

Variability in Surgical Quality among Surgeons in Breast Cancer Surgery

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Abstract

Introduction: Quality assurance is an essential aspect of cancer care. Assessment of surgical quality in breast cancer is still evolving. Variability in surgical care among surgeons has been well documented in literature and we sought to investigate such variation between two groups of surgeons referring patients to our oncology center. **Methods:** A prospective review of patient records of all breast cancer referrals to our department was made. Two groups were identified and segregated based on the performance of mastectomy by a general surgeon (GS) or by a surgical oncologist (SO). Patients treated with modified radical mastectomy for clinical stages 1 - 3 were included for the study. Patient demographic data and disease related information were collected in addition to thorough evaluation of the surgical pathology report. Margin positivity, mean nodal harvest, nodal ratio, inadequate axillary clearance, revision surgery and the use of radiotherapy for inadequate nodal dissection were the parameters evaluated in the study. **Results:** A total of 142 patient records were evaluated 72 designated as group 1 (general surgeons) and 70 as group 2 (surgical oncologist). The median age was 52 years and both groups were evenly balanced for age, laterality of breast lesion, histological type and grade. The mean nodal harvest was 8 vs. 14 nodes, and significant differences were observed in favor of surgical oncology group in margin positivity ($P = 0.01$), inadequate axillary clearance ($P = 0.0001$), and requirement of radiotherapy for inadequate axillary clearance ($P = 0.0001$) but not for revision surgery ($P = 0.134$). An assessment of prognostic factors revealed both groups to be well balanced for confounding factors. **Conclusion:** Breast cancer surgical care is amenable to quality assessment. Variation in oncological clearance exists between surgical oncologist and non-oncology trained surgeons involved in mastectomy for breast cancer. An assessment of factors leading to the observed quality differences may be addressed in future trials to ensure optimal breast cancer care.

Keywords

Breast Cancer, Surgical Quality, Mastectomy

1. Introduction

Quality assurance in oncology is an emerging concept and permits evaluation of all aspects of cancer care delivery. Quality of care provided by breast cancer services is difficult to assess as quality indicators remain undetermined and un-validated. Breast cancer care involves multi-modal management and any quality assessment tool should include all facets of care and treatment. Surgical quality assessment is the most difficult to quantify, conventionally locoregional relapse and survival outcomes have been used but require years to evaluate. Breast cancer surgical care in India revolves around mastectomy as the predominant surgery for all stages though breast conservation surgery rates have steadily increased from 12% to 59% but is offered only in select centers [1]. A study from southern India reports a mastectomy rate of 93% and this probably reflects the pattern of surgical practice outside specialized centers [2]. Majority of breast cancer surgery in India is performed by general surgeons and reports have raised serious concerns regarding surgical quality with 40% requiring repeat mastectomies [3] [4].

Our oncology center receives referral from both general surgeons and surgical oncologists. Hence we sought to assess the quality of breast cancer surgeries of our patients referred to our unit and to note variability if any in quality between the two groups of surgeons offering breast cancer surgery in our region.

2. Methods

A prospective review of patient records of all breast cancer referrals to our department was made. Two groups were identified and segregated based on the performance of mastectomy by a general surgeon (GS) or by a surgical oncologist (SO). Patients treated with modified radical mastectomy for clinical stages I-III were included for the study. Breast conservation surgery for early breast cancer is practiced sparingly by general surgeons and hence patients referred after conservation surgery were not considered. Mastectomy for palliation or done in advanced systemic disease were also excluded from the study. Mastectomy with axillary sampling is considered oncologically inadequate and patients referred after such surgery was not included. Neoadjuvant chemotherapy is known to alter axillary nodal positivity and nodal yield consequently patients requiring neoadjuvant chemotherapy were also excluded from the study.

Patient demographic data and disease related information were collected in addition to thorough evaluation of the surgical pathology report. In the absence of validated oncological quality assessment tools in breast cancer surgery disease related information gained from the pathological evaluation of the surgical specimen were used as quality

measurement instruments in this study. Margin positivity, mean nodal harvest, nodal ratio, inadequate axillary clearance and the use of radiotherapy for inadequate nodal dissection were the parameters evaluated in the study. All surgical specimens were examined as per a common reporting protocol by a single pathology department but located at two sites. A random distribution of the study groups to either site was confirmed. The specimens were examined by two experienced pathologists, both alternating between the two sites. In the event of missing or inadequate pathological data a review of the specimen was requested to ensure comprehensive data collection. Invasive ductal carcinoma or ductal carcinoma in situ (DCIS) at the inked margin was defined as margin positivity and specimens with less than 10 nodes harvested or examined were deemed to have had inadequate axillary dissection. No patient in the study had sentinel node biopsy. The nodal ratio was defined as the ratio of the number of positive nodes to the total number of nodes examined. Requirement for revision surgery (completion mastectomy) after primary tumor surgery was also assessed. Data evaluation was done using the SPSS software version 17 and statistical significance calculated using appropriate tests for significance (chi-square test, student's t-test). A P value of < 0.05 was considered statistically significant.

3. Results

A total of 142 patient records were identified 72 designated as group 1 (general surgeons) and 70 as group 2 (surgical oncologist). The age of the patients ranged from 24 - 80 years with a median of 52 years. Both groups were evenly balanced for age, laterality of breast lesion, histological type and grade. A margin positivity of 10 (13.8%) in group 1 and 1 (1.4%) in group 2 was observed. The mean nodal harvest was 14 nodes in the surgical oncology group and 8 in the general surgical group. Inadequate nodal clearance defined as less than 10 nodes harvested in a mastectomy specimen was noted in 49 (GS: 68%) and 16 (OS: 22%) patients respectively. Twenty four (33%) patients in the general surgical group received radiotherapy for inadequate nodal clearance while only 12 (17%) required radiotherapy in the surgical oncology group for the same indication. A positive nodal ratio of 0.64 in the general surgical group and 0.34 in the surgical oncology group was noted. Statistical significance with a $P = 0.0001$ was observed in favor of surgical oncology group for the variables mean nodal harvest, adequate axillary clearance and radiotherapy for inadequate axillary dissection. The margin positivity differences were also significant with a $P = 0.01$. Four patients (0.05%) in group 1 required revision surgeries while none in group 2, however, the differences were not statistically significant with $P = 0.13$. A tabulation of the observed results is shown in **Table 1**.

Breast cancer being a heterogeneous disease with tumors of differing clinical aggressiveness it is possible that the adverse results in the general surgical group could be attributed to aggressive tumors in that group. An analysis of established prognostic factors of breast cancer between the two groups (GS & SO) was done to clarify this hypothesis. Stage, hormone positivity, Her 2 neu status, menopausal status, age less than 45

Table 1. Surgical quality variability in Mastectomy among surgeons.

SNO	Quality assessment variable	General surgeons n = 72	Surgical oncologist n = 70	P value
1	Margin positivity	10 (13%)	1 (1.4%)	P = 0.01
2	Nodes retrieved (mean)	8	14	P = 0.0001
3	Radiotherapy for inadequate axillary clearance	24 (33%)	12 (17%)	P = 0.0001
4	Inadequate axillary clearance	49 (68%)	16 (22%)	P = 0.0001
5	Nodal ratio	0.64	0.34	P = 0.0001
6	Revision surgery	4 (5%)	0 (0%)	P = 0.134

years and tumor size were analyzed for significant differences between the two groups (**Table 2**). However none of these prognostic features differed significantly indicating that the two groups were balanced with regards to tumor aggressiveness and biology.

4. Discussion

Quality indicators in breast cancer care are only evolving and only a few include surgical care variables. The European society of breast surgeons in its policy statement regarding breast cancer care has included four indicators including nodal yield, revision surgery rate, and sentinel node biopsy parameters as surgical quality indicators. A minimum standard of at least 80% for single surgery, 90% for receiving sentinel node biopsy and 95% for adequate axillary clearance is recommended for quality control in breast cancer surgery [5].

Surgeon as a factor in determining positive margin has been studied in breast conservation surgery, however, such information is sparse regarding mastectomy. A Positive margin after mastectomy has a relative risk of 2.6 for locoregional recurrences. An overall margin positivity of 7% was noticed in our study however the results vary from 2.5% - 10% in published literature [6]. The general surgical group had a higher positive margin of 13% compared to the surgical oncology group (1.4%). The risk factors for positive margins after mastectomy remain undefined and one study reports age less than 50 yrs, lymphovascular invasion, tumor size more than 4 cm's and grade III histology as risk factors for margin positivity [6]. Our study groups were balanced for these risk factors and hence the observed effects are likely due to surgeon related factors. Experience of the operating surgeon and data regarding surgery done by trainees surgeons were not collected and may explain the observed differences.

Axillary nodal involvement is an important prognostic factor in breast cancer and surgical staging of the axilla is a reliable approach to assess regional disease. Axillary nodal yield has been well accepted as a surgical quality indicator after modified radical mastectomy [5]. The American college of pathologists and other oncology guidelines recommend a minimum of ten axillary nodes to be examined to avoid under-staging [5]. Node retrieval rate as opposed to nodal positivity rate is a relatively stable variable without influence from disease related factors in reflecting surgical aggressiveness. It

Table 2. Evaluation of breast cancer prognostic factors between the study groups.

SNO	Prognostic factor	General surgeons n = 72	Surgical oncologist n = 70	P value
1	Median Age-yrs	54	51	P = 0.60
2	Pre Menopausal	22	28	
	Post menopausal	50	42	P = 0.31
3	Mean Tumor size cms	3.30	3.77	P = 0.09
	Stage I	8	7	
4	II	36	41	P = 0.65
	III	28	22	
	ER/PR positive	36	38	
5	Her 2 positive	21	26	P = 0.71
	Triple negative	15	16	
6	Histological Grade III	18	21	P = 0.87

has been shown to vary between operating surgeons and pathologists examining the specimen [7] [8]. A higher nodal harvest was noticed in the surgical oncology group compared to general surgical group (8 vs. 14 nodes). Sixty eight percent (68%) of axillary nodal dissection specimens yielded less than the recommended ten nodes in the general surgical group while the same was twenty two percent (22%) in the surgical oncology group. A difference in average nodal retrieval between oncologist and non oncology trained surgeons has been reported by some authors [8]. All pathology specimens in the study were examined at a single pathology department however functioning at two different sites but by applying a unified examination protocol. Inter observer variation between the pathologists examining the specimen as a reason for the differences in the nodal retrieval is unlikely but remains unproven in this study. Re examination of the axillary specimen is known to yield a higher retrieval rate however was not done in this study.

Revising the surgical margin to achieve negative margins is an established practice in breast conservation surgery and it is common to observe variability among surgeons in the re excision rate [9]. Re excision rate has been suggested as a surgical quality indicator after breast conservation surgery but its role after mastectomy remains un-validated [5]. Revision surgery is unlikely after mastectomy however may be done at times for gross breast tissue residue. We observed a non significant trend towards revision surgeries (5%) in the general surgical group in our study. It is noteworthy that these revision surgeries were recommended by surgical oncologists and may reflect a decision bias.

Post mastectomy radiation for inadequate nodal clearance is adopted at our center as an institution policy as an element of under staging the axilla exists if less than ten nodes are examined. A significant difference in patients irradiated for this indication was noticed in this study (33% vs. 17%) and can be attributed to the lower mean nodal retrieval (8 vs. 14 nodes) in the general surgical group. A higher nodal positivity (0.64 vs. 0.34) was observed in the general surgical group suggesting aggressive disease in this cohort. However studies have shown that nodal positivity ratio is inversely dependent on the total nodes retrieved per specimen and consequently specimens with lower nod-

al harvest yield a higher ratio and hence not necessarily suggesting aggressive disease [10].

Our study has identified important differences in quality indicators between two groups of surgeons offering mastectomy for breast cancer. Our results concur with the results of Tewari *et al.* who showed adverse oncological outcomes in breast cancer when surgery was not done at dedicated oncology centers [3]. Retrospective nature of the study and non inclusion of oncological endpoints like recurrence rate and survival outcomes are the limitations of this study.

5. Conclusion

Breast cancer surgical care is amenable to quality assessment. Variation in oncological clearance exists between surgical oncologist and non-oncology trained surgeons involved in mastectomy for breast cancer. It is unlikely the observed results have been influenced by disease related factors, however, it remains to be proven if these differences translate to adverse results in long term oncological outcomes like recurrences and survival. Further study is required to identify the reasons behind these observed differences in surgical quality. The experience, exposure and quality of surgical training may be objectively assessed to identify surgical quality related issues and overcoming these would translate to optimal breast cancer care.

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