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Comparison of Breast Cancer Reporting in Institutional based Laboratories with Standalone Laboratories in a City in Western India

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Abstract

Background: *Surgeons need complete, accurate surgical pathology reports with diagnostic reasoning to reach an optimum therapeutic plan for best possible prognosis. International guidelines have led to checklists for pathological reporting and surgeons will be well to be aware of how to ensure good tissue sample collection, storage, transport and communication with the pathologist on diagnosis concordance or discrepancy and further planning.*

Material and Methods: *The different international guidelines for pathology reporting of cancer were studied and the checklist by CAP was taken as a benchmark to assess the reporting of different laboratories and the concordance and level of reporting adherence with the type of reporting laboratory. Reports from different level laboratories in a tier 2 city were taken for analysis and compared against the checklist. The results were collated and summarized with statistical workup.*

Results: *The reports from standalone laboratories and hospital or institution-based laboratories were compared with 31-point checklist by CAP, showed overall 41.94 % (1300/3100) compliance. Ten reports from each of the two types of reporting settings showed group compliance 24.19 % (375/1550) for standalone laboratories compared to 59.68 % (925/1550) institutional based laborites.*

Conclusion: *This study shows that the quality of surgical pathology reports for breast cancer is not satisfactory. Therefore, there is great need to create awareness among histopathologists regarding the importance of accurate breast cancer surgical pathology reporting and to introduce a standardized checklist according to international guidelines for better treatment planning.*

Keywords: Quality, Breast Cancer, Surgical, Pathology, Reports

Introduction

Cancer is a leading cause of death worldwide, it accounted for nearly 10 million deaths in 2020 [1]. Cancers of breast & cervix are leading cause of cancers in women whereas lung & oral cavity cancers are common in males [2]. Early detection of cancer plays pivotal role in long term survival as evidenced by literature studies. There have been continuous efforts by apex health authorities globally, world health assembly in 2017 urging the governments of countries for accelerating cancer prevention programmes and emphasize on early detection of cancers. The 2030 UN agenda for sustainable development aims to reduce premature mortality from cancer.

The treatment of breast cancer requires a multidisciplinary approach – surgery, chemotherapy and radiotherapy. The surgery remains the mainstay of treatment for breast cancer – to-

tal mastectomy to breast conservation surgery even suited for a developed country like India [3]. It is therefore important that reliable, quick, reproducible, objective and universal reporting formts are followed all over the world, this in turn will enable evidence-based decision making for breast cancer treatment across the globe [4].

The diagnosis of breast cancer is based on histopathology, Immunohistochemistry (IHC) and molecular characteristics. The American joint committee on cancer staging manual 8th edition expanded breast cancer staging in 2017 by integrating prognostic biomarkers like histological, tumor grade, ER, PR, her 2 Neu and mutagenic test-based risk prediction along with anatomic TNM staging.

The college of American Pathologists (CAP) gave a checklist of items required in a complete surgical pathology report of breast cancer so that the key elements in reporting of breast specimens during biopsy interpretation are not missed and a standardized protocol is adopted. This would foster better communication, understanding of surgical pathology reports and will enable Oncologist / oncosurgeons to have best treatment options available to patients [5, 6].

The Indian scenario is challenging due to diversified health care setting, paucity of resources lack of specialty rained oncopathologists and lack of standardized reporting formats.

We conducted a retrospective analysis of resected breast specimen reported in different settings in tier II city of western India to evaluate the adequacy of histopathology reports of surgically resected breast cancer specimens.

Materials and Methods

The study was a retrospective review of all synoptic Pathology reports of patients undergone Modified Radical Mastectomy (MRM) in tier 2 city in Western Indian state over a period of one year, Jan 2022 to Dec 2022. Simple lumpectomy, breast excision biopsy, aspiration biopsy and core needle biopsy were excluded from the study. The study was approved institutional ethics committee [7, 8].

We obtained photocopy of pathology reports that were anonymised for any patient identity, labeled by a unique number from laboratories and institutes (Hospitals or Medical colleges) in the city. The completeness of report was assessed by CAP guideline including major key elements- Tumor size, Histological type, grade, margins, and vessel invasion & adjoining breast changes. The study examined 100 reports of MRM specimens for women with breast cancer in tier II city In India. The reports were collected randomly from five stand alone laboratories and five laboratories based in hospital / medical colleges. A set of 10 reports from every centre were analyzed and all elements of CAP reporting guidelines were checked. For statistical analysis two groups were made – stand alone laboratory and institute, the average completeness of two groups were compared for every reporting characteristic (31 in number) mentioned in CAP guideline. The statistical analysis was done using on line free software (Med calcs). The two groups were compared using Fischer x2 test.

Results

The reports from stand alone laboratories and hospital or institution-based laboratories were compared with 31-point checklist by CAP, showed overall 41.94 % (1300/3100) compliance. Ten reports from each of the two types of reporting settings showed group compliance 24.19 % (375/1550) for standalone laboratories compared to 59.68 % (925/1550) institutional based laborites. (Fig -1 & 2) In terms of standalone laboratories lymph node number, Pathological stage, histological grade and margin involvement were reported by majority of laboratories whereas other items were not addressed. The institutional reporting was by far better than stand alone laboratories as tumpor size, lymph node number & size, histological type & grade, margins and pathological stage were reported by all. The items that were inadequate in reports were tumor focality, distant metastasis, DCIS margins, and metastasis into skin & isolated tumor cells in lymph nodes. (Table -1)

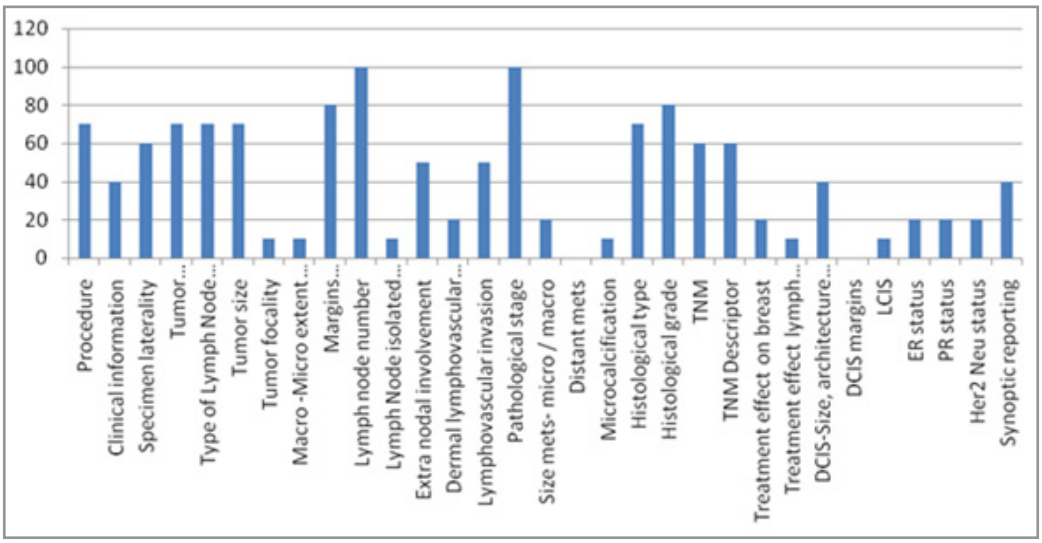

Figure 1: Overall Compliance to CAP checklist for breast cancer reporting

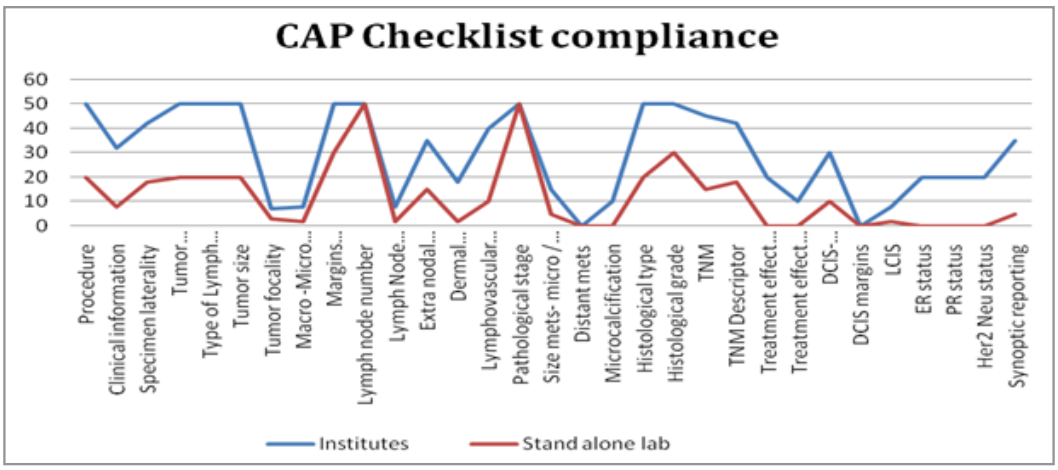

Figure 2: Compliance to CAP checklist for breast cancer reporting institute vs stand alone laboratory

Table 1: Comparison of various items in breast cancer report between two types of laboratories- Stand alone vs institute

Characteristic	Total	Institute	Stand alone lab	Statistically significant
Distant mets	0	0	0	p>.001
DCIS margins	0	0	0	p>.001
Microcalcification	10	10	0	p<.001
Treatment effect lymph node	10	10	0	p<.001
Treatment effect on breast	20	20	0	p<.001
ER status	20	20	0	p<.001
PR status	20	20	0	p<.001
Her2 Neu status	20	20	0	p<.001
Macro -Micro extent tumor skin	10	8	2	p>.001
Lymph Node isolated tumor cells	10	8	2	p>.001
LCIS	10	8	2	p<.001
Dermal lymphovascular invasion	20	18	2	p<.001
Tumor focality	10	7	3	p<.001
Size mets- micro / macro	20	15	5	p<.001
Synoptic reporting	40	35	5	p<.001
Clinical information	40	32	8	p<.001
DCIS-Size, architecture grade, pattern	40	30	10	p<.001
Lymphovascular invasion	50	40	10	p<.001
Extra nodal involvement	50	35	15	p<.001
TNM	60	45	15	p<.001
Specimen laterality	60	42	18	p<.001
TNM Descriptor	60	42	18	p<.001
Procedure	70	50	20	p<.001
Tumor site(Quadrant, nipple distance)	70	50	20	p<.001
Type of Lymph Node sampled	70	50	20	p<.001
Tumor size	70	50	20	p<.001
Histological type	70	50	20	p<.001
Margins invloved/uninvolved	80	50	30	p<.001
Histological grade	80	50	30	p<.001
Lymph node number	100	50	50	p>.001
Pathological stage	100	50	50	p>.001
	1300/3100	925/1550	375/1550	

The hormone receptor status ER, PR & Her 2 Neu were also reported by 10% in institutional laboratories [9, 10].

Discussion

The overall compliance of the breast histopathology reporting with current CAP recommendations stood at 41.94% in our study with an approximate ¼ th of standalone and ¾ th of institutional laboratories following CAP guidelines. This is a huge gap bearing in mind that in Surgical oncology there is increasing breast cancer patient [11]. The Cancer Program Standards 2004 publication of the Commission on Cancer (CoC) requires that 90 % of pathology reports that include a cancer diagnosis will contain the scientifically validated data elements outlined on the surgical case summary checklist of the College of American Pathologists (CAP) publication, Reporting on Cancer Specimens [12, 13]. The Asian Breast Cancer Cooperative Group 2019 consensus document advocates evidence-based yet flexible and individualized use of international treatment guidelines in Asia because these guide-lines are based on data from predominantly non-Asian postmenopausal women, whereas young Asian women have distinctive clinicopathologic characteristics [14]. Using molecular profiling and gene expression testing, it has become possible to predict the future behavior of breast cancer, thereby marking the beginning of the era of precision medicine in the disease [15]. For recurrence risk at present, the risk assessment tools that are popularly used in India include IHC4, luminal A/B subtyping, and PREDICT Overview of Breast Cancer and Implications of Overtreatment of Early-Stage Breast Cancer [16]. These may have the potential to be used as biomarkers for early detection at the screening stage [17].

Tumor size, grade, histological type and margin clearance are most essential parameters in breast histopathology reporting and were underreported by stand alone laboratories than institution-based ones [18, 19]. The DCIS margins, ER- PR Status, treatment effect on histopathology, skin involvement and dermal lymphovascular invasion were underreported in the present study. The findings of our study are in line with the study by Kricker et al who conducted an audit in Australia of 1500 breast cancer reports issued by 147 laboratories involving 392 pathologists. There is dire need of dissemination of knowledge in a proactive manner pertaining to reporting of essential parameters in histopathology report because passive approach is unrewarding with less chances of improvement [20]. The institution-based reports have all essential items like tumor size, site, histological grade, type, pathological stage, lymph node involvement, TNM, laterality & extranodal involvement satisfactory in comparison to stand alone laboratory, these findings are similar to study by Daramola et al from Nigeria [21].

The variation in the reporting quality between two arms is worrisome and therefore one of the suggested measures is developing checklist & templates as part of synoptic reporting format for reporting surgical pathology specimens [22-24]. The major reasons for this variation include specimen transport mechanism & handling, expertise & training of reporting Pathologist and adherence to international / National guidelines for reporting. Quality assurance program are also useful in this context. A third-party assessment of technical competence of testing in Medical Laboratory should therefore be made mandatory which currently is voluntary as per National accreditation board of testing & Calibration laboratories (NABL) and CAP laboratories program.

The limitation of present study are sample size and the retrospective nature of the study.

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