

Quality of Breast Cancer Diagnosis and Treatment: Audit and Outcome Analysis in North Eastern Cancer Centre of India

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ABSTRACT

BACKGROUND

Quality assurance aims to improve patient outcomes, patient experience and treatment cost. A key factor reflecting the quality of care in the management of patients is the timeliness. This study assesses the quality of breast cancer diagnosis and treatment according to quality indices and also evaluates timeliness of treatment in breast cancer cases at our institute.

METHODS

Breast cancer patients registered in State Cancer Institute in the year 2018 were evaluated. A cohort of 205 patients met our inclusion criteria, which was followed up for one year.

RESULTS

95.12% patients were operated after proper record of histopathology, grade, stage, ER and PR status. 98% had positive cyto/histological diagnosis before surgery. 37.2% patients of invasive ca \leq 3 cms underwent breast conserving surgery. Average time taken for start of treatment after first visit is 42.23 ± 8.6 days. During one year follow up, 5 patients expired whereas 11 developed metastasis/local recurrence.

CONCLUSIONS

In the treatment outcomes, our institute met with nearly all the quality indices of international standards except breast conserving surgery rates. There is wide scope of improvement in expediting start of treatment.

KEYWORDS

Quality Analysis, Audit, EUSOMA

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BACKGROUND

Breast cancer has a fairly well-established treatment pathway, and is an ideal case for quality improvement studies. Quality assurance is a newer field of study in healthcare management that aims to improve patient outcomes, patient experience and treatment cost.¹ The European Society of Breast Cancer Specialists– EUSOMA has selected basic indicators that clearly defined quality parameters, continuous internal audit to optimize adherence to evidence based guidelines and treatment results.^{1,2} Another key factor reflecting the quality of care in the management of patients with breast cancer is the timeliness.³ This study assesses the quality of breast cancer diagnosis and treatment at our Institute according to EUSOMA Quality Indices and also evaluates the timeliness of treatment in breast cancer cases at our Institute.

METHODS

A total of 340 breast cancer patients registered in 2018 at State Cancer Institute (SCI), Guwahati. A cohort of 205 patients met our inclusion criteria, which were followed up for one year.

Exclusion Criteria

- Patients who were operated outside.
- Patients who received neoadjuvant chemotherapy outside.
- Patients with benign breast lump.
- Patients who were lost to follow after initial work up.

The usual workup for these patients included a complete blood haematocrit, biochemistry, bilateral mammography along with breast ultrasonography in selected cases. In locally advanced breast cancers (LABCs), a metastatic workup included a chest x-ray, ultrasonography of the abdomen and pelvis or computed tomography scan of the thorax/abdomen/pelvis in selected cases and bone scan. All the cases are discussed in multidisciplinary tumour board meeting before initiation of treatment. Women with early breast cancer (EBC) were offered breast-conserving surgery (BCS) in the absence of known contraindications, i.e., inability to take radiation therapy, extensive micro-calcifications or multicentric disease, persistent positive margins, and inflammatory breast cancer.

If the patient presented with locally advanced cancer or large operable breast cancer or the breast tumour ratio was inadequate for conservation, neoadjuvant chemotherapy (NACT) was offered to downsize the tumour and reviewed for feasibility of post chemotherapy breast conservation surgery. Some cases were considered for conserving surgery with a pedicled latissimus dorsi flap for partial volume replacement. Those who were not eligible for conservation or did not chose it were offered a modified radical mastectomy (MRM). All patients who were operated for breast cancer underwent level III axillary clearance. Among

patients who underwent upfront surgery, those with lymph node-positive disease received adjuvant chemo, anthracycline-taxane-based regimen. Premenopausal women with hormone receptor (HR)- positive disease received 5 years of adjuvant tamoxifen, while postmenopausal women were given 5 years of an aromatase inhibitor. Her2 Neu positive patients received trastuzumab in neoadjuvant and adjuvant treatment.

All women undergoing breast conservation surgery were advised 5 weeks of adjuvant radiation to the involved breast. Postmastectomy women with T1-2N0-1 stage were not offered adjuvant radiation. Women presenting with LABC were given adjuvant radiation to the chest wall. All women with four or more positive axillary lymph nodes and those receiving NACT for LABC (irrespective of number of positive nodes) received adjuvant radiation to the chest wall or breast and supraclavicular fossa.

Patient follow-up was updated through electronic medical record and by retrieving patient files from the medical record section.

RESULTS

Indicators	Eligible Cases	Result		Min. Required (%)
		(N)	(%)	
Positive preoperative cyto/histological diagnosis	205	200	98%	80%
Operated invasive carcinoma for which histological type, grading, ER/PR status, stage recorded	205	195	95.12%	90%
More than 9 lymph nodes removed in axillary node dissection	205	165	80.48%	85%
Post-op RT in non-metastatic carcinoma treated with BCS	16	15	93.75%	90%
BCS in invasive Ca with total size up to 30mm	43	16	37.20%	70%
Hormonotherapy in endocrine sensitive invasive carcinoma	98	72	73.46%	80%
Adjuvant chemotherapy in ER negative (pT1c+ or N+) invasive carcinoma	98	76	77.55%	80%
Preoperative staging tests missing	121	5	4.12%	
Clear margins at surgery margins >1 mm after surgery	205	192	93.65%	

Table 1. Evolution of Quality Indicators as Formulated by EUSOMA (The European Society of Breast Cancer Specialists)

	Eligible Cases	Result	%
Early breast cancer	205	84	40.97
Locally advanced breast cancer	205	121	59.02
Defaulted *	205	27	13.17
Metastasis/Recurrence	205	11	5.36
Expired	205	5	2.43
Lost to follow up **	205	10	4.86

Table 2. Demographic Factors

* Left treatment midway,
** Didn't come for review ≥6 months

First visit to multidisciplinary meeting	33.02 ± 9.8
First visit to treatment initiation	42.23 ± 8.6

Table 3. Treatment Time (in days)

Outcome Measure	Eligible Cases	Result	%
waiting time for treatment initiation from first visit ≤30 days	205	74	36.09
waiting time for treatment initiation from first visit ≤42 days	205	59	28.78
waiting time for treatment initiation from first visit ≤60 days	205	44	21.46
waiting time for treatment initiation from first visit ≤90 days	205	28	13.65

Table 4. Treatment Time (in Days)

95.12% patients were operated after proper record of histopathology, grade, stage and ER, PR status. 98% had positive cyto/histological diagnosis before surgery. 80.48% had more than 9 lymph nodes removed and 93.75% received radiotherapy after BCS. 37.2% patients of invasive ca ≤ 3 cms underwent breast conserving surgery. 73.46% patients received hormonal therapy and 77.55% received chemotherapy. 93.6% patients had clear margins in their first surgery. (Table 1). Average time taken for start of treatment after first visit is 42.23 ± 8.6 days and 36% patients get their treatment started within 30 days of first coming to hospital. In demographic factors, majority of patients (59.02%) were locally advanced. During one year follow up 5 patients expired whereas 11 developed metastasis and or local recurrence.

DISCUSSION

Current practices are governed by standard guidelines and defined outcomes. State Cancer Institute, Guwahati Medical College gets referral patients from entire North East India. Institute is committed to provide high standard and time bound treatment to its patients. This study attempted to analyse breast cancer treatment as an example of a process, which could be improved.

Quality Indices (EUSOMA)

The European Society of Breast Cancer Specialists - EUSOMA - has started a voluntary certification process to assess the clinical performance in dedicated European units² (Perry et al., 2008; Greco et al., 2006; Del Turco et al., 2010). So far, many breast units in Europe have been recognized to comply with the requirements requested by EUSOMA and other European Union guidelines on the basis of information collected by a questionnaire and by a site visit carried out by an independent team of breast cancer experts. A set of QIs was defined by experts from different disciplines based on a literature review. EUSOMA has selected 10 basic indicators to be used for certification purposes.² These clearly defined quality parameters, continuous internal audit and external social control by means of a site visit are of paramount importance to optimize adherence to evidence-based guidelines and treatment results.

Of the several components of interest, the one from the patient's point of view is effective care, curative or palliative. At the next level are indices that reflect patient satisfaction. Timeliness of care is increasingly being referred to as a key quality indicator. Studies have also demonstrated that timeliness significantly impacts treatment outcomes as well. And above all in any quality initiative, timeliness is the easiest parameter to measure. The early cases accounted for 40.97%, and number of LABC cases were 59.02%. This figure is in accordance with other studies conducted inside India,⁴ however in Western Countries LABC cases are much lesser.

In this audit, 37.2% of the patients (for tumour size ≤ 3 cm) underwent BCS, which is way lesser than the benchmark set by EUSOMA. Very low rates for BCS have been reported in India from most centers,⁴ and reasons are mainly due to unacceptability of safety of conservative surgery by physicians and thereafter the patients. Other reasons are patient's inability to stay in hospital for radiotherapy and compliance issues.^{5,6} A report from Mayo Clinic Rochester documented that mastectomy rates have increased in recent years due to prevalent use of MRI breast for preoperative workup,⁷ we however do not use MRI for pre-BCS evaluation, except for highly selected cases.

Patients who were started on hormonal therapy were 73.46% as against 80%. It was observed, there were many defaulters in this group which led to such a discrepancy. State Cancer Institute performed very well in all other indicators formulated by EUSOMA. A Taiwanese study shows that when breast cancer patients are diagnosed and treated in complete accordance with widely accepted standards of care, they survive longer and have better outcomes (Cheng et al., 2009).⁸ This prospective study followed 1378 newly diagnosed breast cancer patients from 1995-2001 in a single cancer hospital, tracking 10 indicators of care quality and assessing the progression of disease up to June 2007. Adherence to all 10 QIS by 100% of patients was associated with better overall (HR 0.46, 95% confidence interval 0.33-0.63) and progression-free survival (HR 0.51; 95% confidence interval: 0.39-0.67). Adherence to either the four treatment indicators, or the six diagnostic indicators by 100% of patients was also associated with a significant improvement of survival.⁸

Timeliness, Delay and Causes

The waiting time from screening to surgery/ chemo embraces much of the entire process of care (time from first assessment to biopsy and metastatic work up, time from first assessment to result, time from result of assessment to first surgery/chemo). Even though 30 to 40 days of treatment delay are not expected to affect clinical outcomes,⁹ they can cause anxiety and impair quality of life, in addition to contradicting the idea itself of early detection.

Our study observed that only 36% of patients get their treatment started within 30 days and when combined, 65% of patients start their treatment within 7 weeks. Average time taken for initiation of treatment at our Institute is 42.2 days which is much lesser as compared to International standards. As quoted by an Italian study Ponti et al,¹ "waiting period results have been worsening over the years, and in 2011-2012 the decreasing trend continued, with as few as 30% of patients being operated within 60 days of the screening examination".

We feel there should be a target time of 4 weeks (28 days) and all the patients should get their treatment started within stipulated time. There is wide scope of improvement in reducing this waiting time. Reasons for delay are multifactorial which include patient populations with suboptimal awareness, and healthcare systems that are

typically overburdened. The delay due to imaging was the most common reason for delay. Maximum time goes for metastatic work up and for getting biopsy results. There is a huge inflow of tissue samples in Pathology at the Medical College which explains the delay, similar is the case with Radiodiagnosis department. Availability of Hormone Receptor kits is a problem in our set up as they are expensive and have a limited shelf life.

Patient Related Factors

The importance of patient related factors cannot be overlooked in analysing delays in treatment clinical pathway. The delay is usually seen either in presenting to the hospital or in ensuring compliance with the clinical pathway. Patients come from far-flung North-Eastern regions, the demographics and logistics of a heavily populated developing country also have a role to play. While the quality of counseling determines compliance to an extent, the ability of patients to understand and adhere to an agreed schedule is also important. In our study population, 90% of patients were of low socioeconomic status, with one third of them being below the poverty line. Significantly, more than half of all patients presented 3 months after they were aware of a lump in their breasts. Socioeconomic factors and personal factors play a strong role in contributing to the delay in treatment.^{10,11}

Another aspect of treatment which we need to gradually introduce is sentinel lymph node (SLN) biopsy, which makes staging possible with considerably fewer complications than axillary clearance.¹²

Probable Remedies

Process of discussing the problem and finding solutions is an important first step in initiating process change. All the teams involved in treating breast cancer patients should be included in a brainstorming session to pinpoint specific reasons for delay and finding answers. Setting target times and intense tracking by constant feedback constitute an important component for achieving quality, timely care.

Resource management and patient awareness are important determinants in the quality of care provided. Patient and attendant counseling is the backbone of establishing a trustworthy, positive doctor-patient relationship. This audit aimed at identifying strong and weak areas in breast cancer management so that we continue same practices in strong areas and explore all possible mechanisms to strengthen those parts where we are lacking in providing quality and timely care.

CONCLUSIONS

The importance of auditing institutional data cannot be stressed more strongly to help better understand the benefits of current practices based on evidence. It also

serves as a benchmark for comparing outcomes following further improvements in practices that can be brought into patient care with advancing technology and medical treatment.

Our institute is performing exceptionally well in breast cancer diagnosis services. All the quality indices of breast cancer treatment meet the international standards except breast conserving surgery rates. There is wide scope for improvement in delivering timely care.

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