the excision are negative.

CARCINOMA *IN SITU*

The two recognized categories of carcinoma *in situ* — ductal (DCIS) and lobular (LCIS) carcinoma *in situ* — are based on their presumed sites of origin: the major lactiferous or terminal ducts and the lobular units, respectively. The two entities may have very different biological characteristics and clinical outcomes. DCIS is part of a biological continuum that begins with atypical hyperplasia in the ducts with progression to DCIS and then to invasive ductal cancer. Patients with surgically excised DCIS are at high risk for developing a subsequent invasive ductal cancer in the ipsilateral breast. The comedo type of DCIS appears to be more aggressive biologically than are non-comedo types because it is associated with a higher risk of subsequent invasive cancer. LCIS, on the other hand, is not necessarily a component of progressive disease that leads eventually to invasive lobular carcinoma. The presence of LCIS identifies patients who at high risk for subsequently developing a breast cancer that is more often invasive ductal carcinoma rather than lobular carcinoma. Furthermore, both breasts are equally at risk for development of cancer.

DCIS

The goal of surgery for DCIS is to prevent progression to an invasive cancer or to remove a coexisting invasive lesion. An algorithm for treating DCIS based on the size of the lesion is depicted in Figure 2. The standard treatment for DCIS has been a total mastectomy (often with low axillary nodal dissection) for patients with larger, symptomatic tumors. However, the widespread use of mammography has resulted in detection of smaller tumors (< 2.0 cm) for which breast conservation therapy should be considered.

Mastectomy has been routinely applied for the management of DCIS for several decades, in view of the potential hazards of synchronous and metachronous invasive carcinomas and the extensive multicentricity that characterize this entity. In these earlier studies,[8–13] the incidence of a subsequent invasive carcinoma after biopsy alone for DCIS was approximately 30% or greater over 20 years of follow-up. The invasive lesions usually appeared after a 5- to 10-year delay. The cancers that occurred within 5 years usually arose within the same quadrant as the biopsy site in the ipsilateral breast and were usually of ductal histology, whereas those that occurred later were just as likely to be located in another quadrant of the ipsilateral breast.[14,15]

Total mastectomy should be considered the "gold standard" against which less extensive forms of treatment for DCIS must be compared.[16] Combined data from seven series for women with DCIS treated with mastectomy[7,17,23] demonstrated a local recurrence rate of only 3.1% and a mortality of 2.3%. These results also demonstrated that metastatic risks still exist even for early invasive cancers detected by screening. Ipsilateral mastectomy rather than bilateral mastectomy has been considered adequate since the overall incidence of contralateral breast cancer appears to be about the same as in women with invasive carcinoma.[17] Breast reconstruction is an option and may be done at the time of mastectomy.

The likelihood of detecting axillary nodal metastasis is less than 2% in patients with palpable DCIS mass (e.g., > 2 cm in diameter)[14] but is approximately 0% when the primary breast lesion is detected only by mammography. The consensus is that an axillary node dissection for DCIS without a known invasive component is unnecessary, except in cases of larger, symptomatic tumors in which microinvasive disease may be present in an unsampled area of the tumor specimen.

The continuing debate is whether total mastectomy is necessary for all patients with DCIS or whether patients with small tumors can be safely treated by breast conservation surgery and irradiation.[15] The excellent results that have been demonstrated for breast conservation treatment of invasive carcinoma[24,25] have appropriately led to attempts to apply this approach to the treatment of DCIS. Several series have reported local recurrence rates ranging from 10% to 63% with follow-up periods of up to 14 years after local excision alone for DCIS.[16,20,26,27] The incidence of recurrence is greater for palpable tumors of larger size[7,27,28] and when pathologic confirmation of clear margins is less rigorous. Most recurrences arise in the original biopsy site, implicating inadequate clearance of margins rather than intrinsic biologic behavior of DCIS. These recurrence rates continue to increase with longer follow-up intervals, with a substantial portion occurring more than 5 years after initial diagnosis of DCIS.[16] It is for this reason, as well as evidence that younger patients have a high risk of locoregional failure after breast-sparing therapy,[29–31] that some authors recommend total mastectomy in young women with DCIS.[28]

Segmental mastectomy followed by irradiation of the intact breast has been increasingly applied for DCIS in view of its established efficacy for invasive breast carcinoma.[32–34] The combined data from recent studies of this treatment for DCIS[35–40] demonstrate an overall local breast recurrence rate of 9.4% and a mortality rate of only 1.7% (362 women; median follow-up, ≤ 92 months). The short follow-up periods and the substantial overlap of these results with those of local excision alone, however, make the contribution of radiation therapy difficult to ascertain.[41]

The National Surgical Adjuvant Breast Project (NSABP) Protocol B-17 addressed whether radiation therapy could reduce local recurrence of DCIS treated by segmental mastectomy with pathologically confirmed negative margins. Patient accrual (n = 818) was completed in December 1990, and the data will require time to mature. More than 80% of the patients entered into this study had limited asymptomatic DCIS, with only 4% having a palpable tumor larger than 2 cm.

Since DCIS may be more extensive than expected at the time of diagnosis, regardless of the mode of detection, a new NSABP Protocol (B-24) has been activated to determine whether (1) radiation therapy can effectively achieve local control within the ipsilateral breast regardless of the extent of surgery or the extent of DCIS, and (2) the antiestrogen tamoxifen has an additive effect in reducing the recurrence rate in either breast. Tamoxifen has been shown to decrease both ipsilateral recurrence and contralateral breast cancer after breast conservation surgery for invasive breast cancer (NSABP Protocol B-14).[42,43]

One important perspective on breast conservation treatment of DCIS is that more than 50% of all local recurrences are invasive, indicating the potential for systemic disease and possible death from a lesion that should theoretically be cured by complete removal. Several studies have suggested that local recurrence after breast conservation surgery for all forms of carcinoma can be successfully treated with a high likelihood of success.[44,45] and that it does not carry the ominous prognosis that has been shown for recurrence after mastectomy.[46] Other studies, however, suggest that locoregional recurrence in this setting may result in a diminished probability of survival.[30,47] Therefore, initial treatment of DCIS should not be compromised simply based on the premise that local recurrence can easily and safely be managed should it occur.

Thus, the therapy options for DCIS are similar to those for invasive breast carcinoma, although evidence of the safety and efficacy for breast-sparing therapy of DCIS is less conclusive.

Breast-sparing therapy should be offered to women with DCIS as long as its uncertainties and risks are fully discussed and understood by the patient. Such therapy would consist of a segmental mastectomy (with negative margins confirmed pathologically) and postoperative radiation therapy.[48] Until more data on the protective role of radiation therapy and hormone therapy becomes available from ongoing clinical trials, total mastectomy with the option of breast reconstruction is recommended if attempts at wide local excision reveal extensive foci and/or residual DCIS or if histologically clear margins cannot be obtained. This would particularly apply to larger lesions, such as those with a diameter of 2 cm or greater. Since only 10% of patients with DCIS will develop a contralateral breast cancer, a prophylactic mastectomy of the opposite breast is not required. There is no role for cytotoxic chemotherapy in the treatment of DCIS.

Segmental mastectomy as the sole treatment modality may be applied cautiously in carefully selected patients. This option may be most appropriate in cases of "inci-

dental DCIS," especially of the non-comedo type, in which microscopic foci (< 0.5 cm) are found in specimens of predominantly benign breast tissue with no clinical or radiographic manifestations suggestive of malignancy and the margins are clear of tumor.[49,50]

Comprehensive lifelong surveillance after treatment is essential for all women with DCIS to facilitate early detection of any subsequent malignancies. A follow-up mammogram of the treated breast should be obtained within 6 months if breast-sparing treatment was carried out, to confirm removal of the suspicious lesion that led to diagnosis. Yearly mammography should be completed thereafter. Physical examination should be carried out every 6 months in the 5 years after diagnosis, when the risk of ipsilateral or contralateral recurrence is greatest, and then annually thereafter.

LCIS

LCIS is usually diagnosed in premenopausal women as an incidental finding in a breast biopsy done for other indications. The risk of subsequent development of an invasive carcinoma after treatment with biopsy alone is 30%, with approximately 15% risk in each breast. The majority of these invasive cancers will occur 15 years or longer after the initial diagnosis, with 40% detected more than 20 years later.

The current concept of LCIS as a "marker" of increased risk for developing breast cancer rather than as a site of origin for cancer[51] is supported by the findings that if an invasive cancer subsequently occurs, 50% to 65% of the time it will be of ductal rather than lobular histology and that all breast tissue is at equal risk. Thus, the treatment options should include lifelong observation of both breasts with mammography and physical examination or bilateral total mastectomies with consideration of breast reconstruction.

Nonoperative observation is not a risk-free management option. The combined data from 515 patients with LCIS in five follow-up series[17,52–56] showed a 7% mortality rate from breast cancer. Rates of subsequent invasive carcinoma of up to 37% and subsequent mortality rates of up to 16% have been documented in these women.[52] These correspond to a 12-fold increased risk over that expected in the general population.[57] However, the goal of observation is to detect subsequent carcinomas that develop in either breast at an early stage, when the likelihood of cure is high, and the feasibility of this goal is supported by the results of several mammographic screening trials.[58–60]

No demonstrated benefit exists for wide excision of LCIS to obtain clear margins, because this disease diffusely involves all genetically identical breast tissue. Consequently, ipsilateral total mastectomy or radiation therapy to the ipsilateral breast is not indicated. Routine contralateral biopsy in the absence of standard indications is not justified since the likelihood of finding a lesion requiring treatment (i.e., invasive carcinoma or DCIS) is small, the clinical significance of contralateral LCIS may be negligible, and negative biopsy results have never been clearly shown to be associated with reduced risk.[17,61]

Bilateral total mastectomy may be selected as a therapeutic option for those cases of LCIS in which some type of surgical treatment is deemed necessary or chosen by the patient in view of the bilaterality of subsequent risk. The current sophistication of breast reconstructive techniques may make bilateral mastectomy a more acceptable option than in the past, especially in young high-risk patients. Subtotal mastectomy and subcutaneous mastectomy are not considered adequate treatment options, because there is no evidence that either approach will eliminate the risk of recurrence.[51] The incidence of axillary nodal metastases associated with LCIS is less than 1%, so an axillary node dissection is not required.

EARLY STAGE INVASIVE BREAST CANCER

The goals of breast cancer treatment are: (1) cure, (2) local disease control, (3) staging, (4) a satisfactory cosmetic result (i.e., minimal disfigurement), and (5) rehabilitation. Each of these goals must be considered to achieve an acceptable treatment plan. A further distinction must be made between cancer prevention (such as in patients with *in situ* breast cancer) and cancer treatment (for those with invasive breast cancer).

In many circumstances, variations in surgical treatment do not influence survival outcome. Nevertheless, the type of surgical procedure used (alone or in combination with radiation therapy) may profoundly affect the other goals of breast cancer treatment described above. For example, a lumpectomy with tumor involvement at the surgical margin is associated with a 20% or higher failure rate in the breast that subsequently will require a mastectomy. Even if a breast recurrence requiring mastectomy does not affect overall survival, a 20% failure rate for a situation that could have been avoided is not an acceptable surgical outcome. Further, a limited axillary dissection may result in understaging of the patient (which may in turn influence subsequent decisions regarding adjuvant systemic therapy) and also expose the patient to the risk of having a subsequent operation for axillary recurrences in the future. A radical local excision (e.g., quadrantectomy) can cause significant disfigurement to the breast in some patients; this is too radical a

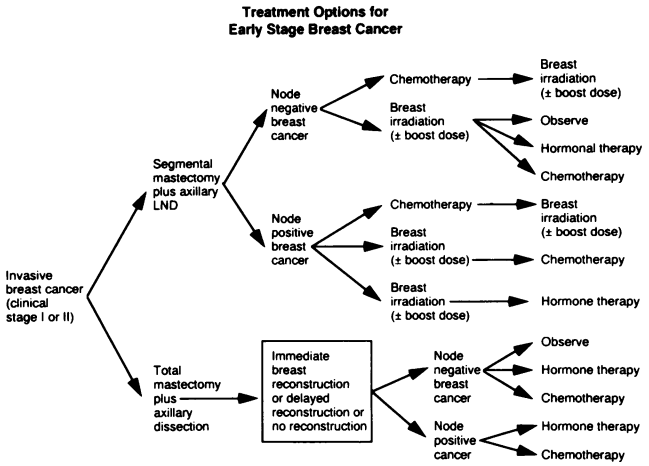

Figure 3. An algorithm depicting treatment options for early stage breast cancer. The first-level treatment decisions involves options for local/regional treatment. The basic choice here is between breast conservation surgery plus irradiation or modified radical mastectomy with the option of breast reconstructive surgery. A second level of decision is made postoperatively regarding the deployment of adjuvant chemotherapy or hormonal therapy.

local form of treatment for most patients if a segmental mastectomy can achieve the same cancer control with less distortion. Finally, performing a modified radical mastectomy without offering the option of breast reconstructive surgery is simply not good rehabilitation for many breast cancer patients.

Three surgical options are available for patients with early stage invasive breast cancer: modified radical mastectomy; breast conservation surgery with irradiation; and breast reconstruction, either at the time of mastectomy (immediate) or at some designated later time interval (delayed) (Fig. 3). For most patients the goal should be to preserve or recreate a normal-appearing breast (Fig. 4).

Modified Radical Mastectomy

Standard modified radical mastectomy consists of removal of the entire breast and an axillary node dissection.[62] At present, the histologic status of the axillary nodes (positive or negative) and the extent of nodal involvement (number of positive nodes) are the best indicators of prognosis.[63] Although there is no evidence that removal of axillary nodes improves survival rates,[64] an axillary node dissection provides more reliable staging than clinical assessment of the axilla and reduces the risk of a subsequent regional recurrence. A formal level I–II axillary node dissection (removal of axillary lymph nodes lateral to and behind the pectoralis minor muscle) accurately defines prognostic subsets of patients, i.e.,

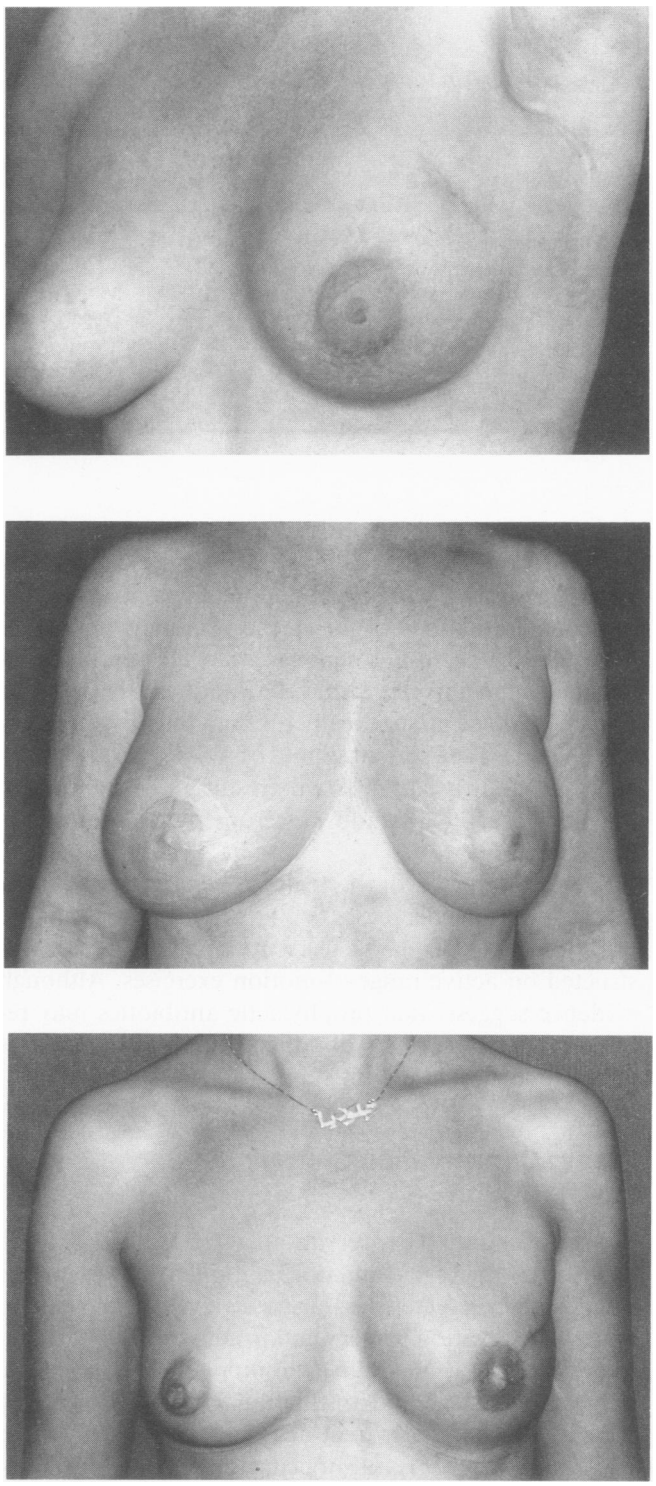

Figure 4. Three different surgical approaches used for treating breast cancer that preserved or restored a normal appearing breast. A) A patient with a breast conservation therapy consisting of segmental mastectomy, axillary dissection and breast irradiation. B, C) Patients with two different forms of immediate breast reconstruction after total mastectomy and axillary dissection. Immediate breast reconstruction can be achieved using either an autologous flap, such as a TRAM flap (B), or a breast prosthesis, (C).

Table 2. RISK FACTORS ASSOCIATED WITH BREAST RECURRENCES BREAST CONSERVATION SURGERY

Factor	Recurrence Rates
No breast irradiation[24,77,86,140,146]	25–43%
Surgical margin positive[139,150–153] or near tumor	20–35%
Extensive DCIS[3,31,147–149] (especially in younger age patients)	20–25%
Young age (≤40 years)[30,139,149]	20–25%
Multiple tumors[31,154]	16–35%
High nuclear grade of tumor[31,86,149]	10–20%

those with one to three positive nodes versus those with four or more.[65] In addition to preserving the thoracodorsal neurovascular structures and long thoracic nerve, the surgeon should avoid injuring the pectoralis nerves innervating the pectoralis major muscle. However, the intercostal brachial nerve may be sacrificed because its branches course anatomically through the lower axillary lymph nodes. The patient should be made aware preoperatively that this sacrifice will result in anesthesia of the skin in the axilla and posteromedial aspect of the upper arm.

Suction catheter drains can be removed when the drainage volume decreases to 30 to 40 mL over 24 hours or within 8 to 10 days. The patient shall then be instructed on active range-of-motion exercises. Although evidence suggests that prophylactic antibiotics may reduce the incidence of wound infections, this issue has not been answered definitively.[66,67]

Breast Conservation Surgery and Radiation

The term "breast conservation" refers to an attempt to "conserve" the breast and does not infer that the tumor itself is to be treated less aggressively. The benefit of breast conservation surgery and irradiation is that it preserves the breast, including the nipple. The goal of the combined surgery and irradiation is to maximize the benefits of both cancer treatment and cosmetic outcome while minimizing risks. Surgical risks include disfigurement from excising a large portion of the breast and the risk of a subsequent breast recurrence that may require mastectomy. Radiation risks include edema and altered sensation of the skin, fibrosis of the breast parenchyma, contraction of the breast, rib fractures, brachial plexopathy, damage to the underlying heart and lung, and, rarely, development of sarcoma in the treatment field.[30,68,69] Most of these radiation complications are uncommon in occurrence.[70,71]

Numerous randomized prospective studies have all shown that survival is not significantly different for patients who undergo breast conservation surgery plus irradiation than for those who receive a modified radical mastectomy for early stage breast cancer.[24,25,72–76] However, the pattern of loco-regional failure is different. The majority of loco-regional recurrences after standard mastectomy develop within 2 years of surgery and are usually a harbinger of distant metastases with only a 15% 5-year survival rate. In contrast, most recurrences after breast conservation therapy develop at the site of the original primary lesion. With diligent follow-up, these patients can usually be salvaged with further surgery, with a 60% to 70% 5-year survival rate.[30,44,77] Patient selection is important, since not all patients would benefit, particularly those with features of their cancer that would increase the risk for a later breast recurrence requiring a mastectomy (Table 2).

The surgeon should arrange for the patient to see a radiation therapist before undergoing breast conservation surgery to ensure that the patient is a candidate for this approach and, most important, that the patient is adequately informed about the delivery plan for the radiation therapy (location of radiation center and duration of treatment) and about the potential short- and long-term side effects. Because the goal is to preserve the breast and avoid local recurrence, the surgeon should assess and also discuss with the patient the following selection criteria.

Age of the Patient

No patient is too old to undergo breast conservation therapy. Younger women may actually have a higher rate of therapy failure in the treated breast. Patients 35 years of age or younger who underwent breast conservation therapy at The University of Texas M. D. Anderson Cancer Center had a local failure rate of 14%, compared with a 7% rate for those who were older ($p = 0.04$).[78] However, the disease-free and overall survival rates were not significantly different.

Family History

A strong positive family history of breast cancer is not a contraindication to breast conservation therapy. The patient should, however, be counseled about her risk of developing subsequent ipsilateral or contralateral second primary breast cancer, especially if the affected relative was premenopausal at the time of diagnosis or had bilateral disease.[79,80]

Size of Breast

The breast should be of adequate size to allow appropriate tumor excision with negative margins and still have a reasonable cosmetic result. Conversely, technical difficulties in delivering a uniform dose of radiation may result when treating large, pendulous breasts, with a subsequent increased incidence of fibrosis and contraction. Irradiation of a small breast with a subcutaneous implant also may result in severe capsular contraction.[81]

Collagen Vascular Disease

Patients with discoid or systemic lupus erythematosus or with scleroderma have been found to have exaggerated acute and late side effects from irradiation.[82]

Psychosocial Factors

Patients must have a strong desire to preserve the breast, must be willing to come for daily outpatient irradiation treatments over a 5- to 6-week period, and must be able to return indefinitely for follow-up to exclude treatment failure. The psychological fear of irradiation or of having a relapse within the breast must also be addressed with the patient.

Tumor Size

A solitary lesion smaller than 3 to 4 cm in diameter is preferable, depending on the size of the breast and the location of the tumor. Patients with multiple primary tumors (two or more) are not candidates for breast conservation surgery, except in the case of two small lesions or microcalcifications within a sphere of 3–4 cm, inclusive of the surrounding breast tissue. Conservative surgery for larger tumors is considered investigational.[83]

Tumor Site

A superficial centrally located or subareolar tumor may require removal of the nipple-areolar complex to excise the tumor with negative margins. However, the resulting breast mound may be cosmetically satisfactory to the patient. At present, the feasibility of nipple reconstruction in irradiated skin is unknown.

Tumor Histology

No significant difference in local recurrence has been detected among histologic subtypes of invasive breast cancer.[36,84] The Joint Center for Radiation Therapy in Boston did report that the presence of extensive intraductal cancer (EIC) occupying 25% or more of the tumor lesion with extension outside the invasive component resulted in a 10-year local failure rate of 35%, as compared with an 8% rate when EIC was absent.[2,85] The relapse rate is reportedly higher when it occurs in younger women. In that series, patients had only gross tumor was removed, without pathologic confirmation that the margins were free of tumor. However, we and others have not found that EIC correlates with breast recurrences.[86]

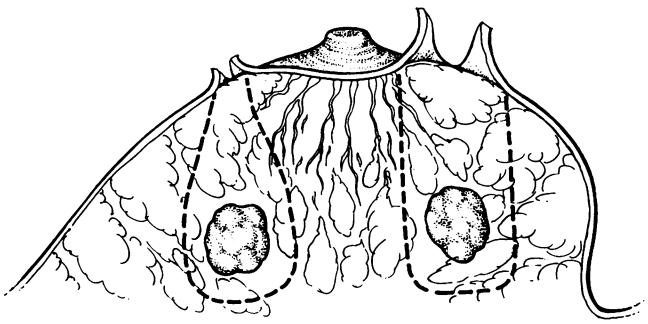

Figure 5. Surgical technique of segmental mastectomy for early breast cancer. This is a three-diminisional excision of the tumor with at least a 1-cm boundary of normal breast tissue. Thick flaps should be raised and the incision made into the breast parenchyma toward the tumor (left panel). It is unnecessary to raise flaps just beneath the skin (as with a modified radical mastectomy) and remove a cylinder of breast parenchyma unless the tumor is superficially located. Raising such thin flaps may cause a depression of the skin overlying the defect and distort the contour of the breast.

Tumor Margin

The tumor should be removed with a histologically clear margin (preferably of 1 cm or more). Biopsy site should be re-excised if the pathology report indicates inadequate or unknown margins or if physical examination or mammography suggests residual cancer. We follow this policy at M. D. Anderson Cancer Center, and we have found that 50% of the re-excisions showed residual tumor.[87]

Axillary Nodal Status

Preferably, the axilla should be clinically negative or contain only small mobile lymph nodes. Patients with fixed or matted axillary nodes should undergo induction chemotherapy and be reassessed for breast conservation surgery if a response is achieved, the primary tumor is reasonably small, and there is no evidence of skin or dermal lymphatic involvement.

Technique

In performing a segmental mastectomy (wide local excision), an elliptical incision is placed directly over the breast mass and includes the needle track or scar from any previous biopsy (Fig. 4a). To achieve the best cosmetic result, a curvilinear transverse incision that conforms to the contour of the breast is used, although a radial (vertical) incision may be preferred for large tumors in the lower quadrants of the breast to diminish

downward retraction of the nipple-areolar complex. The incision for the segmental mastectomy should be separate from the incision for the axillary node dissection. This diminishes subsequent retraction of the breast toward the axilla and also enables the radiation therapist to give a radiation boost to the primary tumor site if necessary.

After the incision is made, flaps are raised in all directions to mobilize the skin from the underlying breast tissue. These flaps are thick unless the tumor is superficially located. An en bloc excision around the tumor or biopsy cavity is performed with a 1-cm or greater margin of normal breast tissue obtained in all three dimensions (Fig. 5). Excising the entire quadrant of the breast is unnecessary and in fact can cause greater distortion of the breast contour.[88] The pectoralis major fascia may be included for deep-seated tumors. When the specimen is removed, the surgeon should personally orient it for the pathologist and request that any close margin be checked by frozen section examination. A portion of the tumor should also be sent for hormone receptor assays and flow cytometry analysis. Radiopaque hemoclips may be used to mark the bed of tumor resection for the radiation therapist. Meticulous hemostasis should be obtained. The defect in the breast is not closed with sutures, and drains are not necessary. The skin is closed with a running subcuticular suture for cosmesis. A level I–II axillary node dissection is performed as in the standard modified radical mastectomy.

Radiation therapy is begun 2 to 3 weeks after surgery when the wounds have healed and the patient is able to abduct the arm out of the treatment field. If adjuvant chemotherapy is given, radiation therapy can be deferred until the chemotherapy has been completed, especially if a doxorubicin combination is used (Fig. 3). Currently, a randomized prospective study is being conducted at M. D. Anderson Cancer Center to determine whether the order in which radiation therapy and adjuvant systemic chemotherapy are given has an impact on local recurrence rate.

If the patient had stage I disease, only the breast is irradiated, with a dose of 50 Gy given through tangential ports to include the breast and underlying chest wall. Computerized dosimetry is used to ensure a uniform dose throughout the breast. It remains controversial whether a boost dose of 1000 cGY is necessary to achieve local disease control. In our practice, we do not routinely use a boost dose of radiation, especially for small tumors (< 1 cm) if the surgical margins are clear and the patient does not have a combination of risk factors that would substantially increase the risk of local recurrence (Table 2).

Axillary irradiation should not be performed in a patient who has had a level I and II axillary dissection. In some circumstances, we would consider axillary irradiation when there is extensive extranodal tumor or multiple positive axillary nodes. The combination of complete axillary dissection and radiation therapy is likely to significantly increase the risk of breast and arm edema, and there is no additive benefit gained by using the combination of treatments when either alone is sufficient for local disease control.[71]

Complications

Of the 525 women who underwent breast conservation therapy at M. D. Anderson Cancer Center between 1955 and 1985,[30] moderate to severe fibrosis developed in the treated breast in 10.1%, late rib fractures occurred in 2.6%, arm edema was present in 7.8%, and symptomatic pneumonitis was noted in 4.9%. A presumed radiation-induced angiosarcoma developed in one patient 12 years after treatment. One patient with scleroderma had massive necrosis of the treated breast that required chest wall reconstruction.

No significant difference in the incidence of contralateral breast carcinoma has been detected as a result of the use of radiation therapy.[89,90]

Cosmetic Results

An estimated 90% of patients in the M. D. Anderson Cancer Center series who were followed for at least 10 years had a good cosmetic result (Fig. 4a). In most studies,[91–93] satisfactory cosmetic results have been achieved if extensive axillary node dissection combined with axillary irradiation is avoided and if the radiation dose to large volumes is restricted to 50 Gy. Excessively wide resection of normal breast tissue surrounding the tumor also results in a less satisfactory appearance. In addition, the use of concomitant adjuvant chemotherapy may increase the radiation-induced fibrosis of the breast and thus augment breast retraction.[94,95]

The psychologic effects of preserving the breast as compared with the effects of mastectomy are most significant in terms of positive body image. However, there are no major differences between treatment groups with respect to general psychologic adjustment, anxiety, and marital satisfaction.[96–100]

Breast Reconstruction

Breast reconstructive surgery represents a major advance in cancer rehabilitation for the patient undergoing a total mastectomy. Traditionally, a 2-year waiting period after mastectomy was advocated because 80% of recurrent disease would have become manifest by then

and reconstruction was thought to mask detection of loco-regional recurrences.[101,102] However, in our experience, subpectoral implants or myocutaneous flap reconstructions have not interfered with either detection or treatment of loco-regional recurrences in the small groups of stage I and II patients who have had such recurrences.[103] Therefore, breast reconstructive surgery should be considered part of standard management for patients undergoing total mastectomy and it should be considered for most patients, unless the additional procedure would increase the operative risk or the patient has indicated that this additional procedure is unnecessary for her quality of life[104–108] (Fig. 4b, c).

Clinical decision-making regarding reconstruction involves (1) the timing of reconstructive surgery (immediate or delayed), (2) the type of reconstruction (autologous flaps or implants), (3) the experience and availability of the reconstructive surgeon, and (4) patient preference.

Immediate breast reconstruction offers the advantage of only one hospitalization, induction of anesthesia and postoperative recovery; the ability to maximize skin preservation over the breast parenchyma during mastectomy; improved aesthetic outcome; and the lessening of potential emotional trauma experienced by the patient because of the loss of the breast. The chief reason for the improved aesthetic results with immediate reconstruction is the preservation and use of uninvolved breast skin in the reconstruction.[109] Only the nipple, biopsy scar, and breast parenchyma need to be removed. Preservation of the remaining skin envelope, including the inframammary fold, is helpful in reshaping the breast contour. An additional technical advantage is conferred by the absence of established scar tissue.

On the other hand, delayed reconstructive surgery should be considered when: (1) the patient is ambiguous about having reconstruction surgery; (2) if the prolonged anesthesia will increase operative risk; (3) the risk of wound infection or necrosis would delay the onset of adjuvant systemic therapy; or (4) postoperative radiation therapy is being considered. These latter two reservations are especially important in patients with larger tumors or multiple axillary nodal metastases that are evident at the time of mastectomy.

Options for breast reconstruction include (1) breast prosthesis (either saline-filled or gel-filled), (2) expandable breast prosthesis, (3) latissimus dorsi myocutaneous flap, (4) transverse rectus abdominous musculocutaneous (TRAM) flap (as a pedicle graft or with a free microvascular anastomosis), or (5) a gluteal musculocutaneous free flap. We prefer the TRAM flap or latissimus flap because each uses the patient's own tissues and provides a superior cosmetic result over the long term[109] (Fig. 4b).

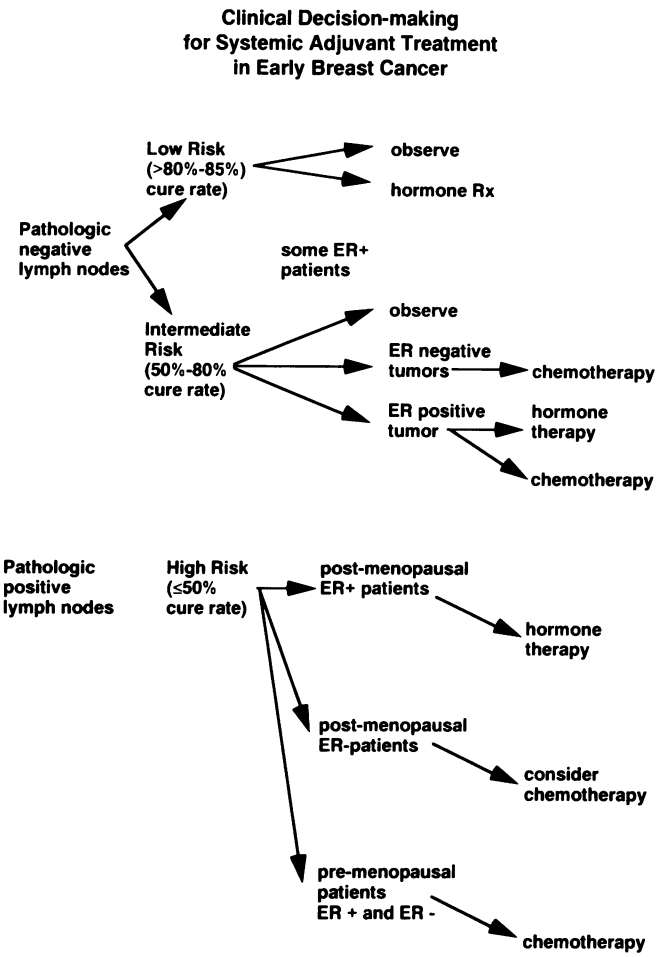

Figure 6. An algorith depicting treatment options for adjuvant systemic therapy. The clinician should estimate the probability of cure with surgical treatment alone and then consider adjuvant systemic therapy as a recommendation when the potential benefits outweigh the toxicities and risks.

The scars of the donor site are also better hidden and the patient's abdomen is flattened ("tummy tuck"). However, tissue transfer operations take longer and require greater operative skill and experience to achieve good results.

The use of a breast prosthesis (implant) is satisfactory for many patients (Fig. 4c). The life-span of prostheses beyond 10 to 20 years is still unknown, and it has not yet been conclusively determined whether they may contribute to or induce secondary diseases such as autoimmune disorders. However, the weight of evidence, at present, suggests that the presence of a silicone prosthesis does not increase the risk for developing a second cancer or contribute to the development of an autoimmune disease.[110] Prospective data regarding this issue are being collected.

Psychologic considerations are also important in selecting a reconstructive procedure. By postponing recon-

struction to select out the women with poor prognoses, the opportunity for improved quality of life is lost. The option of breast reconstruction should be discussed with patients before mastectomy. If a patient expresses an interest in reconstruction, consultation with the reconstructive surgeon should be obtained to determine the optimal type of reconstructive procedure based on the operative defect and the symmetry requirements of the opposite breast.

ADJUVANT SYSTEMIC THERAPY

After surgery, an important decision must be made about the use of adjuvant systemic chemotherapy or hormonal therapy (Fig. 6). This decision will depend on information from the pathology examination of the mastectomy specimen and axillary lymph nodes, including assays for tumor markers and hormone receptors.[111,112] In many instances, consultation with a medical oncologist will provide important input. The surgeon should be an active partner in this decision-making process and should understand the proper application of systemic therapy for different histologic presentations and stages of disease. The surgeon should not be a passive partner and leave these decisions solely to the medical oncologist. The patient will benefit from the blend of perspectives that results from the training and experience of both the surgeon and the medical oncologist regarding adjuvant therapy decisions. Therefore, the surgeon must be fully informed and keep up to date about the results of clinical trials involving adjuvant therapy for subsets of patients with early breast cancer.[113]

The decision-making process for adjuvant systemic therapy involves two basic steps: (1) estimating the risk of systemic micrometastases based on prognostic factors and (2) assessing the known benefits, risks, and complications of each systemic drug regimen. One convenient approach to the first step is to categorize patients with early stage breast cancer into one of three groups using currently available prognostic factors: (1) low risk (10% to 20%) for systemic metastases, (2) intermediate risk (20% to 50%), and (3) high risk (> 50%) (Fig. 6).

Tumor size and nodal status are unquestionably the primary factors used to delineate risk groups for metastatic disease.[114,115] Low-risk patients (e.g., those with tumors ≤ 1 cm in diameter and negative nodes) should not be considered for adjuvant systemic therapy, except perhaps in prospective protocols, because there is no proven benefit for any of the currently available agents, which are associated with risks and additional costs. High-risk patients (e.g., those with nodal metastases or primary tumors ≥ 3.0 cm) should be considered for adjuvant systemic therapy as standard treatment because in this subgroup the benefits outweigh the risks as documented in numerous prospective randomized clinical trials.[116–118] The recent National Institute of Health Consensus Conference concluded that "adjuvant therapy has become the standard of care for the majority of cases of breast cancer with axillary lymph node involvement."[118] Intermediate-risk patients (e.g., those whose tumors are 1.5 to 3.0 cm and who have negative nodes but other poor prognostic features) might also be considered for adjuvant therapy. Early results from clinical trials suggest that women in this subgroup with node-negative breast cancer may benefit from systemic therapy in terms of improved disease-free survival.[42,116–118] However, an increased overall survival rate has so far been demonstrated only for patients with node-negative tumors larger than 3 cm in diameter. Our results in a surgical series of node-negative patients treated with locoregional therapy indicate a 25% to 30% probability of relapse.[119] However, women with small tumors (≤ 1 cm) may have a lower rate of recurrence (< 10%).[115]

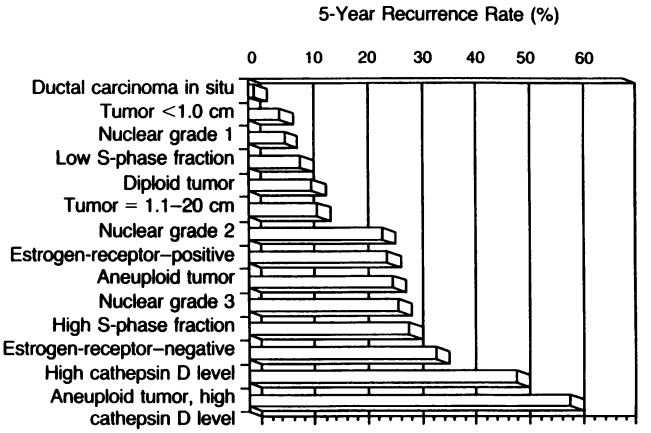

Figure 7. Risk assessment for microscopic metastasis based on various prognostic factors in patients with node-negative breast cancer. Patients who have a relapse rate of less than to 10 to 20% are not candidates for systemic therapy, since the probability for cure after surgical treatment is high. On the other hand, the decision to recommend adjuvant systemic therapy becomes more compelling as the risk for relapse increases. The relapse rates shown are estimates based on a compilation of data from the literature and are not absolute values. (Reprinted with permission from McGuire WL et al. "How to use prognostic factors in axillary node-negative breast cancer patients." J Natl CA Inst 1990; 82:1006.

Numerous other prognostic factors correlate with survival, such as estrogen receptor status,[120] presence or absence of the oncogene erbB-2 (*neu*),[121–123] levels of protease cathepsin D[124] and angiogenesis factor VIII,[125] nuclear grade[126] and flow cytometry DNA index and S-phase.[127] Guidelines that use these various factors in risk assessment for metastasis have been proposed.[112,128] (Fig. 7). However, a reproducible model that uses combinations of these factors to accurately and consistently

predict relapse rates has not been developed. Until an improved methodology to predict recurrence rates is available, our patients with invasive tumors larger than 1 cm or with positive axillary nodes will be entered into postoperative adjuvant therapy protocols.

The chemotherapy combination of cyclophosphamide, methotrexate, and 5-fluorouracil (CMF) is a widely used adjuvant treatment for premenopausal breast cancer patients. However, we prefer a doxorubicin-based regimen containing 5-fluorouracil, adriamycin, and cyclophosphamide (FAC) that may be a more effective adjuvant therapy, especially in patients who have more than three positive nodes.[129] Patients receive six cycles of chemotherapy given at maximum doses, as determined by hematologic and systemic tolerance. To answer the question of whether the addition of a crossover regimen will further increase survival over standard therapy, our patients who are younger than 50 years, regardless of estrogen receptor (ER) status, are offered the chance to be randomly assigned to receive either six cycles of FAC or six cycles of FAC followed by four cycles of methotrexate and vinblastine (MV). An alternative for patients with 10 or more positive axillary nodes is a randomized trial of standard chemotherapy (FAC) with or without consolidation with high-dose intensification chemotherapy (cisplatin, etoposide, and cyclophosphamide).

Premenopausal women with node-positive and ER-positive breast cancers should not receive adjuvant tamoxifen as a less toxic substitute for combination chemotherapy, according to results of prospective clinical trials.[130] It is still controversial whether tamoxifen should be added to a chemotherapy regimen in these patients. Based on preliminary results from the NASBP,[42] adjuvant tamoxifen should be considered selectively only in node-negative ER-positive breast cancer patients. However, we prefer to offer adjuvant chemotherapy to these premenopausal patients, especially those with larger tumors (≥ 2.0 cm) and poor prognostic features.

For postmenopausal patients who have an ER-positive tumors and nodal metastases, tamoxifen alone has been proven to have a survival benefit almost equivalent to that of CMF-type chemotherapy regimens.[130] The optimal duration of tamoxifen therapy is unknown, but a minimum of 2 to 5 years has been recommended. To determine whether a more aggressive chemotherapy regimen can increase survival rates above that achieved with tamoxifen, a current M. D. Anderson study for postmenopausal women with ER-positive tumors randomly assigns patients to receive either tamoxifen or six cycles of FAC and four cycles of MV. At M. D. Anderson, postmenopausal women with ER-negative tumors are randomized to the same treatment arms as the premenopausal women (FAC versus FAC + MV).

Table 3. REPORTED TOXICITIES FROM ADJUVANT SYSTEMIC THERAPY FOR BREAST CANCER

I. Chemotherapy (CMF or FAC regimens)
  A. Common occurrences (>50% of patients)
    Weight gain
    Alopecia
    Nausea and vomiting
    Leukopenia
    Thrombocytopenia
    Amenorrhea
  B. Occasional (<10–15%)
    Hemorrhagic cystitis
  C. Uncommon (<1%)
    Sepsis
    Cardiac toxicity
    Secondary malignancies
    Thrombophlebitis
II. Tamoxifen Hormonal Therapy
  A. Common occurrences (>50% of patients)
    Hot flashes
  B. Occasional (<10%)
    Weight gain
    Thrombophlebitis
    Nausea
    Vaginitis
  C. Uncommon (<1%)
    Pulmonary embolus endometrial carcinoma (controversial)

Women with invasive tumors smaller than 1 cm regardless of ER status and with histologically negative axillary lymph nodes are encouraged to enter the NSABP Protocol B-21 after breast conservation surgery. This study includes three treatment arms: breast irradiation alone, irradiation plus tamoxifen, and tamoxifen alone.

The risks and complications of adjuvant therapy must be considered when recommending adjuvant systemic therapy (Table 3). With adjuvant chemotherapy, toxicity during treatment can be significant in some patients, and there are occasional treatment-related mortalities.[131] Secondary malignancies have also been reported, especially leukemia.[132–134] Because of these life-threatening risks, adjuvant chemotherapy should not be used in low-risk patients who are likely to be cured by surgical treatment alone. Even though tamoxifen has a more favorable therapeutic index, it should not be used indiscriminately. Some patients experience bothersome symptoms such as hot flashes, and a few may experience serious complications such as phlebitis and pulmonary embolism.[135,136] One study has suggested that long-term, high-dose tamoxifen is associated with a higher risk of developing endometrial carcinoma,[43] but this observation has not

been confirmed in other tamoxifen trials.[42] Adjuvant therapy is associated with significant health-care costs, especially when applied on a national basis.[137,138]

SURVEILLANCE AND FOLLOW-UP

After receiving appropriate breast cancer treatment, the patient is still at risk for two manifestations of disease: development of a second primary breast cancer in the contralateral breast and clinical emergence of local or distant metastasis. To the extent the patient is cured, the risk of developing a second primary breast cancer increases over the years (about 0.7% per annum for life), whereas the risk of developing local or distant metastasis decreases over time (especially after 10 years).

Screening to detect cancer in the contralateral breast should follow the recommendations promulgated by the American Cancer Society, which include annual mammography (two views), annual physician examination, and monthly breast self-examination. For individual patients at high risks, aggressive cancer prevention intervention that includes prophylactic mastectomy may be appropriate, although this approach is not warranted for the vast majority of patients. Long-term administration of tamoxifen may diminish the risk for developing contralateral breast cancer;[42,43] however, this observation should not be used as the sole justification for administration of the drug until prospective clinical trials specifically designed to address this question are completed.

Surveillance for distant metastatic disease should be tempered by the patient's initial stage of disease. For patients with early breast cancer, a judicious metastatic workup should be performed at regular intervals. Natural history studies have demonstrated that 75% of recurrences occur within the first 2 years and 95% within the first 5 years. However, local recurrences in breast cancer patients treated by conservation surgery and irradiation occur over a much longer span of time.[139,140]

The evidence is emerging from multiple studies that the practice of ordering an elaborate number of tests is associated with high cost, low yield, and low specificity. Moreover, at least six studies have suggested that screening for asymptomatic metastases in breast cancer patients does not result in earlier detection or in any demonstrable improvement in patient survival rates compared with testing only those patients who present with symptomatic metastases.[141] Even under close scrutiny, an average of only 20% of patients will present with asymptomatic metastases as their first sign of relapse during regular follow-up.[142–144] Although asymptomatic metastases may be detected 6 to 12 months before symptoms appear, according to several studies, there is little evidence to date that earlier administration of systemic chemotherapy or hormonal therapy improves survival rates.[141,145]

Breast cancer can metastasize to any organ in the body. However, there are specific recognized patterns of recurrence. Surveillance for first recurrences should therefore comprise a selective, not a comprehensive, metastatic evaluation. In our practice, we perform a metastatic survey at 3- to 4-month intervals during the first 2 years postoperatively, at 6-month intervals to the fifth postoperative year and yearly thereafter. This evaluation consists of a history and physical examination, chest x-ray, and measurement of serum liver enzymes, particularly alkaline phosphatase. Optionally, a bone scan can be done to detect early bone metastasis at the second and fifth year. If this is done, it is useful to be able to refer to a baseline bone scan performed before or after surgery, especially for patients with stage II breast cancer, who are at greater risk for developing bone metastasis compared with patients with stage I breast cancer. Educating patients about the signs and symptoms of possible recurrences and instructing them to seek medical consultation if such symptoms appear in the interval between scheduled follow-up visits is also prudent and cost-effective.

REHABILITATION

Rehabilitation for the patient should begin at the time of diagnosis as the outcome of treatment will depend in part on the patient's perception of how her goals have been achieved. For this reason, the surgeon must be a careful listener and incorporate the patient's perspective before arriving at a final decision about a treatment plan. A disfigured but intact breast may be the best "quality of life" for some patients, whereas others achieve greater "peace of mind" with a total mastectomy and a reconstructed breast. Other psychosocial needs that patients may not verbalize but instead rely on the surgeon to anticipate are listed.

Fear of Recurrence

The patient often assumes that changes in the treated breast after surgery, radiation therapy, and chemotherapy may be an indication of a recurrence. This fear can be minimized by explaining and treating side effects as promptly and effectively as possible.

Psychosocial Effects of Mastectomy

The decision whether to use an external prosthesis after mastectomy or to proceed with breast reconstruction is highly individual, depending on women's level of

physical activity, style of clothing, and willingness to reveal the diagnosis of breast cancer to others. In some circumstances, women will drastically alter their lifestyle and refuse to wear bathing suits, evening gowns, or other apparel that might reveal the presence of an external prosthesis and raise questions about the diagnosis of breast cancer. In these circumstances, patients may fear that the diagnosis of breast cancer may change relationships with friends or associates with whom they work or socialize. Some patients will go to extremes to alter their lifestyle in an effort to hide the diagnosis. Alternatively, the use of breast reconstructive surgery may provide the patient more freedom of activity and clothing apparel that enables them to resume the lifestyle and clothing style they enjoyed before the diagnosis of breast cancer. For some women, a mastectomy without reconstruction is not perceived as a disfiguring procedure that adversely affects her life; these patients are perfectly comfortable wearing an external prosthesis and are openly communicative to others about the diagnosis and therapy of their disease.

The patient should be reassured about her fears of resuming exercise or usual activities and encouraged to contact a support group such as Reach to Recovery. This American Cancer Society organization services are free but a patient must be referred by her physician.

Sexuality

Certain myths about cancer still exist that may affect the patient's sexuality. Both women and husbands or partners may feel that caressing of their breasts played a role in the development of this cancer or may lead to a recurrence or interfere with treatment. The patient's partner may also have fears of "catching cancer" or of "becoming radioactive." Involvement of the husband and family in the discussions about the diagnosis, treatment options and side effects, and in participating in the post-treatment care often enhances the ability of the patient's family to adjust to the disease and its treatment.

SUMMARY

(1) A biopsy should be performed on any suspicious palpable lesion, whether or not it is seen on a mammogram.

(2) A biopsy should be performed on any suspicious area seen on a mammogram, but not clinically palpable.

(3) An open biopsy should be performed as a wide excision, and the pathologist should verify that the surgical margins are clear of tumor to avoid a re-excision of more breast tissue if the patient decides to have breast conservation.

(4) For women with early breast cancer, there is no difference in survival rate in early stage breast cancer in women who undergo either standard modified radical mastectomy with or without breast reconstruction or breast conservation surgery with irradiation.

(5) Contraindications to breast conservation approach include multifocal primary tumors, large tumor/breast size ratio, collagen vascular disease, and lack of patient's commitment to undergo irradiation and close follow-up.

(6) Immediate or delayed breast reconstruction does not interfere with subsequent patient management or detection of regional recurrence.

(7) Adjuvant systemic therapy is indicated in patients with node-positive disease and in selected subsets of patients with node-negative histology.

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