A REVIEW OF BREAST CANCER TREATMENT AT BHAKTAPUR CANCER HOSPITAL

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ABSTRACT

PURPOSE In Nepal, breast cancer is the second most frequent kind of cancer among women. This is our first effort to audit our institute's breast cancer management and compare it to industry-standard quality indicators (QIs).

METHODS: A total of 104 female patients diagnosed with breast cancer and treated for a year at Bhaktapur Cancer Hospital were included in the retrospective analysis. Convenience sampling was the foundation for participant selection. 19 of the 33 QIs in breast cancer management that are relevant to our setting were selected based on recommendations from the European Society of Breast Cancer Specialists. Every patient's QI was computed and compared to the standard aim set by the European Society of Breast Cancer Specialists. Tables displaying the computed frequencies and percentages were shown. For every QI, the binomial 95% of the rates of QI adherence were also computed.

RESULTS: The median age of the 114 patients was 47.5 years, with a range of 24-70 years. The applicable QIs ranged from 5 to 15, with a mean of 9.66 for each subject. Six out of the 19 evaluable QIs had extremely high adherence rates, three had good adherence, and ten had poor adherence. QI 5 and QI 10a had high adherence rates of 88.46% and 94.73%, respectively. QI 1, QI 4a, QI 8, QI 9d, QI 10b,

QI 11a, QI 11b, QI 13b, QI 13e, and QI 14b had the lowest compliance rates, which were 53.84%, 78.21%, 0%, 83.16%, 76.92%, 36.0%, 33.33%, 4.76%, 30.55%, and 10.81%, in that order.

FINAL VERDICT In our scenario, a number of QIs had poor levels of adherence, indicating substantial opportunity for improvement. For the purpose of raising the caliber of our treatment, we shall keep routinely auditing these QIs.

I. INTRODUCTION

Breast cancer is the second commonest cancer among female in Nepal. The GLOBOCAN has estimated that there were 20,508 new cancer cases and 13,629 cancer deaths in Nepal in 2020, of which breast cancer is the fourth commonest cause of cancer-related death (both sexes, 7.7%).1 Our hospital had registered 345 patients with new breast cancer in 2019 and 260 patients with new breast cancer in 2020, accounting for 10.09% and 10.3% of all new cancer cases, respectively.

Treatment for breast cancer involves multidisciplinary care across modalities like surgery, pathology, radiotherapy, and systemic therapy. As the care process is complex, various clinical practice guidelines are available to ensure that optimal care is provided.2-5

The European Society of Breast Cancer Specialists (EUSOMA) proposed a list of 33

benchmark quality indicators (QIs) in 2010 to allow standardized auditing and quality assurance of care provided at local and national levels.6 The list of QIs was updated in 2017 to encompass new developments in diagnosis and treatments. Variability in the compliance with these QIs has been reported in several national and regional audits.7-9

Our hospital is a public sector hospital where cancer treatment is provided at highly subsidized costs. Despite this, there is a significant out-ofpocket expenditure for a substantial number of patients. In addition, patients availing treatment have widely disparate education and social and economic profiles. Hence, it is expected that there will be variability in adherence to clinical practice guidelines in our setting. The primary objective of the study is to audit the breast cancer treatment data of our institute and determine the adherence to selected EUSOMA QI in our institute. We aim to use these data to hospital-level guidelines formulate for enhancing uniformity of cancer care, audit the quality of care, and incorporate them in our newly formulated hospital-based breast cancer treatment guidelines.

II. METHODS

Study Design

Cross-sectional study—medical audit.

Setting

We reviewed outpatient department (OPD) clinical record files of patients who were registered at our hospital between April 14, 2019, and April 13, 2020.

Participants

Formal random sampling was not performed. A convenience sample of all patients with a diagnosis of breast cancer who were registered in the hospital between the aforementioned dates were used. Patients were selected on the basis of availability of their record files. Patients who had not received treatment at our center (and had come for a few visits for opinion only) were

excluded. Also, patients with multiple primary tumors and metastatic disease were excluded from the study. Patients whose chemotherapy or targeted therapy were ongoing were excluded. Ongoing endocrine therapy was allowed.

Variables and Outcome Measures

QIs chosen for this study were taken from the EUSOMA guidelines published in 2010.6 A series of meetings were organized between the radiation oncology, medical oncology, and surgical oncology departments in our hospital in which these QIs were discussed individually. We included 19 QIs on the basis of their relevance to our setup. Four (4) QIs were excluded as they pertained to investigations and procedures not available at our center. In addition, as the focus of this audit was to evaluate the quality of treatment provided, QIs related to follow-up and rehabilitation such as appropriate follow-up, availability of nurse counseling, and data manager were excluded.

Sentinel lymph node biopsy is not possible in our hospital because of unavailability of frozen section equipment. QI included pertained to staging workup (QIs 1, 14a, and 14b), preoperative diagnosis (QI 3), completeness of prognostic/ predictive marker characterization (QIs 4a and 4c), waiting time for primary treatment (QI 5), multidisciplinary discussion (QI 8), appropriate surgical approach (QIs 9a and 9d), postoperative radiotherapy (QIs 10a and 10b), avoidance of overtreatment (QIs 11a and 11b), appropriate endocrine therapy (QIs 12a and 12b), appropriate chemotherapy, and other medical therapy (QIs 13a, 13b, and 13e).

For staging workup, we had reviewed whether all patients had undergone pretreatment staging investigations including chest x ray, ultrasonography of abdomen, and bone scan wherever indicated. Clinical stage was extracted from the OPD record file. All cases were reviewed for completeness of preoperative pathologic diagnosis and completeness of

prognostic/ predictive markers. Data of histopathologic type; grading; estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) status; pathologic stage; size of the invasive component; and margin status were abstracted. Additional details retrieved included waiting time for primary treatment (either surgery or preoperative chemotherapy) measured from the date of registration at hospital, type of surgery, radiotherapy, and systemic therapy.

QI adherence was calculated on the basis of the provided definitions for each QI for each patient. If data were missing, then QI was considered to be nonadherent. All the data were compiled and recorded in a spreadsheet. At first, total numbers of QIs applicable to each patient were calculated (eg, for patients receiving hormonal therapy in hormonesensitive tumors, with the same QI not applicable to ER-, PR- patients). Then, QIs adhered were calculated for all. Patients were categorized into different groups on the basis of age, grade, stage, etc, and for them, mean and range were calculated. The QI adherence rate for each QI was calculated by dividing the number of patients for whom the QI adherence was documented by the total number of evaluable patients. Adherence to QI was considered as very high when compliance was above the standard target, high when compliance was between the minimum standard and the target, and low when compliance was below the minimum standard. Reasons for lack of adherence to QI were also evaluated in terms of the patient's factor, institutional factors, physician's preference, and unknown causes In addition, for each patient, we calculated the total number of QIs applicable for that patient and the total number of these QIs adhered to.

TABLE 1. Patient Characteristics in the Study

Patient Characteristic	Value
Age, No. (%), years	
Median	47.5
≤ 40	27 (26.73)
> 40	77 (74.03)
Tumor grade, No. (%)	
1	1 (0.96)
2	64 (61.53)
3	34 (32.69)
Missing	5 (4.80)
Mean	26
SD	29.29
Clinical stage, No. (%)	
IIA	16 (15.38)
118	4 (3.84)
IIIA	31 (29.8)
IIIB	4 (3.84)
IIIC	1 (0.96)
Unknown	48 (46.15)
Mean	17.33
SD	18.71
Phenotype subtype, No. (%)	
Luminal A/B (ER or PR+ and HER2-)	34 (32.69)
Luminal A/B, HER2 (ER or PR+ and HER2+)	12 (11.53)
HER2 (ER/PR- and HER2+)	10 (9.61)
Triple-negative	26 (25)
ER/PR/HER2 unknown	9 (8.65)
ER/PR+ and HER2 unknown	7 (6.7)
ER/PR- and HER2 unknown	6 (5.7)
Mean	14.85
SD	10.77
Freatment received, No. (%)	
Surgery	101 (97.11)
BCS + AD	21 (20.79
MRM	80 (79.20)
Surgery indicated but defaulted	3 (2.88)
Mean	61
Radiotherapy	77 (74.03)
Radiotherapy in LINAC	48 (46.15
Radiotherapy in telecobalt	29 (27.88
Radiotherapy indicated but defaulted	13 (12.5)
Mean	38.5
Chemotherapy	97 (93.26
Neoadjuvant	12 (11.53
Adjuvant	80 (76.92
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5 (4.8)		
32.33		
41.42		
47 (45.19)		
1 (0.96)		

Abbreviations: AD, axillary dissection; BCS, breast conserving surgery; ER, estrogen

receptor; HER2, human epidermal growth factor receptor 2; LINAC, linear accelerator; MRM,

modified radical mastectomy; PR, progesterone receptor; SD, standard deviation.

Statistical Analysis

Summary statistics for numerical data included the median with range. For categorical data, frequencies and percentages were calculated. Binomial 95% of the rates for QI adherence were also calculated for each QI. Descriptive summary of the reasons for lack of adherence is provided. In addition, summary statistics (mean and range and standard deviation) are provided for the number and proportion of applicable QIs adhered per patient. In addition, these were calculated for important pretreatment patient characteristics. However, given the retrospective nature of the audit and the small sample size, formal statistical tests for associations were not conducted.

Ethics Statement

Research approval was obtained from the Nepal Health Research Council institutional review board and hospital administration before conducting the study.

III. RESULTS

Three hundred thirty-two (332) patients with new breast cancer were registered in 2019/2020 (2074 BS—Nepal year) during the study period. Of these, 56 patients were excluded as they did not take further therapy, 40 patients had metastatic disease, and for 13 patients, OPD record files were lost. After further exclusion of 119 patients whose treatment was ongoing at the time of this audit (systemic therapy or targeted therapy), 104 patients were evaluable.

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Characteristics of the 104 patients are presented in Table 1. All patients were female. Compliance with individual QI is shown in Table 2.

TABLE 2. Definition of European Society of Breast Cancer Specialists QIs and Compliance in 104 Patients

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Abbreviations: BCT. breast conservation therapy; ER. estrogen receptor; FISH. fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; PR, progesterone receptor; QI, quality indicator; RT, radiotherapy; USG, ultra-sonogram.

Pretreatment Evaluation and Workup

Of the four QIs related to pretreatment evaluation, low adherence was seen for two QIs. The reason for lack of adherence to QI 1 was unknown/missing records from clinical files for clinical staging workup. In most of the cases,

clinical examinations at first assessment were not recorded in the OPD record file and copies of mammogram and ultra-sonogram axilla were missing from the file. For QI 14b, prestaging workup was not completed in 33 patients (89.19% patients with stage III or more). This is because of the unavailability of investigations (bone scan) at our hospital and patient's cost issues.

Surgery

Low adherences were in five QIs of six QIs for surgery. The waiting time to start treatment was in the range of 2-62 days. Twelve (11.88%) patients in our study had their primary treatment started after 6 weeks of diagnosis, most common cause being patient factor (financial and logistic issues—arrangement of government funds and temporary stay nearby the hospital). An established breast multidisciplinary team (MDT) multidisciplinary discussion was missing in all cases (QI 8).

The reason for inadequate axillary dissection in 18 of the 101 patients remains unknown and undocumented. The compliance for breast conservation therapy in our setup is only 36% for tumors, 3 cm in invasive breast cancer cases and 33.33% in tumors, 2 cm in noninvasive cancers. The values are far less than the minimum target to be achieved. This was because of preference of treating surgeons and choice of patients related to their educational and socioeconomic status. Patients usually choose modified radical mastectomy (MRM) as their perception of less chance of recurrence after MRM and chances of avoidance of postoperative radiotherapy in MRM cases, which ultimately reduces their total cost of treatment.

Completeness of Prognostic/Predictive Markers

Low adherence was found in one QI of two QIs in the completeness of prognostic/predictive markers. For 80 patients of 101 invasive breast cancer cases, all prognostic and predictive markers were recorded in the file. Twentytwo patients had data of histopathologic type and grade of disease, but data were missing for ER/PR and HER2 status. The reason behind this is the unavailability of immunohistochemistry for the examination of ER/PR and HER2 status at our center and usually sent outside after a histopathologic report.

Radiotherapy

Low adherence was recorded in postoperative radiotherapy in tumors with \geq N2a disease after MRM. Seven patients defaulted treatment for whom post-operative radiotherapy after MRM (\geq N2a) was indicated. Four patients defaulted to radiotherapy after chemotherapy, two patients defaulted to adjuvant treatment after surgery, and one patient defaulted after neoadjuvant chemotherapy and surgery. The primary reason for default in radiotherapy is the long waiting time for radiotherapy (3 weeks to 2 months) in our hospital and the patient's logistic and financial factors.

Systemic Therapy

Low compliance was in three of four QIs in systemic treatment. Of 21 HER2-positive cases in our study, only one patient (4.76%) had received adjuvant trastuzumab, whereas none could afford neoadjuvant trastuzumab. The finding is the result of various factors, with most important being the remarkably high cost of trastuzumab in our country. Compliance for neoadjuvant chemotherapy for the indicated patients is only 30.55% in our study. This may be because of a patient's anxiety to undergo surgery as soon as possible after diagnosis, sometimes physician's preference, and lack of MDT discussion before management in our setup.

Six (11.32%) hormone-sensitive patients defaulted endocrine therapy after surgery. One of six patients of clinical stage IIIC defaulted after neoadjuvant chemotherapy and surgery,

one patient defaulted after surgery for further adjuvant treatment, and other four patients defaulted after chemotherapy. The result of low compliance is only patient factors related to logistics.

Patient-Specific QI Adherence Rate

Applicable QIs were calculated for all patients on the basis of QI criteria (either ER/PR+ or –, HER2+ or –, tumor size \leq or . 3 cm for invasive tumors and \leq or . 2 cm for noninvasive tumors, staging of tumor, and other related factors). The number of QIs adhered per patient ranged between 2 and 10 with a mean of 6.88. Applicable QIs were in the range of 5-15 with a mean of 9.66 per patient. The percentage of applicable QI indicators adhered to range between 33.33% and 90.90% with a mean of 69.80%. Table 3 shows the distribution of the QI adherence rates with pretreatment patient characteristics.

Factors Influencing Low Compliance to QIs

Patient-related factors like financial and educational status and other logistic factors including arrangement of temporary stay nearby the hospital and lack of family support have influenced choices of patients regarding the line of management. Relatively high costs for chemotherapy and trastuzumab, costs for management of side effects, availability of family members/caregivers to take care of patients during treatment, and costs for stay of patients and caregivers around hospital during the length of treatment are the primary causes of low compliance of patients for the completion of treatment. Poor educational status of women, lack of priority to women's health, and awareness of cancer management further credit to low adherence to treatment.

Few investigations like immunohistochemistry for hormonal status markers and bone scan are not available at our hospital, which not only increases the cost and timeline of management but also increases the chance of missing those

investigations during management. MDT for breast cancer treatment is not established here. We do' not have our hospital-based guideline or checklists of the essential examination and investigations during workup. Investigation reports are recorded in OPD record files. Retrospective review of these files revealed missing records of investigations required for proper clinical staging of tumors, which is one of the major causes of low compliance of staging workup in our study. In addition, lack of government insurance policies to cover cancer treatment in our setup and deficit of awareness programs for proper guidance of cancer management prioritize patient's choice of treatment.

TABLE3.InfluenceofKeyPatientCharacteristics on the QI Adherence Rate

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Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor; QI, quality indicator; SD, standard deviation; TNBC, triple negative breast cancer.

IV. DISCUSSION & CONCLUSION

The main goal of the research was to gather baseline data for a quality improvement study that would be conducted in the future. As part of this study, all patients with breast cancer will follow the same institutional procedure. As part of a quality improvement project, the reported QIs are part of our protocol and will be audited on a regular basis. Numerous QIs in our context

have poor levels of adherence, as the present audit indicates.

Established in 1992, Bhaktapur Cancer Hospital is a comprehensive cancer hospital with 125 beds that receives government funding. Every year, it treats roughly 20,000 patients with cancer using oncologic treatments. Additionally, it is the only government cancer facility having radiation capabilities in the whole city. Consequently, a significant percentage of patients register for radiation on its own. The majority of the registered patients come from middle-class and lower-class backgrounds. Since there are only two facilities outside of Kathmandu that provide full oncologic care, a significant number of patients come from outside the city.

Due to the lack of formal government or commercial health insurance programs, the majority of cancer treatments are also paid for out of pocket. For every patient receiving a cancer diagnosis, the government does provide financial assistance in the amount of 100,000 Nepalese rupees (\$800-900 US dollars). At our hospital, however, the whole cost of treating breast cancer is between \$2,500 and \$3,000, not including fees for tests or the cost of trastuzumab when necessary. With a per-capita GDP of \$1,155 per year (World Bank projections for 2020),10 there is a substantial out-of-pocket expense.11 For a one-year course, the most affordable biosimilar trastuzumab available in the nation costs between \$5,000 and \$6,000.

Numerous research have shown how clinical practice standards improve treatment quality. The QIs before and after institution adherence to the practice standards were compared by the centers in these investigations.12 Limited research conducted in European hospitals has shown the use of QIs as instruments for assessing organizational care.13, 14 In a similar vein, a Spanish research developed a set of QIs that formed the foundation of a plan for benchmarking cancer services among Spanish hospitals in an effort to raise standards of treatment.15

QIs were estimated in a Norwegian research using clinical breast cancer registry data from 2012 to 2016. Over the previous years, there has been an increase in adherence to advised therapy. It was feasible to make adjustments and continue therapy after the introduction of new guidelines thanks to the registration of treatment provided at all hospitals.16

Based on resource availability, the Breast Health Global Initiative group created resourcestratified recommendations for the treatment of breast cancer, which separated the health care delivery system into four tiers.17 The goal of the guideline was to enhance health care delivery systems by addressing the resource limitations in low- and middle-income countries (LMICs) and by establishing the fundamental standards for practice in relation to the tiered system. Investigations have shown that our hospital is in the restricted setting category due to the lack of a bone scan and specimen radiography at our facility. The lack of sentinel lymph node mapping and biopsy pushes surgical therapy down to the lowest tier of care. Based on additional resources available. systemic treatment and radiation are classified as maximum. It is now difficult to compare treatment in our institution using the stratified guidelines due to these differences.

When comparing preoperative investigations and diagnosis with the stratified guideline's limited resource level, the standard of QIs matches the target level. However, in the same setting, systemic therapy and radiation therapy groups exhibit lower QI compliance when compared to the maximal resource level. In our research, the QI of neoadjuvant chemotherapy is

30.55%, while the QI of postoperative radiation is only 76.92% in the MRM group.

The 2018 Breast Health Global Initiative made evident the urgent need for methodical and planned techniques to convert resource-stratified recommendations into clinical practice.18 The key components of adopting resource-stratified recommendations in low- and middle-income countries (LMICs) include stakeholder identification, scenario analysis, cancer control planning, and phased strategy execution.

Identifying the course of therapy for a patient, resolving treatment delays, and encouraging their involvement in care are all critical components of managing patient-related variables.

Furthermore, our research indicates that there is a great deal of space for development. We have also spoken about a number of mitigating techniques to raise QI adherence rates based on the audit's results. While some of these mitigating techniques may be used institutionally, others would need interacting with government and public stakeholders.

One of the study's main conclusions was that, of those who began therapy, only 53% had their clinical stage documented. This may have an impact on the treatment's overall results, such as overall and disease-free survival. Patients with metastatic illness had been disqualified. Nonetheless, it is possible that some individuals with unclear staging developed metastatic illness. Without more documentation, we are unable to confirm this. Treatment for metastatic illness inevitably implies that patients may not have gotten proper systemic therapy at the right stage or may have had unnecessary local therapy. Therefore, staging and documentation need more careful consideration.

Starting the process of an MDT discussion for instances of breast cancer is one of the main mitigation methods that we want to put into practice. Four QIs will likely be indirectly impacted and five QIs directly by this. According to a 2013 research by Taylor et al.,19 MDT-based treatment is preferable for raising the standard of care for breast cancer patients. There is much clinical evidence to back up the use of MDT practice, including improved patient outcomes, treatment planning, and diagnostic accuracy.20 Numerous studies have shown excellent MDT compliance prior to beginning breast cancer treatment.21, 22 We anticipate that establishing a multidisciplinary tumor board meeting on a regular basis would improve our practice's adoption of breast conservation and neoadjuvant chemotherapy.

The use of hypofractionation for the majority of patients is another important institutional mitigation technique. It has been shown that hypofractionated radiation is not inferior than traditional fractionation.23, 24 Furthermore, actual data from our neighboring nation shows how successful this method is in the real world.25 Hypofractionation is anticipated to enhance patient access to radiation therapy, decrease waiting times, lower treatment costs, and shorten the duration of treatment overall.

Finding and preserving test findings that were conducted elsewhere is still difficult in the absence of an institutional electronic medical record system. The absence of record-keeping facilities and insufficient documentation contributed directly to the poor adherence to the two QIs in the pretreatment workup and assessment. Institutions would need to make large investments in order to implement an electronic medical record system. On the other hand, research by Raut et al.26 indicates that our situation could make the implementation of an open-source electronic medical record possible. To increase adherence to these QIs, we want to create a uniform case record form in the meantime. While invasive cancer had only 78.21% compliance, benign tumors had full documentation of PR and ER status. Research

has indicated that prognostic and predictive markers are crucial for the proper management of endocrine therapy as well as for prognosis, planning. and scheduling chemotherapy (adjuvant and neoadjuvant agents), as well as for the timing and selection of surgical management patients with breast cancer.27, in 28 Immunohistochemical testing would need to be implemented at our facility with institutional support in order to improve this QI. While waiting for such testing facilities, we want to establish relationships with other public sector labs. Thirteen individuals had just HER2 testing since it was anticipated that they would not be able to pay for trastuzumab as part of their therapy. The normal assessment approach for breast malignancies does not include HER2 testing, according to our national breast cancer care guideline.29 This aligns with the fundamental level of resource-stratified recommendations for low- and middle-income countries (LMICs), which just include basic hormone treatments and cancer medications.

Expanding interactions with external stakeholders is necessary to achieve better adherence to certain QI. For instance, even with the availability of biosimilars, the majority of patients cannot afford trastuzumab.30 Therefore, implementing a nationwide policy such as price restriction or greater government financing assistance for these pharmaceuticals would be necessary to improve access to trastuzumab treatment. One reason for noncompliance is a lack of reasonably priced accommodations for the extended course of therapy. In order to increase the number of reasonably priced hostels or dorms where patients and their caregivers may stay while undergoing treatment, we want to communicate with governmental and nonprofit organizations. Research has shown that women with breast cancer who have a delayed diagnosis and treatment have a worse prognosis.31, 32

By agreement, we have eliminated a few QIs that were connected to the preoperative workup, surgery, and follow-up plans. A magnetic resonance imaging scan was not included due to availability and cost concerns. The hospital does not have a genetic counselor on staff, thus treating doctors provide the necessary counseling. Due to the very low number of patients in the group who were eligible, single operations for noninvasive cancer were removed from the surgical QIs. Our facility does not undertake sentinel lymph node dissection due to a lack of necessary equipment. Additionally absent were OIs for rehabilitation, follow-up, and counseling.

Moreover, a few other restrictions are significant. QIs were inspected for patients who received therapy at a single location in this retrospective analysis with a small sample size. To find out how well every patient with breast cancer is treated, a nationwide or regional research is needed. Because of the little followup, the outcome data are likewise preliminary. QI pertaining to rehabilitation and follow-up will need independent auditing. But these statistics have also assisted us in identifying important institutional mitigation methods that should be put into practice going forward in order to increase QI adherence.

In conclusion, we are now reaching the minimum goal level for LMICs in accordance with resource-stratified recommendations for breast cancer. We shall attempt to raise the standard of breast cancer treatment provided by our hospital by implementing mitigation methods in phases as they are addressed. For this, a prospective research on quality improvement is being prepared. These QIs are included in a hospital-based guideline that we developed for the treatment of breast cancer.

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