At Tata Memorial Hospital, as a dedicated breast service at a tertiary cancer center in India, incompletely performed breast surgeries are encountered very frequently; however, there is a lack of published data on incompletely performed breast surgeries, revision surgeries, and their outcomes. Between March 2000 and November 2003, the authors audited 850 breast cancer patients who presented at their institute who had undergone surgery outside the institution. On the basis of study criteria, these patients were evaluated for completeness of surgery. Patients in whom the surgical intervention was considered incomplete were evaluated for a completion revision surgery. Of 850 patients, 424 (50%) had undergone surgical intervention with therapeutic intent. Of these 424 patients, 191 (45%) had received incomplete surgical intervention. Completion revision surgery was performed for 153 patients. Complete data were available for 148 patients, of which 123 patients had residual lymph nodes in the axilla. The median number of lymph nodes dissected was 8, and 64 patients had metastatic lymph node(s) left behind. A high proportion of patients with breast cancer who presented at the institute had undergone incomplete surgery outside in nonspecialty centers. Almost half of those patients who underwent incomplete surgery had surgically excisable disease left behind. The possible detrimental impact of inadequate surgical intervention may be very large in India and in other low-resource settings.

KEYWORDS: breast cancer, revision surgery, axillary dissection, axillary levels, quality assurance, surgical training.

Not only does one-sixth of the world’s population reside in India, but, in many ways, India is the face of the developing world. Breast cancer incidence is increasing in India, and the lifetime risk of breast cancer for women from metropolitan cities currently is almost 1 in 30.1 With rising incidence associated with rapid urbanization,2 the time has come to give due respect to this disease and devise appropriate public health strategies. Although the US has a 2.5 times higher incidence rate of breast cancer compared with India, breast cancer kills more women annually in India than in the US.3 The most commonly cited reasons for such high mortality are late presentation and poor availability and/or nonaffordability of adjuvant treatments. In India, surgery is the most curative treatment option for breast cancer. However, there have not been any systematic efforts to evaluate the role of inadequate surgical treatment in terms of higher mortality rates.
Surgery for breast cancer has evolved over the past century from Halsted's radical mastectomy to breast-conservation surgery (BCS) with a period of extended radical mastectomy common during the 1960s. Currently, modified radical mastectomy (MRM) or BCS is the standard of care for surgical treatment of breast cancer. These surgeries essentially have 2 components: optimum excision of the tumor or breast tissue and optimum treatment of the axilla. In mastectomy, optimum excision of breast means complete removal of breast tissue along with pectoral fascia. Thin skin flaps are raised through a subcutaneous plane, and 95% of all breast tissue is excised superiorly up to the clavicle, medially up to the sternum, inferiorly up to lower costal cartilages, and laterally in continuity with the axilla, with the latissimus dorsi muscle as the lateral boundary. In BCS, wide excision of the lump is performed, including surrounding normal breast tissue, to achieve pathologically tumor-free margins. Both types of surgeries also incorporate appropriate axillary treatment. Although the extent of axillary dissection is a widely debated issue, sentinel lymph node biopsy (SNB) is indicated only in small tumors with clinically nonpalpable lymph nodes. A complete axillary dissection means dissection of all 3 levels of the axilla; both European and American guidelines recommend complete axillary dissection if gross lymph node involvement is suspected clinically.

Leaving behind breast tissue or thick skin flaps in a mastectomy increases the chance of local recurrence, whereas leaving metastatic lymph nodes behind in the axilla may increase the chance of regional recurrence; hence, the importance of optimum surgery cannot be overemphasized. We very frequently encounter incompletely performed breast surgeries, eg, mastectomy with a significant amount of residual breast tissue, or untouched axilla, or both. Published literature lacks data on such incompletely performed surgeries or on revision surgeries undertaken to correct these incomplete surgeries and the outcomes of those revision procedures. To study revision surgeries performed at our institute, we audited patients with breast cancer who presented to our institute with incomplete surgical treatment received elsewhere.

**MATERIALS AND METHODS**

**Study Period and Settings**

This study was conducted between March 2000 and November 2003 at Tata Memorial Hospital, which is a major tertiary cancer center in India. In the absence of a standard referral system, the majority of patients who present to our institute are self-referrals after the diagnosis of cancer. All new patients with breast cancer who present to the Breast Service at Tata Memorial Hospital are evaluated in a multidisciplinary joint clinic that is attended by breast surgeons, medical oncologists, radiation oncologists, and radiologists. Written informed consent was obtained from all patients who were included in this study. The majority of patients who undergo surgical treatment at our institute undergo complete axillary dissection in accordance with international recommendations. Our audits indicate that, among our patients, the median tumor size was 3.5 cm, 80% of patients had clinically palpable lymph nodes, 15% of patients showed involved level III lymph nodes on histopathological evaluation, only 1% of tumors were grade 1, and 18% of tumors were grade 2.

**Completeness of Surgery Criteria**

Because no precedent could be found in the literature for this type of study, the criteria for assessing completeness of prior surgical intervention was determined by the study authors and included both objective and subjective criteria based on scientific rationale and evidence wherever available. We evaluated all patients who registered at our institute and had surgery elsewhere (<3-month duration between outside surgery and registration) for the completeness of previous outside surgery based on following criteria:

- The surgical record (if available),
- The amount of residual breast tissue/thickness of the flaps,
- The proximity of margins in previous surgery (according to the histopathology report),
- Fullness in the axilla by palpation, and
- Less than 8 lymph nodes dissected according to the histopathology report (only if any lymph node showed evidence of metastasis or if the primary tumor was classified as T3/T4).

If outside surgical records and pathology reports did not contain all requisite information or if any of these reports were unavailable, which were common occurrences, then a decision was made based on the clinical evidence. Primary clinical staging, pathologic staging, and data on prognostic markers, such as estrogen receptor, were not available for many patients.

**Clinical Assessment**

The amount of residual breast tissue, the thickness of flaps, and the fullness in axilla were judged...
subjectively by experienced clinicians. Flaps were considered thick if there was drooping of flaps viewed in profile in the sitting position.

Rationale for Completeness of Surgery Evaluation Criteria
The median number of lymph nodes dissected from axillary level I and II in randomized trials is between 7\textsuperscript{17} and 11.\textsuperscript{18} The definition of adequate axillary staging is a minimum of 6 lymph nodes dissected according to the International Union Against Cancer TNM classification system\textsuperscript{19} or 10 lymph nodes dissected according to the European Society of Mastology consensus statement.\textsuperscript{14} Hence, in patients who had metastasis in at least 1 lymph node or who had T3/T4 primary tumors, we considered previous surgery inadequate if <8 lymph nodes had been dissected. The exception was a subgroup of T1/T2 tumors if there was a minimum of 4 pathologically negative nodes without any of them being positive; this was considered an adequate staging procedure. This criterion was based on the high (99%) negative predictive value of axillary sampling.\textsuperscript{20}

Criteria for Deciding on Revision Surgery
The decision whether to perform revision surgery was based on the extent of previous surgery and the requirement of local and systemic adjuvant therapy. For example, patients with residual breast tissue who otherwise would require adjuvant radiotherapy were not offered revision surgery if axillary levels I and II appeared to have been addressed satisfactorily. In such patients, axillary level III was included in the field of radiotherapy. Similarly, patients with small tumors, adequate breast tissue excision, and all negative axillary lymph nodes (at least 4 to indicate adequate sampling) did not undergo revision surgery. All other patients who had undergone either incomplete breast surgery or incomplete axillary dissection underwent a revision surgery (Fig. 1). Surgical and histopathology reports were maintained for all patients.

Statistical Analysis
All data were analyzed using SPSS 11.0 statistical software (SPSS Inc. Chicago, Ill). Frequencies of the number of nodes dissected and the number of nodes positive at revision surgery were calculated. Chi-square tests were used for parametric comparison of proportions. All $P$ values reported are 2-sided.

RESULTS
During the study period, 3951 new patients with nonmetastatic breast cancer registered at our institute. Of these, 850 patients (21.5%) had undergone some form of surgical intervention outside (Table 1). Nearly half of those surgeries ($N = 424$) performed outside our institution were with the intention of definitive surgical treatment in the form of MRM. In these 424 patients who had undergone MRM outside, the removal of breast tissue was deemed incomplete in 46 patients (11%), and axillary dissection was deemed incomplete in 98 patients (23%).

<table>
<thead>
<tr>
<th>Type of Outside Surgery</th>
<th>No. of Patients</th>
<th>Type of Surgery, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast-conserving surgery</td>
<td>36</td>
<td>4.3</td>
</tr>
<tr>
<td>MRM</td>
<td>424</td>
<td>49.9</td>
</tr>
<tr>
<td>Mastectomy (other types)</td>
<td>91</td>
<td>10.7</td>
</tr>
<tr>
<td>Wide excision only</td>
<td>237</td>
<td>27.9</td>
</tr>
<tr>
<td>Others</td>
<td>62</td>
<td>7.3</td>
</tr>
<tr>
<td>Total</td>
<td>850</td>
<td>100</td>
</tr>
</tbody>
</table>

MRM indicates modified radical mastectomy.

FIGURE 1. Study profile. BCS indicates breast-conservation surgery; MRM, modified radical mastectomy.

TABLE 1
Types and Percentages of Surgeries Performed Outside
patients (11%) had both incomplete breast tissue excision and incomplete axillary lymph node dissection. Overall, previous surgical treatment was identified as incomplete in 191 patients (45%). One hundred fifty-three of these 191 patients underwent revision mastectomy accounted for 4.2% of the operative workload. Forty-two of the 148 patients who had data available were candidates for chemotherapy before revision surgery, which also allowed time for inflammation and induration from the previous surgery to settle down before undertaking revision surgery. Twenty-two of 148 patients underwent revision surgery for the incomplete removal of breast tissue, whereas the remaining 126 patients underwent revision surgery either for incomplete axillary dissection alone or for both incomplete removal of breast tissue and incomplete axillary dissection.

The most common operative findings were post-surgical fibrosis and induration at the lower part of level I, occasionally extending up to the medial pectoral pedicle. There were no operative complications, such as injury to the axillary vein requiring repair, injury to nerves, or injury to the latissimus dorsi pedicle; postoperative complications were not documented.

There were 22 patients who underwent revision mastectomy primarily for the incomplete removal of breast tissue. Although the specimens obtained during revision surgery indicated incomplete breast tissue excision, they did not show residual primary tumor.

Residual lymph nodes in the axilla were identified in 123 of 148 patients (83%). The median number of lymph nodes dissected was 8 (mean, 8.49 dissected lymph nodes; range 0-33 dissected lymph nodes), and the median number of positive nodes was 1 (mean, 2.53 positive lymph nodes; range, 0-25 positive lymph nodes). Sixty-four of 123 patients (53%) had at least 1 metastatic lymph node excised in the revision surgery. Of the 25 patients who had no residual lymph nodes, 3 patients (12%) underwent revision surgery with the presumption of incomplete axillary dissection (the specificity of clinical examination for assessment of the residual axillary basin was 88%), and remaining 22 patients underwent revision surgery for the incomplete removal of breast tissue.

In the 42 patients who received chemotherapy before revision surgery, the median number of positive lymph nodes was 2 (mean, 3.69 positive lymph nodes; range, 0-25 positive lymph nodes). However, the number of positive lymph nodes did not differ significantly in this prerevision surgery chemotherapy group compared with the no prerevision surgery chemotherapy group (chi-square test, 1.127; \( P = .288 \); not significant). The higher rate of positive lymph nodes observed in the chemotherapy group was nonsignificant and may have been caused by chance.

Thirty-six patients in the study group had undergone BCS, all in specialty centers. All of those 36 surgeries were judged adequate according to our criteria.

DISCUSSION

Before discussing our study, it is important to shed light on the current status of breast surgery training in India. Breast surgery as a subspecialty does not exist in India. The majority of breast surgeries are done by general surgeons. Currently, general surgeons learn breast surgery during their 3-year residency program after they have completed medical school. However, there are wide interinstitutional variations in the case load, and there is no set minimum number of procedures to be performed or to be assisted by a candidate before he or she is awarded a surgical degree. Very few surgeons (approximately 15-20 every year) pursue the additional 3 years of surgical oncology training, during which they receive some breast surgery training.

During the study period, 21.5% of patients who presented at our institute had previous surgical intervention outside; half of those interventions were performed with therapeutic intent in nonspecialty centers. Of those surgical interventions, 45% were considered suboptimal. The median number of axillary lymph nodes left behind in these unfortunate patients was 8; and greater than half of these patients had at least 1 metastatic lymph node left behind. This means that nearly 20% of the patients with breast cancer who presented to our institute and who had undergone a therapeutic surgical intervention performed in nonspecialty centers had surgically excisable disease left behind.

Although this is a single-institution experience, the overall situation in India is not likely to be very different. India has very few specialty cancer treatment centers for its vast population. In the absence of official figures, it is our estimate that from 80% to 90% patients undergo primary cancer treatment at nonspecialty centers, especially for superficial cancers such as breast cancer.
Surgery is the most curative of all the treatments for solid tumors, and incomplete surgical treatment is bound to worsen survival. A large meta-analysis that involved 3000 patients and compared axillary dissection versus no axillary dissection reported a 5.4% absolute detriment in survival in the no axillary dissection group. These survival figures are from studies that enrolled patients with clinically negative axilla; leaving behind lymph nodes when they are palpable may lead to a much larger detriment in long-term outcomes. Although we are working very hard today to improve survival in cancer patients by just a few percentage points by experimenting with various expensive drugs, we cannot afford to overlook the quality of surgical treatment we are offering to our patients. Our findings pertaining to suboptimal surgeries and excisable disease left behind are startling from this point of view.

Incomplete axillary dissection is the most common component of these incomplete surgeries. Today, it may seem reasonable to argue against axillary dissection when looking at the number of SNB procedures performed in the West. However, that argument does not necessarily hold true for the developing world. SNB is recommended only for localized (clinically lymph node-negative) breast cancers, a very common situation in western countries. Conversely, patients in developing countries typically present late with involved axillary lymph nodes; only 20% patients have clinically negative lymph nodes, whereas <10% have clinically negative lymph nodes and small (T1/T2) tumors (unpublished Tata Memorial Hospital data; N = 1109 patients). Forty percent of clinically lymph node-negative patients have lymph node metastases on histopathologic evaluation. Because the majority of patients in the developing world are not suitable candidates for SNB, and because SNB facilities are almost nonexistent, it is recommended that patients who are treated at limited resource facilities should undergo standard axillary lymph node dissection.

We have observed that, in incomplete surgeries, it is most common to leave Berg axillary levels II and III undissected. The incidence of metastasis to level III is 40% in patients who have >4 positive lymph nodes in levels I and II (unpublished Tata Memorial Hospital data; N = 1519 patients), which is a common situation in Indian patients. Second, level III recurrences are difficult to salvage surgically. For these reasons, complete axillary dissection that includes level III at the first clinical suspicion of lymph node involvement seems to be an appropriate strategy for the developing world. All surgeons who treat patients with breast cancer in the developing world must be trained to perform complete axillary dissection competently.

One drawback of our study is that some of the criteria for surgical completeness were subjective clinical decisions. However, reliable objective methods for the assessment of criteria such as flap thickness or the amount of residual axilla are lacking. The decision to perform revision surgery was made by an experienced multidisciplinary team. It has been reported in other studies that a second opinion suggests a change in clinical decisions in 32% to 52% of patients, and our assessment could be a reflection of this second-opinion effect. Revised decisions in these studies were suggested by multidisciplinary teams such as ours, and studies have demonstrated that patients who are treated by multidisciplinary teams have superior survival because of better treatment. However, it should be noted that the settings of these other studies were very different from our setting.

We also did not document the number of patients in whom adjuvant treatment decision changed after revision surgery (complete surgical staging). Such information would have helped further in ascertaining the rate of incomplete adjuvant treatment received because of suboptimal surgical staging. Survival data from our study are not yet mature; however, these data will not be very meaningful in view of the absence of a control group (even historic) and the incompleteness of primary staging data.

According to current international standards, a woman aged 60 years with a 2-cm hormone receptor-negative tumor and uninvolved lymph nodes is given chemotherapy for an anticipated 2% absolute improvement in survival. Leaving behind excisable disease in 20% of our patients, thus compromising their survival, seems unjustified.

In the absence of controlled clinical trials, we believe that our findings reflect the general situation in India and call for urgent implementation of standardized training program for breast surgery, quality-assurance measures in surgical practice, and standardization of procedures performed in all settings. In addition, the role of audits in all surgical centers cannot be overemphasized. The magnitude of lives saved by adequate/optimum surgery in developing countries could be as big as that achieved with the use of adjuvant therapies in the developing world.

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