

Breast Conservation Surgery

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Abstract : Breast conservation therapy for early-stage invasive breast cancer provides survival equivalence to mastectomy. Careful patient selection and surgical technique are necessary to minimize local recurrence. Studies over the past fifteen years have identified the risk factors for local recurrence. Patients previously thought to be ineligible for breast conservation earlier like locally advanced breast cancer, macromastia, cancer in pregnant women can be managed by modified BCT approaches. Local recurrences should be managed aggressively as long term survival can be frequently achieved.

Keywords: *Breast conservation therapy, Neoadjuvant chemotherapy, breast irradiation, local recurrence.*

Surgical management of breast cancer has undergone extensive transition from over the past century. From Halstedian radical mastectomy to extended radical mastectomy and modified radical mastectomy: surgery for breast cancer has evolved to more conservative approaches over the past century. The National Surgical Adjuvant Breast Cancer Project (NSAB) B-4 study demonstrated that less extensive chest wall surgery was not associated with inferior disease control.

Although breast conservation was proposed as far back as the 1930s¹, insight regarding breast cancer biology and the concept that lumpectomy and breast irradiation could adequately control local extent of disease did not receive widespread acceptance until several decades later, when several Phase III clinical trials were initiated in USA & Europe. Long term result from these trials have been reported, with the consistent demonstration that breast cancer survival in early stage breast cancer regardless of whether they are treated with breast sparing procedure or mastectomy is equal.

Trends in use of breast conservation therapy

Despite the abundance of data on the safety of breast conservation in stage II & I breast cancer it has not gained wide spread acceptance even in the USA. Reported patterns of BCT vary between 10-45%^{2,3}. Indian data for BCT is not easily available and its use is confined to few centers only.

Eligibility and Exclusion criteria for breast conservation therapy

Established criteria for BCT eligibility are predicted on three issues 1) Capability to deliver breast irradiation 2) Achieving a cosmetically acceptable breast 3) Obtaining margin negative lumpectomy. The accepted **guidelines** as per the American College of Radiology and the American College of Surgeon (4) include the following:

- | Multicentric disease (tumors in the separate quadrants of the breast)
- | Diffuse, malignant appearing micro-calcifications on pre-operative mammogram – this usually suggest Extensive Intraductal Carcinoma in Situ (EICS)
- | Prior therapeutic chest irradiation with fields that overlap the proposed breast field.
- | Radiotherapy is contraindicated in pregnancy, because of scatter effect on fetus.
- | Positive margin on lumpectomy and re-excision specimen.
- | History of collagen vascular disease such as scleroderma or lupus erythematosus – these patients may experience excessive radiation toxicity.

- | Tumor size preferably less than 5cm. Preoperative downsizing with chemotherapy may increase breast conservation rates and better cosmesis.

Special considerations in breast conservation surgery

Following additional issues deserve particular attention

- | Impact of family history of breast cancer
- | Impact of tumor histology (Lobular carcinoma & Lobular carcinoma in situ)
- | Definition of what exactly constitutes a pathologically negative margin.
- | Extensive intraductal component.

Family history

There was a concern that genetic predisposition to breast cancer might increase the likelihood of subsequent neoplastic events in the treated breast. Numerous studies have investigated the issue and found no increased risk of local recurrence following BCT in this subgroup of patients⁵.

Approximately 10% of breast cancer patients have mutations in BRACA 1 & BRACA 2 genes. There was a similar belief that these mutations may lead to higher local recurrences and radiation to breast would lead to greater toxicity and increased risk of new primary tumor. Available data though limited, suggest that breast conservation can be done in selected group of patients. But patients should be counseled about the risk of higher ipsilateral new primaries. Also patients with these mutations have a higher incidence of contralateral breast cancer averaging four to five folds than sporadic cancers⁶⁻⁸.

Primary tumor histology

Invasive lobular carcinoma is notorious for its insidious presentation, vague area of thickened breast tissue and lacking any specific finding on mammogram and ultrasound. A substantial amount of microscopic disease may underlie this nonspecific and misleading clinical picture. Not surprisingly, margin control may become a challenging problem under such circumstances. Moreover, lobular carcinoma is associated with higher incidence of caontralateral breast cancer. There is also a higher possibility of breast field effect of diffuse microscopic tumor foci in ipsilateral side.

Margin evaluation

The margin is characterized as the closet microscopic distance between the inked lumpectomy tissue edge and any cancerous

tissue invasive or ductal carcinoma in situ (DCIS). Obtaining a negative margin in the lumpectomy specimen of a breast cancer patient is the basic pre-requisite for standard of care in BCT. The conceptual goal is to resect the area of grossly apparent cancer and control the microscopic occult disease elsewhere in the breast with radiation. Positive margin may be difficult to control in post surgical hypoxic field and it may also represent excessive tumor burden. Numerous studies have shown an increased risk of local recurrence in patients with positive margins. Despite this there is no consistent universally accepted definition for tumor free distance that constitutes a negative margin.

NSAB has defined margin negativity as absence of any cancerous cells at the inked rim of lumpectomy specimen. Variations in the extent of margin negativity probably accounts for variability in BCT related recurrence rates. Several studies have tried to critically evaluate the minimal margin clearance required for adequate tumor control without unnecessary sacrifice of normal tissue. In general, a minimum of 2mm tumor free margin clearance results in reliably low recurrence rates. The number of margin positive foci, presence of EIC positive lesion all influence recurrence rates. *In practice one should aim for a 1cm margin during excision and 2mm margin on microscopic examination.*

Conservative Surgery without Radiation Therapy

An unresolved question is whether RT is necessary in all patients with invasive breast cancer after CS. Six randomized clinical trials with published results have compared CS alone with CS and RT in patients with early-stage breast cancer^{9,10}. These trials vary with regard to patient selection, the details of the surgery and RT, the use of adjuvant systemic therapy, and the length of follow-up. These trials all show a large reduction in the rate of local recurrence after RT, with an average crude rate of reduction of approximately 75% (range, 63% to 89%). None of the six trials shows a significant survival benefit for RT; however, in the trials with published data, the survival rate is slightly better for irradiated patients than for non-irradiated patients. A large trial (or perhaps a metaanalysis of multiple smaller trials) is necessary to detect a small, but clinically significant difference in survival, if it in fact exists.

Attempts have been made to identify a subgroup of patients (based on various clinical and histologic features) that has a low risk of local recurrence after CS alone. It was not possible to identify such a subgroup^{10,11}. *Local recurrence rates are generally lower in trials using more extensive surgery than in those using lumpectomy and in older patients than in younger patients.*

The use of adjuvant systemic therapy substantially reduces the rate of local recurrence in patients treated with CS and RT,¹² but does not seem to reduce greatly the rate of local recurrence after CS alone. There are no published trials directly comparing CS with and without either chemotherapy or tamoxifen. Information on this is available from indirect comparisons within randomized clinical trials for both adjuvant chemotherapy and tamoxifen.

There is particular interest in avoiding RT in older patients. It is often less convenient for such patients to receive RT, and their local recurrence rate appears lower after CS alone compared with younger patients. Results so far indicate that no such category could be identified and breast radiation reduces the risks in all categories of patients¹⁰.

In conclusion, the use of breast irradiation after CS is associated with a large reduction in the rate of local recurrence. The available

data from the randomized trials do not show a survival benefit; however, none of the available trials has the statistical power to eliminate a small survival difference. A subset at low risk of local recurrence following CS has not been clearly identified, and RT is currently considered standard. The addition of adjuvant systemic therapy to CS alone has not been demonstrated to decrease local recurrence. In elderly patients, particularly those with significant comorbidity, RT is commonly omitted because of the practical difficulties of delivering such therapy in this group of patients.

BCT & Neoadjuvant chemotherapy

Preoperative chemotherapy has become a standard of care for locally advanced breast cancer patients. It results in primary response rates of approximately 80% and disease progression in 2-3 %¹³⁻¹⁵. The sequence allows improved operability and in vivo assessment of chemosensitivity. Concerns that downsized tumors might leave a field of satellite nodules rather than shrink concentrically, however, lead to resistance regarding BCT in these patients.

The benefits of induction chemotherapy have led to its application in early stage disease. Several randomized control trials have proved its efficacy and shown its efficacy in improving eligibility for BCT without increasing local recurrence rates. Clinical assessment of response tends to overestimate the pathological response by approximately threefold. *Resecting the site of the original tumor is therefore mandatory in obtaining accurate chemo sensitivity information and optimal marginal control. Local recurrence rates are higher when radiotherapy replaces surgery in patients with complete response¹³.*

The NSAB 18 randomized 1500 women with stage I-III breast cancer to receive preoperative vs. postoperative chemotherapy. The trial showed statistically significant higher breast conservation rates in patients receiving preoperative chemotherapy with equal local recurrence rates. However subset analysis showed that local recurrence rates were higher in patients who were down staged to become eligible for BCT than those who were eligible for BCT at presentation. This could be explained by various factors such as predominantly T3 tumors, inconsistent use of radiation boost, use of tamoxifen only in patients over 50 years & the criteria of absence of tumor cells for margin negativity. A more aggressive approach for margin control might be necessary for lumpectomies down staged by chemotherapy. Newman et al¹⁵ from MD Anderson also showed higher conversion to BCT by the use of preoperative chemotherapy. However on histopathological examination of the mastectomy specimen revealed clinical assessments of BCT eligibility following induction chemotherapy was inaccurate in patients with invasive lobular carcinoma, multicentric disease and diffuse micro calcifications.

Patients should be monitored very closely to assess the response to treatment. Base line USG and Mammography along with clinical monitoring should be done to assess the tumor size after completion of all preoperative chemotherapy cycles. Those showing dramatic response should have an image guided clip placement to guide the location of tumor in case of complete response. Mammograms may uncover diffuse calcifications masked by tumor size.

Induction chemotherapy is therefore a reasonable and safe treatment provided the clinician is certain that patient will require postoperative chemotherapy. Maximizing the benefits of neoadjuvant chemotherapy requires a truly multidisciplinary

approach between the surgeon, radiotherapist, medical oncologist, pathologist & radiologist.

Macromastia

Patients with heavy breast present particular challenge to radiation oncologist. The larger breast requires larger dose, dose inhomogeneity causes skin toxicity and very ptotic is difficult for proper fixation & positioning. Bilateral reduction mammoplasty and tumor directed segmental resection overcomes many of these problems.

Bilateral breast cancer

Heaton et al [16] have demonstrated the safety of BCT in synchronous or metachronous bilateral breast cancer patients. They emphasized the importance of avoiding overlapping radiation fields.

Inadequate breast- to-tumor size ratio

Traditionally breast reconstruction has been recommended for patients with small breast. Few studies have shown the feasibility of plastic procedures using local rotational flaps or mammoplasties to remodel the lumpectomy defect.

Central subareolar tumors and Paget's disease

Previously these were considered a relative contraindication for BCT. If the disease is unifocal and there is no diffuse micro calcification on mammography a central segmental resection can be done with delayed nipple areola reconstruction after completion of radiation [16].

Local recurrence

Local recurrence deserves special mention. Many patients will experience prolonged survival and should be detected early and treated appropriately.

Biological significance

Local recurrence is an independent marker of underlying tumor biology. Those patients whose tumor outgrows margin negative lumpectomy and breast irradiation do tend to have more aggressive disease. Fischer et al showed this in Cox regression outcome analysis of NSAB – 06 study. Patients were 3.41 times more likely to develop subsequent distant metastases than those without local recurrence. Because overall survival is equivalent between BCT and mastectomy patients, it can be reasonably inferred that local recurrence is a risk factor for distant metastases but it does not cause them.

Risk Factors

The concept of local recurrence as a marker of tumor biology does not justify inadequate surgery or poor patient selection. Untreated residual disease left in the breast places the patient at risk for uncontrolled systemic spread. Every attempt should be made to avoid local recurrence due to inadequate surgery. A clear understanding of the risk factors associated with higher recurrences is warranted.

As discussed young age, margin involvement, EIC and omission of postoperative have all been documented to be associated with higher incidence of local recurrence in multiple studies. This may warrant additional surgeries in future. In deciding between BCT and lumpectomy all these factors must be considered and the final decision left to the patient.

Adjuvant systemic therapy both in the form of chemotherapy or hormonal therapy can suppress local recurrences in BCT patients¹⁷. Less well documented risk factors for local recurrence include estrogen receptor negativity, lymphovascular invasion, micro calcification on preoperative mammogram. But none of these weaker risks should be considered a contraindication to BCT as long margin negativity can be insured. Delay of more than 7 weeks in starting breast radiation increased local recurrence rates. Similarly, it was found that when radiation was delivered first the local recurrence rates though were lower the distant metastases rates were higher. As distant failure has a greater impact on long-term survival the conventionally accepted practice is to give chemotherapy first. Concomitant chemo radiation increases the chances of treatment related toxicity.

Management and outcome

Because of the association between local and distant recurrence, it is reasonable to conduct a metastatic work up in patients presenting with local recurrences. Majority will be isolated recurrences. Almost half of recurrences occur at or near the primary tumor site at a median time interval of 3 – 5 years from the time of surgery. Remote site of recurrences develop after a more prolonged time and represent new primaries^{18,19}. A minority present as diffuse inflammatory patterns of recurrence.

Standard management for patients with a local recurrence will be a salvage mastectomy and an immediate reconstruction may be offered. Risk factors for distant metastases following a local recurrence include a short interval to detection of local recurrence, nodal status and extent of recurrence. Overall five-year survival following treatment for local recurrence ranges from 50% to 80% and disease free survival averages 50 – 60%²⁰⁻²⁵.

Technique and Complications of Breast-Conserving Surgery

The goal of breast-conserving surgery is to minimize the risk of local recurrence while leaving the patient with a cosmetically acceptable breast. The surgical technique of *lumpectomy* differs from that used for mastectomy in that lumpectomy is not an en bloc cancer operation. *Quadrantectomy* is another type of breast-conserving surgery that is designed to remove an anatomic segment of breast tissue and frequently includes removal of the overlying skin and underlying pectoral fascia. Because excision of a large amount of breast tissue is the major factor responsible for a poor cosmetic outcome after BCT, lumpectomy is considered the appropriate initial surgical approach in many centers.

Other surgical factors that influence the cosmetic appearance are the size and placement of the incision, the management of the lumpectomy cavity, and the extent of axillary dissection. A number of technical aspects of lumpectomy are worth emphasizing. In general, the incision should be placed directly over the area of the tumor. This is true even when a biopsy is performed for a mammographically detected lesion. In the upper part of the breast, incisions should be curvilinear or transverse and follow the natural skin creases (Langer's lines) of the breast. In the lower part of the breast, the choice of a curvilinear or radial incision depends on the contour of the patient's breast, the distance from the skin to the tumor, and the amount of breast tissue to be resected. It is not necessary to remove skin (except for superficial tumors) or to remove needle tracks from core-needle biopsies or FNAC. Preservation of the subcutaneous fat and the avoidance

of thin skin flaps are also important in maintaining normal breast contour. Raising flaps is necessary only to allow access to the tumor. Meticulous hemostasis is important because a large hematoma distorts the appearance of the breast and makes reexcision and follow-up evaluation more difficult. The presence of a post biopsy hematoma, however, is not a contraindication to BCT. It is best to avoid reapproximation of the breast tissue since this can result in distortion of the breast contour, which may not be apparent with the patient supine on the operating table. The best cosmetic results usually are obtained by allowing the lumpectomy cavity to fill in with serum and fibrin. Drainage of the lumpectomy cavity should be avoided. Finally, the incision should be closed with a subcuticular suture to avoid cross-hatching of the skin.

A critical step in lumpectomy is the evaluation of the completeness of excision of the tumor. To allow adequate histologic evaluation, the specimen should be removed as a single piece of tissue and should not be transected unless the pathologist is present. The use of marking sutures to orient the specimen for the pathologist allows reporting of the status of individual margins. Gross inspection of the specimen in the operating room allows identification of positive or close margins, facilitating immediate reexcision. Frozen-section histologic study is sometimes useful to evaluate grossly suspicious areas, but the routine use of frozen sections to evaluate grossly normal margins is of doubtful value. The ideal amount of grossly normal breast tissue around the tumor that should be resected has already been discussed earlier. A resection of 0.5 to 1.0 cm of grossly normal breast tissue results in histologically negative margins in a large percentage of patients. Larger resections may be necessary for invasive ductal carcinomas with an extensive intraductal component and for infiltrating lobular carcinomas. Thin pieces of tissue can be shaved off each wall of the biopsy cavity and sent as separate specimens, with the new margin surface marked for the pathologist. Metal clips can be left at the edge of the cavity for subsequent radiotherapy planning. When axillary dissection is performed as part of breast-conserving surgery, a separate incision should be used, except in patients with tumors high in the tail of the breast. A curvilinear incision at the edge of the hair-bearing axillary skin provides the best cosmetic result. The incision should not extend anterior to the fold of the pectoralis major or posterior to the latissimus dorsi.

The primary indications for a reexcision are positive or unknown histologic margins of resection on the initial excision. Several studies have demonstrated residual carcinoma in approximately one-half of cases when reexcision is performed for positive or unknown margins^{25,26}.

No consensus exists on the best technique for reexcision. When reexcision is done within 1 to 2 weeks of the biopsy, it is not usually possible to re-excise an entire biopsy cavity as a single specimen without sacrificing large amounts of breast tissue. One technique of reexcision in most cases is to re-excise each of the walls of the biopsy cavity separately. If the initial specimen is marked with orienting sutures, reexcision can be limited to the involved margins. When longer intervals have elapsed between the biopsy and the time of reexcision, contraction of the biopsy cavity may allow excision of the entire cavity as a single specimen without sacrificing excessive amounts of breast tissue. The status of the final margin should be used to determine the patient's suitability for BCT.

There are relatively few complications of breast-conserving surgery. Wound infection is infrequent, although rates of infection may be increased when reexcision is performed. The late occurrence of breast abscess after BCT has been reported. The median time to abscess development was 5 months (range, 1.5 to 8.0 months). The only factor found to correlate with abscess formation was larger size of the lumpectomy specimen. Cellulitis of the breast occurring at a median of 4 months after BCT also has been reported in approximately 3% of cases²⁷.

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Fig.1: The lump marked along with the margins of resection [T1N0M0]

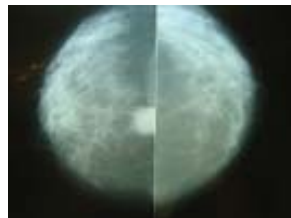


Fig.1a: Mammographic findings of the lump



Fig.4: The specimen with axillary lymph nodes



Fig.5: The specimen



Fig.2: After Lumpectomy

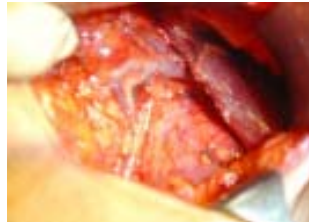


Fig.3: Axillary dissection in progress, axillary vein may be seen



Fig.6: The incisions closed



Fig.7: After two years

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